UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2026

OR

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

For the transition period from_____ to _____

Commission File Number: 001-39103

CABALETTA BIO, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**82-1685768**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
2929 Arch Street, Suite 600 Philadelphia, PA	**19104**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (267) 759-3100

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.00001 per share	CABA	The Nasdaq Global Select Market

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

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

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

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

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

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

As of October 30, 2026, the registrant had 215,720,392 shares of common stock, $0.00001 par value per share, outstanding.

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Summary of the Material and Other Risks Associated with Our Business

- We are a late-stage clinical biotechnology company with a limited operating history, have incurred significant losses since our inception, and anticipate that we will continue to incur significant losses for the foreseeable future.
- We are highly dependent on our relationships with Lonza Houston Inc., or Lonza, and/or Cellares Corporation, or Cellares, for our current manufacturing needs for our Phase 1/2 RESET, or Restoring Self-Tolerance, clinical trials for resecabtagene autoleucel, or rese-cel (formerly referred to as CABA-201), and if manufacturing capacity at any of these manufacturing partners is reduced or otherwise delayed or limited, including due to legislative action, or if we, Lonza, Cellares or any third-party manufacturers encounter difficulties in manufacturing our product candidates, this could adversely impact the supply of product candidates for and enrollment in our trials.
- We are reliant on intellectual property licensed to us by Nanjing IASO Biotherapeutics Co., Ltd., or IASO, and termination of this license agreement would result in the loss of significant rights, which would have a material adverse effect on our business.
- If we are unable to obtain and maintain sufficient intellectual property protection for our current product candidates and technologies or any future product candidates, we may not be able to compete effectively in our markets.
- We will need to raise substantial additional funding before we can expect to complete development of any of our product candidates or generate any revenues from product sales.
- Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- If we are unable to successfully develop our current programs into a portfolio of product candidates, or experience significant delays in doing so, we may not realize the full commercial potential of our current and future product candidates.
- If we encounter difficulties enrolling patients in our RESET™ clinical trials for rese-cel or future clinical trials, these clinical development activities could be delayed or otherwise adversely affected.
- If we are unable to advance our product candidates through clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.
- Results of earlier studies may not be predictive of future study or trial results, and we may fail to establish an adequate safety and efficacy profile to conduct clinical trials or obtain regulatory approval for our product candidates.
- If serious adverse events, undesirable side effects or unexpected characteristics are identified during the development of any of our product candidates, we may need to delay, abandon or limit our further clinical development of those product candidates.
- Manufacturing and administering our product candidates is complex and we may encounter difficulties in technology transfer to a contract manufacturing organization.
- We may be unable to reach agreement with the FDA or comparable foreign regulatory authorities on the methodologies for, and assessment of, comparability of different versions of a product candidate used in non-pivotal studies, pivotal studies and for intended commercial use or may be unable to establish such comparability.
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- We may establish our own manufacturing facility and infrastructure in addition to, or in lieu of, relying on third parties for the manufacture of our product candidates, which will be costly and time-consuming and may not be successful.
- Our future success depends in part upon our ability to retain our key employees, consultants and advisors and to attract, retain and motivate other qualified personnel.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, including the sections entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," contains express or implied forward-looking statements that are based on our management's belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties and other 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 these forward-looking statements. Forward-looking statements in this Quarterly Report on Form 10-Q include, but are not limited to, statements about:

- the success, cost and timing and conduct of our clinical trial programs, including our Phase 1/2 RESET™ clinical trials for rese-cel, and any other product candidates, including statements regarding the timing of initiation, enrollment and completion of the clinical trials and the period during which the results of the clinical trials will become available;
- the expected timing and significance around the announcement of safety, biologic activity and/or any additional clinical data from our RESET™ clinical trials for rese-cel;
- the timing of and our ability to obtain and maintain regulatory approval of our product candidates, including rese-cel, and any other product candidates, in any of the indications for which we plan to develop them, and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- our expectations for the tolerability and clinical activity of rese-cel and our ability to advance this product candidate through our license agreement with IASO;
- the potential benefits of our Orphan Drug, Rare Pediatric Disease and Fast Track designations;
- our expected use of proceeds from sales of our common stock in "at-the-market" offerings and other offerings, and the period over which such proceeds, together with existing cash, will be sufficient to meet our operating needs;
- our plans to pursue research and development of other product candidates;
- the potential advantages of our proprietary Cabaletta Approach for B cell Ablation platform, called our CABA® platform, and our product candidates;
- the extent to which our scientific approach and CABA® platform may potentially address a broad range of diseases;
- the potential benefits and success of our arrangements with IASO, Oxford, Lonza and Cellares;
- our ability to successfully leverage our research and translational insights;
- our expectations regarding the results observed with the similarly-designed construct employed in recent academic publications, including the dosing regimen, and the implications on rese-cel;
- our ability to successfully commercialize our product candidates, including rese-cel and any other product candidates;
- the potential receipt of revenue from future sales of rese-cel and any other product candidates, if approved;
- the rate and degree of market acceptance and clinical utility of rese-cel and any other product candidates;
- our estimates regarding the potential market opportunity for rese-cel and any other product candidates, and our ability to serve those markets;
- our sales, marketing and distribution capabilities and strategy, whether alone or with potential future collaborators;
- our ability to establish and maintain arrangements or a facility for manufacture of rese-cel and any other product candidates;
- our ability to obtain funding for our operations, including funding necessary to initiate and complete our RESET™ clinical trials of rese-cel and any ongoing preclinical studies of other product candidates;
- our expectations for the efficiency of the trial design for our RESET™ clinical trials for rese-cel and the potential success and therapeutic benefits of rese-cel, including our belief that rese-cel may enable an "immune system reset" and provide deep and durable responses in patients across an increasing number of autoimmune diseases;
- the potential achievement of milestones and receipt of payments under our collaborations;
- our ability to enter into additional collaborations with existing collaborators or other third parties;

- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates and our ability to operate our business without infringing on the intellectual property rights of others;
- our expectations regarding international expansion and the results of our efforts to do so;
- the success of competing therapies that are or become available, and our competitive position;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- the impact of government laws and regulations in the United States and foreign countries, including any newly introduced legislation;
- the effect of any geopolitical conflicts or new or increased international tariffs, including mitigation efforts and economic effects, on any of the foregoing or other aspects of our business operations, including but not limited to any preclinical studies or research and development efforts, ongoing clinical trials and future clinical trials; and
- our ability to attract and retain key scientific or management personnel.

These factors should not be construed as exhaustive and should be read in conjunction with the other cautionary statements that are included in this Quarterly Report on Form 10-Q. The forward-looking statements contained in this Quarterly Report on Form 10-Q are made as of the date of this Quarterly Report on Form 10-Q, and we undertake no obligations to publicly update or review any forward-looking statement, whether as a result of new information, future developments or otherwise. Therefore, you should not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Quarterly Report on Form 10-Q.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

CABALETTA BIO, INC.
Condensed Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	September 30, 2026	December 31, 2025
Assets	(unaudited)	
Current assets:		
Cash and cash equivalents	$ 299,383	$ 82,982
Short-term investments	—	50,617
Prepaid expenses and other current assets	10,464	5,272
Total current assets	309,847	138,871
Property and equipment, net	1,008	1,922
Finance lease right-of-use assets	12,364	15,700
Operating lease right-of-use assets	4,706	3,431
Other assets	8,566	5,159
Total assets	$ 336,491	$ 165,083
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 9,045	$ 6,636
Accrued and other current liabilities	20,353	19,298
Finance lease liabilities, current portion	13,684	20,758
Operating lease liabilities, current portion	4,250	3,461
Total current liabilities	47,332	50,153
Finance lease liabilities, net of current portion	4,738	2,879
Operating lease liabilities, net of current portion	502	—
Total liabilities	52,572	53,032
Commitments and contingencies (see Notes 5 and 6)		
Stockholders' equity:		
Preferred stock, $0.00001 par value: 10,000,000 shares authorized as of September 30, 2026 and December 31, 2025; no shares issued or outstanding at September 30, 2026 and December 31, 2025	—	—
Voting and non-voting common stock, $0.00001 par value: 600,000,000 (593,590,481 voting and 6,409,519 non-voting) shares authorized as of September 30, 2026 and 300,000,000 (293,590,481 voting and 6,409,519 non-voting) shares authorized as December 31, 2025; 215,720,392 voting shares issued and outstanding as of September 30, 2026 and 100,479,323 voting shares issued and outstanding as of December 31, 2025	2	1
Additional paid-in capital	948,460	628,982
Accumulated other comprehensive income	—	25
Accumulated deficit	(664,543)	(516,957)
Total stockholders' equity	283,919	112,051
Total liabilities and stockholders' equity	$ 336,491	$ 165,083

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

CABALETTA BIO, INC.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Operating expenses:				
Research and development	$ 47,144	$ 39,824	$ 128,927	$ 106,480
General and administrative	7,563	6,764	22,097	23,150
Total operating expenses	54,707	46,588	151,024	129,630
Loss from operations	(54,707)	(46,588)	(151,024)	(129,630)
Other income (expense):				
Interest income	2,144	1,808	4,824	4,705
Interest expense	(511)	(584)	(1,664)	(1,449)
Other income, net	21	498	278	437
Net loss	$ (53,053)	$ (44,866)	$ (147,586)	$ (125,937)
Other comprehensive income:				
Net unrealized gain (loss) on available-for-sale investments, net of tax	—	22	(25)	23
Net comprehensive loss	$ (53,053)	$ (44,844)	$ (147,611)	$ (125,914)
Net loss per common stock share, basic and diluted	$ (0.28)	$ (0.44)	$ (0.98)	$ (1.75)
Weighted-average common shares outstanding, basic and diluted	186,784,096	102,262,904	150,263,791	71,816,247

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

CABALETTA BIO, INC.
Condensed Consolidated Statements of Stockholders' Equity
(in thousands, except share amounts)
(unaudited)

	Common Stock					
	Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
Balance—December 31, 2024	50,743,101	$ 1	$ 501,435	$ —	$ (349,101)	$ 152,335
Stock-based compensation	—	—	5,161	—	—	5,161
Net loss	—	—	—	—	(35,943)	(35,943)
Balance—March 31, 2025	50,743,101	$ 1	$ 506,596	$ —	$ (385,044)	$ 121,553
Issuance of common stock, warrants and pre-funded warrants, net of issuance costs of $6,442	39,200,000	—	93,558	—	—	93,558
Issuance of common stock from ATM offering, net of sales agent commission and fees	1,384,865	—	2,595	—	—	2,595
Issuance of common stock under employee stock purchase plan	123,933	—	197	—	—	197
Stock-based compensation	—	—	5,705	—	—	5,705
Net unrealized gains on available-for-sale securities	—	—	—	1	—	1
Net loss	—	—	—	—	(45,128)	(45,128)
Balance—June 30, 2025	91,451,899	$ 1	$ 608,651	$ 1	$ (430,172)	$ 178,481
Stock-based compensation	—	—	5,815	—	—	5,815
Issuance of common stock in connection with exercise of stock options	13,334	—	14	—	—	14
Issuance of common stock upon exercise of pre-funded warrants	4,799,971	—	—	—	—	—
Net unrealized gains on available-for-sale securities	—	—	—	22	—	22
Net loss	—	—	—	—	(44,866)	(44,866)
Balance—September 30, 2025	96,265,204	$ 1	$ 614,480	$ 23	$ (475,038)	$ 139,466

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

CABALETTA BIO, INC.
Condensed Consolidated Statements of Stockholders' Equity
(in thousands, except share amounts)
(unaudited)

	Common Stock					
	Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balance—December 31, 2025	100,479,323	$ 1	$ 628,982	$ 25	$ (516,957)	$ 112,051
Issuance of common stock from ATM offering, net of sales agent commission and fees	8,055,260	—	22,568	—	—	22,568
Issuance of common stock upon exercise of common stock warrants	2,775,100	—	6,938	—	—	6,938
Issuance of common stock in connection with exercise of stock options	15,113	—	32	—	—	32
Stock-based compensation	—	—	5,256	—	—	5,256
Net unrealized losses on available-for-sale securities	—	—	—	(25)	—	(25)
Net loss	—	—	—	—	(43,515)	(43,515)
Balance—March 31, 2026	111,324,796	$ 1	$ 663,776	$ —	$ (560,472)	$ 103,305
Issuance of common stock, net of issuance costs of $9,801	51,725,000	—	140,201	—	—	140,201
Issuance of common stock from ATM offering, net of sales agent commission and fees	2,077,107	—	6,162	—	—	6,162
Issuance of common stock upon exercise of common stock warrants	2,500,000	—	6,250	—	—	6,250
Issuance of common stock in connection with exercise of stock options	19,144	—	34	—	—	34
Issuance of common stock under employee stock purchase plan	80,490	—	160	—	—	160
Stock-based compensation	—	—	5,499	—	—	5,499
Net loss	—	—	—	—	(51,018)	(51,018)
Balance—June 30, 2026	167,726,537	$ 1	$ 822,082	$ —	$ (611,490)	$ 210,593
Issuance of common stock from ATM offering, net of sales agent commission and fees	1,924,835	—	5,984	—	—	5,984
Issuance of common stock upon exercise of common stock warrants	46,011,900	1	115,029	—	—	115,030
Issuance of common stock in connection with exercise of stock options	57,120	—	101	—	—	101
Stock-based compensation	—	—	5,264	—	—	5,264
Net loss	—	—	—	—	(53,053)	(53,053)
Balance—September 30, 2026	215,720,392	$ 2	$ 948,460	$ —	$ (664,543)	$ 283,919

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

CABALETTA BIO, INC.
Condensed Consolidated Statements of Cash Flows
(in thousands)
(unaudited)

	Nine Months Ended September 30, 2026	2025
Cash flows from operating activities:		
Net loss	$ (147,586)	$ (125,937)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	16,019	16,681
Depreciation	1,055	1,298
Non-cash finance lease expense	10,253	8,363
Non-cash operating lease expense	2,937	2,718
Accretion of operating lease liabilities	312	426
Amortization of discount on investments	(368)	(665)
Loss on foreign currency exchange rates	81	146
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(5,192)	(1,917)
Other assets	(3,407)	(1,314)
Accounts payable	2,240	3,256
Accrued and other current liabilities	452	4,379
Lease liabilities	(3,234)	(3,170)
Accrued interest payable under finance lease	(381)	(1)
Net cash used in operating activities	(126,819)	(95,737)
Cash flows from investing activities:		
Proceeds from maturities of investments	50,960	—
Purchases of investments	—	(99,037)
Purchases of property and equipment	(142)	(1,024)
Net cash provided by (used in) investing activities	50,818	(100,061)
Cash flows from financing activities:		
Proceeds from the issuance of common stock, net of issuance costs	140,201	—
Proceeds from issuance of common stock upon exercise of common stock warrants	128,217	—
Proceeds from the issuance of common stock, warrants and pre-funded warrants, net of issuance costs	—	93,558
Issuance of common stock from ATM offering, net of sales agent commission and fees	34,714	2,595
Proceeds from issuance of common stock in connection with the exercise of stock options	167	14
Proceeds from issuance of common stock under employee stock purchase plan	160	197
Principal payments on finance leases	(11,019)	(4,349)
Net cash provided by financing activities	292,440	92,015
Effect of exchange rate changes on cash and cash equivalents	(38)	27
Net increase (decrease) in cash and cash equivalents	216,401	(103,756)
Cash and cash equivalents—beginning of period	82,982	163,962
Cash and cash equivalents—end of period	$ 299,383	$ 60,206
Supplemental disclosures		
Cash paid for interest	$ 2,047	$ 1,449
Right-of-use assets obtained in exchange for finance lease obligations	$ 7,273	$ 17,655
Right-of-use assets obtained in exchange for operating lease obligations	$ 4,213	$ —

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

1. Basis of Presentation

Cabaletta Bio, Inc. (the Company or Cabaletta) was incorporated in April 2017 in the State of Delaware as Tycho Therapeutics, Inc. and, in August 2018, changed its name to Cabaletta Bio, Inc. The unaudited condensed consolidated financial statements include the accounts of Cabaletta and its wholly owned subsidiaries: Cabaletta Bio GmbH and Cabaletta Bio (Germany) GmbH.

The Company is headquartered in Philadelphia, Pennsylvania. Cabaletta is a late-stage clinical biotechnology company focused on the discovery and development of engineered T cell therapies for autoimmune diseases. Principal operations commenced in August 2018.

Risks and Uncertainties

The Company does not expect to generate revenue from sales of engineered T cell therapies for autoimmune diseases or any other revenue unless and until the Company completes preclinical and clinical development and obtains regulatory approval for one or more product candidates. If the Company seeks to obtain regulatory approval for any of its product candidates, the Company expects to incur significant commercialization expenses.

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations and the need to obtain additional financing. As a result, the Company is unable to predict the timing or amount of increased expenses or when or if the Company will be able to achieve or maintain profitability. Further, the Company is dependent on third parties for certain research and development activities, including manufacturing services (Note 5 and Note 6). Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval, prior to commercialization. Even if the Company is able to generate revenues from the sale of its product candidates, if approved, it may not become profitable. If the Company fails to become profitable or is unable to sustain profitability on a continuing basis, then it may be unable to continue its operations at planned levels and be forced to reduce its operations.

Liquidity

In accordance with Accounting Standards Codification (ASC) 205-40, Going Concern, (ASC 205-40) the Company evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern. The Company has sustained annual operating losses since inception and expects to continue to generate operating losses for the foreseeable future. As of September 30, 2026, the Company has incurred an accumulated deficit of $664,543 and has cash and cash equivalents of $299,383.

As disclosed in the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2026, the Company had previously identified conditions that raised substantial doubt about its ability to continue as a going concern. During the quarter ended September 30, 2026, the Company raised additional funds through the exercise of common stock warrants for proceeds of $115,030 and sold 1,924,835 shares pursuant to the 2025 ATM (at-the-market) Program for net proceeds of $5,984. As a result of this cash raise, the conditions that previously raised substantial doubt are no longer present. The Company expects that its cash and cash equivalents as of September 30, 2026, will be sufficient to fund its projected operations for at least 12 months following the date the Company files this Quarterly Report on Form 10-Q with the Securities and Exchange Commission (SEC).

The Company intends to raise additional capital through a combination of equity offerings, debt financings, government funding arrangements, strategic alliances or other sources. However, if such financing is not available at adequate levels and on a timely basis, or such agreements are not available on favorable terms, or at all, as and when needed, the Company will need to reevaluate its operating plan and may be required to delay or discontinue the development of one or more of its product candidates or operational initiatives.

2. Summary of Significant Accounting Policies

Unaudited Interim Financial Information

The accompanying unaudited condensed consolidated financial statements have been prepared in conformity with generally accepted accounting principles (GAAP) and the applicable rules and regulations of the SEC regarding interim financial reporting. Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification (ASC) and Accounting Standards Updates (ASU) of the Financial Accounting Standards Board (FASB). As permitted under these rules, certain footnotes and other financial information that are normally required by GAAP have been condensed or omitted. The unaudited condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

In the opinion of management, the accompanying unaudited condensed consolidated financial statements include all normal and recurring adjustments (which consist primarily of accruals and estimates that impact the financial statements) considered necessary to present fairly the Company's financial position as of September 30, 2026 and the results of its operations and its cash flows for the interim periods ended September 30, 2026 and 2025. The results for the three and nine months ended September 30, 2026 are not necessarily indicative of results to be expected for the year ending December 31, 2026, any other interim periods, or any future year or period. The balance sheet as of December 31, 2025 included herein was derived from the audited financial statements as of that date. The unaudited condensed consolidated financial statements, presented herein, do not contain the required disclosures under GAAP for annual financial statements. These unaudited condensed consolidated financial statements should be read in conjunction with the Company's audited financial statements, which are included in the Company's 2025 Annual Report on Form 10-K, filed with the SEC on March 23, 2026 (2025 Annual Report).

Use of Estimates

The preparation of the condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the consolidated financial statements and the reported amounts of expenses during the reporting period. Significant estimates and assumptions made in the accompanying condensed consolidated financial statements include but are not limited to advance payments and accruals related to the Company's research and development expenses. The Company evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results could differ from those estimates.

Off-Balance Sheet Risk and Concentrations of Credit Risk

Financial instruments, which potentially subject the Company to significant concentrations of credit risk, consist of cash and cash equivalents, which are invested in U.S. treasury-based money market funds, and available-for-sale debt securities, which are invested in U.S. treasury securities. A portion of the Company's cash is maintained at federally insured financial institutions, and account balances may at times exceed federally insured limits. The Company has not experienced any losses in such accounts and management believes that the Company is not exposed to significant credit risk. The Company has no off-balance sheet risk, such as foreign exchange contracts, option contracts, or other foreign hedging arrangements.

The Company considers all highly liquid investments purchased with original maturities of three months or less from the purchase date to be cash equivalents. Cash equivalents consist primarily of amounts invested in money market accounts and U.S. treasury securities.

Significant Accounting Policies

There have been no significant changes to the Company's accounting policies during the nine months ended September 30, 2026, as compared to the significant accounting policies described in Note 2 of the "Notes to the Financial Statements" in the Company's audited financial statements included in its 2025 Annual Report.

Fair Value Measurement

Assets and liabilities recorded at fair value on a recurring basis in the balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must

maximize the use of observable inputs and minimize the use of unobservable inputs. The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

Level 1—Observable inputs such as unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date.

Level 2—Inputs (other than quoted prices included in Level 1) that are either directly or indirectly observable for the asset or liability. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.

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

Recently Issued Accounting Pronouncements

In November 2024, the FASB issued ASU 2024-03, Income Statement (Subtopic 220-40): Reporting Comprehensive Income-Expense Disaggregation Disclosures. ASU 2024-03 requires enhanced disclosures about components of expense captions on the face of the income statement. This standard will be effective for fiscal years beginning after December 15, 2026. Early adoption is permitted. ASU 2024-03 applies on a prospective basis for periods beginning after the effective date. However, retrospective application to any or all prior periods presented is permitted. The Company is currently planning to adopt this guidance when effective and is assessing the impact of the adoption on the Company’s consolidated financial statements and accompanying footnotes.

3. Fair Value Measurements

Fair value of financial instruments

At September 30, 2026 and December 31, 2025, the Company's financial instruments included cash and cash equivalents, available-for-sale debt securities, accounts payable and accrued expenses. The carrying amounts for cash and cash equivalents, accounts payable and accrued expenses reported in the Company's consolidated financial statements for these instruments approximate their respective fair values because of the short-term nature of these instruments.

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

	September 30, 2026			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Financial assets				
Cash equivalents:				
Money market funds	$ 296,611	$ 296,611	$ —	$ —
Total	$ 296,611	$ 296,611	$ —	$ —

	December 31, 2025			
	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Financial assets				
Cash equivalents:				
Money market funds	$ 81,470	$ 81,470	$ —	$ —
Short-term investments:				
U.S. Treasury securities	50,617	—	50,617	—
Total	$ 132,087	$ 81,470	$ 50,617	$ —

Money market funds are measured at fair value on a recurring basis using quoted prices and are classified as Level 1 inputs. Investments are measured at fair value based on inputs other than quoted prices that are derived from observable market data and are classified as Level 2 inputs.

For debt securities classified as available-for-sale investments, the Company records unrealized gains or losses resulting from changes in fair value between measurement dates as a component of other comprehensive income. The Company did not hold any available-for-sale securities as of September 30, 2026.

	December 31, 2025		
	Amortized Cost	Gross Unrealized Gains	Fair value
Financial assets			
Cash	$ 1,512	$ —	$ 1,512
Money market funds	81,470	—	81,470
Included in cash and cash equivalents	82,982	—	82,982
U.S. Treasury securities - due in one year or less			
Included in short-term investments	50,592	25	50,617
Total	$ 133,574	$ 25	$ 133,599

4. Accrued and Other Current Liabilities

Accrued and other current liabilities consist of the following:

	September 30, 2026	December 31, 2025
Compensation expense	$ 7,946	$ 9,716
Manufacturing and other research and development services	6,909	3,774
Clinical trial research and development services	5,268	5,335
General and administrative services	160	393
Other	70	80
	$ 20,353	$ 19,298

5. Collaborations, Licensing Agreements and Other Agreements

Amended and Restated License Agreement with the Trustees of the University of Pennsylvania and Children's Hospital of Philadelphia

In August 2018, the Company entered into a license agreement with the University of Pennsylvania (Penn), as amended and restated in July 2019 to include the Children's Hospital of Philadelphia (CHOP) as a party, and as amended in May 2020 and October 2021 (the License Agreement) pursuant to which the Company obtained (a) a non-exclusive, non-sublicensable worldwide license to certain of Penn's intellectual property to conduct research, product development, clinical trials, cell manufacturing and other activities, and (b) an exclusive, worldwide, royalty-bearing right and license, with a right to sublicense, on a target-by-target basis, under certain of Penn's intellectual property to make, use, sell, offer for sale, import, and otherwise commercialize products for the treatment of autoimmune and alloimmune diseases. Unless earlier terminated, the License Agreement expires on the expiration or abandonment or other termination of the last valid claim in Penn's intellectual property licensed by the Company. The Company may terminate the License Agreement at any time for convenience upon 60 days' written notice. In the event of an uncured, material breach, Penn may terminate the License Agreement upon 60 days' written notice. Under the terms of the License Agreement, the Company was obligated to pay $2,000 annually for three years beginning August 2018 for funding to the laboratories of each of Drs. Milone and Payne. This was satisfied through completed sponsored research agreements with a total cost of $12,560. During the term of the License Agreement until the first commercial sale of the first product, the Company is obligated to pay Penn a non-refundable, non-creditable annual license maintenance fee of $10. In May 2020, the Company paid Penn an additional, non-refundable, non-creditable license fee of $33 under the amended License Agreement.

The Company is required to pay certain milestone payments upon the achievement of specified clinical and commercial milestones. Milestone payments are reduced by a certain percentage for the second product that achieves a milestone, by an additional percentage for the third product that achieves a milestone, and so on, for each subsequent product that achieves a milestone. In the event that the Company is able to successfully develop and launch multiple products under the License Agreement, total milestone payments could be approximately $21,000. Penn is also eligible to receive tiered royalties at percentage rates in the low single-digits, subject to an annual minimum royalty, on annual worldwide net sales of any products that are commercialized by the Company or its sublicensees that contain or incorporate, or are covered by, the intellectual property licensed by the Company. To the extent the Company sublicenses its license rights under the License Agreement, Penn would be eligible to receive tiered sublicense income at percentage rates in the mid-single to low double-digits. There were no amounts due under the License Agreement as of September 30, 2026.

Master Translational Research Services Agreements

In October 2018 and February 2023, the Company entered into services agreements (the CAART and CARTA Services Agreements) with Penn for research, development and manufacturing services from various laboratories within Penn. The activities are detailed in separately executed Penn organization-specific addenda. In May 2020, the Company amended its Addendum with the Center for Advanced Retinal and Ocular Therapeutics (CAROT) to expand access to vector manufacturing.

Research and development expense related to executed addenda under the master translational research service agreements with Penn recognized in the accompanying statements of operations was $61 and $990 for the three and nine months ended September 30, 2026 and $894 and $4,188 for the three and nine months ended September 30, 2025, respectively. As of September 30, 2026, the Company had no remaining commitments under the CARTA Services Agreement.

Exclusive License Agreement with IASO Biotherapeutics

On October 7, 2022, the Company entered into an Exclusive License Agreement (the IASO Agreement) with Nanjing IASO Biotherapeutics Co., Ltd. (IASO). Pursuant to the IASO Agreement, the Company received an exclusive, worldwide license under certain IASO intellectual property to use a novel clinical-stage anti-CD19 binder to develop, manufacture, commercialize and otherwise exploit T cell products directed to CD19 for the purpose of diagnosis, prevention or treatment of any autoimmune or alloimmune indications in humans. As partial consideration for the exclusive license, IASO received an upfront payment of $2,500. IASO is also eligible to receive up to mid double digit millions in milestone payments based upon the achievement of specified pre-clinical, development and regulatory milestones, and up to an additional low triple digit millions in milestone payments based upon achievement of specified sales milestones, for a total consideration, inclusive of the upfront payment, of up to $162,000, along with tiered mid-single digit royalties on future net sales for licensed products that may result from the IASO Agreement. Upon the U.S. Food and Drug Administration's clearance of the rese-cel Investigational New Drug application for the treatment of systemic lupus erythematosus in March 2023, a milestone payment of $1,000 was recognized in the accompanying statements of operations. A milestone payment of $1,500 was paid to IASO in the first quarter of 2024 after the first patient in a rese-cel trial was dosed. A milestone payment of $2,500 was paid to IASO in the second quarter of 2026 after the first patient in a rese-cel pivotal trial was dosed.

IASO has the right of first negotiation if the Company desires to grant a third party an exclusive license to develop, manufacture, commercialize or otherwise exploit the licensed products in the Greater China region. Pursuant to the IASO Agreement, each of IASO and the Company have agreed, subject to certain exceptions, to refrain from engaging in certain competitive activities with respect to certain programs. The Company also may sublicense through multiple tiers the rights granted to it by IASO under the IASO Agreement at any time, however, it must pay IASO a low double-digit percentage of any revenue obtained from sublicenses or options to third parties, subject to certain customary exclusions. The IASO Agreement will continue on a country-by-country, licensed product-by-licensed product basis until the expiration of the royalty term as identified in the IASO Agreement, unless earlier terminated. Each of the Company and IASO may terminate the Agreement for a material, uncured breach or insolvency of the other party. The Company may also terminate the Agreement at will upon advance written notice and in the event IASO rejects the Agreement due to bankruptcy-related matters. IASO may also terminate the Agreement if the Company fails to achieve certain specified diligence milestones in a timely manner and/or if the Company commences any patent challenges with respect to the patents and patent applications relating to the licensed sequence, in each case upon advance written notice.

Licence and Supply Agreement with Oxford Biomedica

In December 2021, the Company entered into a Licence and Supply agreement (LSA) with Oxford Biomedica (UK) Limited (Oxford), wherein the LSA grants the Company a non-exclusive license to Oxford's LentiVector® platform for its application in the Company's DSG3-CAART program and put in place a multi-year vector supply agreement. Oxford is eligible to receive regulatory and sales milestones in the low tens of millions and royalties in the low single digits on net sales of products that incorporate the Oxford technology. In May 2023, the Company amended the LSA with Oxford to expand the license to include the Company's rese-cel program for an upfront fee of $500. In August 2023, the Company and Oxford entered into a vector supply agreement for rese-cel, and a related second amendment to the LSA, with a total cost under the vector supply agreement of up to approximately $5,000, which has been fully expensed as of December 31, 2024. In February 2024, the Company and Oxford entered into a third amendment to the LSA to update the patent schedule. In June 2024, the Company and Oxford entered into a fourth amendment to the LSA eliminating royalties on net sales of products that incorporate the Oxford technology if Oxford manufactures the vector. Starting in December 2024, the Company and Oxford entered into work orders with a cost of approximately $26,000 for certain process characterization and process performance qualification activities as part of commercial readiness activities. As of September 30, 2026, the Company has recognized project to date expense of $18,868 related to these activities. The Company can terminate the LSA or any work order under the LSA at will upon advance written notice and subject to certain cancellation fees. A milestone payment of $500 was paid to Oxford in the second quarter of 2026 after the first patient in a rese-cel pivotal trial was dosed.

Option and License Agreement with Autolus

In January 2023, the Company entered into an Option and License Agreement (Autolus Agreement) with Autolus Holdings (UK) Limited (Autolus), wherein the Autolus Agreement granted the Company a non-exclusive license to access Autolus' RQR8 technology in its CD19-CAR T cell therapy program, and subject to additional nominal option exercise fees, up to four additional targets. In January 2025, the Company and Autolus agreed to novate the Autolus Agreement with both Autolus and Autolus Limited jointly assuming the rights, obligations and liabilities of Autolus, under the Autolus Agreement. Under the terms of the Autolus Agreement, the Company was required to pay Autolus an upfront license fee of $1,200 that was recognized as expense in the first quarter of 2023 in the accompanying statements of operations, of which $1,100 was paid in 2023 and $100 was paid in January 2024. Autolus is also eligible to receive regulatory milestones of up to $12,000 for each licensed target, sales milestones of up to a total of $15,000 and royalties in the low single digits on net sales of all products that incorporate the RQR8 technology. The Autolus Agreement will continue on a country-by-country, licensed product-by-licensed product basis until the expiration of the royalty term as identified in the Autolus Agreement, unless earlier terminated. The Company can terminate the Autolus Agreement at will upon advance written notice. Each of the Company and Autolus may terminate the Agreement for a material, uncured breach or insolvency of the other party.

6. Commitments and Contingencies

Manufacturing Agreements

In August 2026, the Development and Manufacturing Services Agreement (Minaris Agreement) expired in accordance with its terms. As of September 30, 2026, the Company has no further commitments under the Minaris Agreement.

In December 2024, the Company entered into a Development and Manufacturing Services Agreement (the Lonza Agreement) with Lonza Houston Inc. (Lonza) to serve as one of the Company's manufacturing partners for the global clinical development of rese-cel in multiple indications, including potential late-stage clinical trials and preparations for commercial readiness. The Lonza Agreement has a term of five years and can be extended for an additional three year term upon notice to Lonza at least 18 months prior to the expiration of the Lonza Agreement. The Company can terminate the Lonza Agreement at will upon nine months advance written notice to Lonza subject to the terms of the Lonza Agreement. Lonza can terminate the Lonza Agreement at will upon 24 months advance written notice to Cabaletta subject to the terms of the Lonza Agreement. Under the initial work order, Lonza will perform cell therapy manufacturing activities for Cabaletta's CAR-T cell therapy product, rese-cel, for an initial term of 12 months with the ability to extend the manufacturing period on a rolling basis subject to the terms of the Lonza Agreement.

Other Purchase Commitments

In the normal course of business, the Company enters into various purchase commitments with third-party contract manufacturers for the manufacture and processing of its product candidates and related raw materials, contracts with contract research organizations for clinical trials and agreements with vendors for other services and products for operating purposes. These agreements generally provide for termination or cancellation, other than for costs already incurred.

Indemnification

The Company enters into certain types of contracts that contingently require the Company to indemnify various parties against claims from third parties. These contracts primarily relate to (i) the Company's Amended and Restated Bylaws, as amended, (bylaws) under which the Company must indemnify directors and executive officers, and may indemnify other officers and employees, for liabilities arising out of their relationship, (ii) contracts under which the Company must indemnify directors and certain officers and consultants for liabilities arising out of their relationship, (iii) contracts under which the Company may be required to indemnify partners against certain claims, including claims from third parties asserting, among other things, infringement of their intellectual property rights, and (iv) procurement, consulting, or license agreements under which the Company may be required to indemnify vendors, consultants or licensors for certain claims, including claims that may be brought against them arising from the Company's acts or omissions with respect to the supplied products, technology or services. From time to time, the Company may receive indemnification claims under these contracts in the normal course of business. In addition, under these contracts, the Company may have to modify the accused infringing intellectual property and/or refund amounts received.

In the event that one or more of these matters were to result in a claim against the Company, an adverse outcome, including a judgment or settlement, may have a material adverse effect on the Company's future business, operating results or financial condition. It is not possible to determine the maximum potential amount under these contracts due to the limited history of prior indemnification claims and the unique facts and circumstances involved in each particular agreement.

Litigation

From time to time, the Company may become involved in litigation or legal proceedings. While the outcome of any such proceedings cannot be predicted with certainty, as of September 30, 2026, the Company is not involved in any material litigation or legal proceedings that it would expect to have a material adverse impact on its financial position, results of operations, or cash flows.

7. Segment Information

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the Chief Operating Decision Maker (CODM) in deciding how to allocate resources to an individual segment and in assessing performance. The Company's CODM is the Chief Executive Officer (CEO). The Company has determined it operates in a single operating segment and has one reportable segment. The segment consists of the development of clinical and preclinical product candidates for the discovery and development of innovative engineered T cell therapies and related administrative activities. The CODM assesses performance and allocates resources based on the Company's consolidated statement of operations, which is reported on the income statement as consolidated net loss and considers forecast-to-actuals variances on a quarterly basis for expenses that are deemed

significant. Further, the CODM reviews the segment's assets based on the consolidated balance sheet to assess liquidity and funding capacity. The majority of the Company's assets are located in the United States.

The Company's CODM views specific categories within expenses as significant given the direct correlation between cash burn and profitability as a pre-revenue company. Significant segment expenses, as provided to the CODM, are presented below. For additional information on the year over year change of segment expenses refer to Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
	(in thousands)		(in thousands)	
Research and development expenses:				
Manufacturing of preclinical and clinical supplies	$ 17,521	$ 12,997	$ 42,169	$ 29,639
Personnel	13,125	11,700	38,323	35,066
Clinical trials	13,362	10,872	35,795	28,453
License of intellectual property	—	—	3,000	—
Development services	2,379	3,677	6,913	11,442
Other research and development costs [(1)]	757	578	2,727	1,880
General and administration expenses	7,563	6,764	22,097	23,150
Interest income	(2,144)	(1,808)	(4,824)	(4,705)
Interest expense	511	584	1,664	1,449
Other income, net	(21)	(498)	(278)	(437)
Net loss	$ 53,053	$ 44,866	$ 147,586	$ 125,937

[(1)] Other research and development costs includes costs associated with information technology, travel, medical and scientific symposiums and conferences.

8. Leases

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease and assesses its classification based on the unique facts and circumstances present in the arrangement. The Company leases office and laboratory space and has manufacturing agreements that have been determined to include embedded leases.

Operating lease commitments

The Company leases office and laboratory space which include rent escalations and are subject to additional variable charges, including common area maintenance, property taxes and property insurance. Given the variable nature of such costs, they are recognized as expense as incurred. Additionally, some of the Company's leases are subject to certain fixed fees which the Company has determined to be non-lease components. The Company has elected the practical expedient to account for lease and non-lease components as a single-lease component and has included fixed payments related to non-lease components in calculating the operating lease liability. During 2026, the Company extended the terms for its lab and office leases resulting in an increase in the operating lease right-of-use asset and operating lease liability of $4,213.

Finance lease commitments - Embedded leases

As described further in Note 6, the Minaris Agreement expired in accordance with its terms in August 2026. The terms of the agreement included a dedicated suite with fixed costs and contingent variable costs.

As described further in Note 6, in December 2024, the Company entered into the Lonza Agreement with Lonza to serve as one of the Company's cell processing manufacturing partners. Under the initial work order, Lonza will perform cell therapy manufacturing activities for the CAR-T cell therapy product rese-cel for a term of 12 months with the ability to extend the manufacturing period subject to the terms of the Lonza Agreement. The Lonza Agreement was evaluated under ASC 842 and determined to contain an embedded finance lease commencing in March 2025. During the nine months ended September 30, 2026, the Company extended the lease term in accordance with the Lonza Agreement resulting in an increase of the finance lease right-of-use asset and finance lease liability of $7,273.

Summary of leases under ASC 842

The following table contains information pertaining to the Company's operating and finance leases for the nine months ended September 30, 2026 and 2025.

	Nine Months Ended September 30,	
	2026	2025
Cash paid in the measurement of lease liabilities		
Operating cash flows used for operating leases	$ 3,234	$ 3,170
Operating cash flows used for finance leases	2,047	1,449
Financing cash flows used for finance leases	11,019	4,349
Other information		
Weighted average remaining lease term - finance leases (in years)	1.3	1.2
Weighted average discount rate - finance leases	10.0%	10.9%
Weighted average remaining lease term - operating leases (in years)	1.2	0.9
Weighted average discount rate - operating leases	10.0%	11.0%

For finance leases embedded in CDMO arrangements, interest expense is recognized using the effective interest method, applying the Company's incremental borrowing rate as required by ASC 842, and amortization expense is recognized on a straight-line basis over the shorter of the life of the asset or the term of the lease.

Future lease payments under the non-cancelable leases as of September 30, 2026 are as follows:

	Finance Leases	Operating Leases
October 1, 2026 - December 31, 2026	$ 4,373	$ 1,121
2027	15,503	3,923
Total undiscounted lease payments	19,876	5,044
Less imputed interest	(1,454)	(292)
Total lease liability	$ 18,422	$ 4,752

9. Common Stock

Common Stock

On June 9, 2026, the Company's stockholders approved an amendment to the Third Amended and Restated Certificate of Incorporation to increase the number of authorized shares of common stock from 300,000,000 shares (293,590,481 shares of voting common stock and 6,409,519 shares of non-voting common stock) to 600,000,000 shares (593,590,481 shares of voting common stock and 6,409,519 shares of non-voting common stock). On June 9, 2026, the Company filed a Certificate of Amendment to its Third Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware, and the amendment became effective upon filing.

May 2026 Financing

In May 2026, the Company issued 51,725,000 shares of common stock at a price of $2.90 per share pursuant to a prospectus supplement dated May 4, 2026 to the Company's shelf registration statement on Form S-3 (File No. 333-278126). The offering was underwritten by TD Securities (USA) LLC, Guggenheim Securities, LLC and Cantor Fitzgerald & Co., as joint book-running managers, and H.C. Wainwright & Co., LLC, as lead manager. Aggregate net proceeds were approximately $140,201 after deducting underwriting discounts and commissions and offering expenses.

June 2025 Financing

In June 2025, the Company issued (i) 39,200,000 shares of its common stock and accompanying warrants to purchase an aggregate of 39,200,000 shares of common stock (or pre-funded warrants in lieu thereof) and (ii) in lieu of common stock, to certain investors, pre-funded warrants to purchase an aggregate of up to 10,800,000 shares of its common stock and accompanying warrants to purchase an aggregate of 10,800,000 shares of common stock (or pre-funded warrants in lieu thereof), at an exercise price of $0.00001 per pre-funded warrant. An additional 3,090,190 common stock warrants were issued in the financing for shares purchased by the underwriters in the market to cover overallotment demand. The combined offering price of each share of common stock and accompanying common

stock warrant was $2.00. The combined offering price of each pre-funded warrant and accompanying common stock warrant was $1.99999. The pre-funded warrants are exercisable immediately. The common stock and pre-funded warrants were sold in combination with an accompanying common stock warrant to purchase one share of common stock (or a pre-funded warrant in lieu thereof) for each share of common stock or pre-funded warrant sold. Each common stock warrant has an exercise price per share of $2.50. The common stock warrants are immediately exercisable from the date of issuance and expired on September 12, 2026, fifteen months from the date of issuance. Aggregate net proceeds were $93,558 after deducting underwriting discounts and commissions and offering expenses. As of September 30, 2026, 4,800,000 pre-funded warrants had been exercised and 6,000,000 remain outstanding. In addition, as of September 30, 2026, 51,287,000 common stock warrants had been exercised for proceeds of $128,218. The remaining common stock warrants expired and no common stock warrants remain outstanding.

The pre-funded warrants and common stock warrants were classified as a component of permanent stockholders' equity within additional paid-in capital and were recorded at the issuance date using a relative fair value allocation method. The pre-funded warrants and common stock warrants are equity classified because they (i) are freestanding financial instruments that are legally detachable and separately exercisable from the equity instruments, (ii) are immediately exercisable, (iii) do not embody an obligation for the Company to repurchase its shares, (iv) permit the holders to receive a fixed number of shares of common stock upon exercise, (v) are indexed to the Company's common stock and (vi) meet the equity classification criteria. In addition, such pre-funded warrants and common stock warrants do not provide any guarantee of value or return.

At-the-Market Offering

On March 31, 2025, the Company converted the Form S-3ASR to a Form S-3 (File No. 333-278126) by post-effective amendments. This Form S-3 was declared effective on March 31, 2025. The Company had a Sales Agreement with TD Securities (USA) LLC (as successor to Cowen and Company, LLC) (TD Cowen) to provide for the offering, issuance and sale of up to an aggregate amount of $200.0 million of common stock from time to time in "at-the-market" offerings (2024 ATM Program) pursuant to its S-3, and subject to the limitations thereof. On June 11, 2025, the 2024 ATM Program with TD Cowen was terminated. Prior to termination, the Company sold an aggregate of 2,609,865 shares pursuant to the 2024 ATM Program for total net proceeds of $7,724, consisting of $5,129 in 2024 and $2,595 in 2025.

On August 7, 2025, the Company filed a Registration Statement (File No. 333-289339) with the SEC, which was declared effective on August 15, 2025 (2025 Shelf Registration Statement), in relation to the registration of common stock, preferred stock, debt securities, warrants and/or units of any combination thereof for the purposes of selling, from time to time, the Company's common stock, debt securities or other equity securities in one or more offerings. The Company also simultaneously entered into a Sales Agreement with TD Cowen to provide for the offering, issuance and sale of up to an aggregate amount of $150.0 million of the Company's common stock from time to time in "at-the-market" offerings (the 2025 ATM Program) under the 2025 Shelf Registration Statement and subject to the limitations thereof (the 2025 Sales Agreement). During the year ended December 31, 2025, the Company sold 4,160,176 shares pursuant to the 2025 ATM Program for net proceeds of $10,151. During the nine months ended September 30, 2026, the Company sold 12,057,202 shares, for net proceeds of $34,714.

2019 Stock Option and Incentive Plan

The 2019 Stock Option and Incentive Plan (2019 Plan) was approved by the Company's board of directors on October 14, 2019, and became effective on October 23, 2019. The 2019 Plan provides for the grant of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock units, restricted stock awards, unrestricted stock awards, cash-based awards and dividend equivalent rights to the Company's officers, employees, directors and consultants. The number of shares initially reserved for issuance under the 2019 Plan was 2,342,288, which will be increased each January 1 thereafter by 4% of the number of shares of the Company's common stock outstanding on the immediately preceding December 31 or such lesser number of shares determined by the Company's board of directors or compensation committee of the board of directors. On June 1, 2023, at the 2023 Annual Meeting of Stockholders of the Company, the stockholders of the Company approved Amendment No. 1 to the 2019 Plan, increasing the number of shares of common stock reserved for issuance under the 2019 Plan by 3,000,000 shares. On January 1, 2026, the total number of shares under the 2019 Plan was increased by 4,019,172 shares pursuant to the 2019 Plan Evergreen Provision. As of September 30, 2026, there were 602,380 shares remaining available for issuance under the 2019 Plan.

2025 Inducement Plan

In October 2025, the Company adopted the 2025 Inducement Plan (Inducement Plan). The Inducement Plan was adopted by the Compensation Committee of the Company's board of directors without stockholder approval pursuant to Nasdaq Listing Rule 5635(c)(4). In accordance with Rule 5635(c)(4), awards made under the Inducement Plan, including stock options and restricted stock units, may only be granted to newly hired employees as a material inducement to accept employment with the Company. Stock options granted under the Inducement Plan expire no later than ten years from the date of grant. The number of shares originally reserved for issuance under the Inducement Plan was 275,000 shares. In April 2026, the Company's board of directors authorized an increase in the

number of shares of common stock reserved for issuance under the Inducement Plan to 1,275,000 shares. As of September 30, 2026, there were 700,000 shares available for issuance under the Inducement Plan.

Stock Option Repricing

On May 19, 2025, the Company's Board of Directors approved the repricing of certain outstanding vested and unvested stock options. Pursuant to the repricing, all options granted under the 2018 Plan and 2019 Plan held by current employees, non-employee directors and certain consultants were repriced to $1.92, the closing price of the Company's common stock on May 19, 2025, to the extent such options had an exercise price in excess of 1.5x the $1.92 closing price per share.

As a result of the repricing, 9,900,096 vested and unvested stock options outstanding as of May 19, 2025, with original exercise prices ranging from $2.88 to $23.97, were repriced. The repricing resulted in incremental stock-based compensation expense of $3,021, of which $1,813 related to vested stock option awards and has been fully recognized as of September 30, 2026, and $1,208 related to unvested stock option awards and is being amortized on a straight-line basis over the remaining vesting period of those awards.

Stock Option Activity

A summary of stock option activity is presented below:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding as of January 1, 2026	13,835,372	$ 1.85	7.1	$ 4,968
Granted	4,988,200	3.17		
Exercised	(91,377)	1.83		129
Forfeited/Cancelled	(204,937)	2.76		
Outstanding as of September 30, 2026	18,527,258	$ 2.20	7.1	$ 1,396
Options Exercisable at September 30, 2026	9,978,389	$ 1.83	5.7	$ 941

The aggregate intrinsic value of options is calculated as the difference between the market price of the Company's common stock and the exercise price of the options. The weighted average grant-date fair value of stock options granted during the nine months ended September 30, 2026 and 2025 was $2.74 and $1.46, respectively.

The fair value of each award is estimated using Black-Scholes based on the following assumptions:

	Nine Months Ended September 30,	
	2026	2025
Risk-free interest rate	3.70%—5.05%	3.94%—4.46%
Expected term	5.5 years—6.1 years	5.5 years—6.1 years
Expected volatility	114%—118%	112%—118%
Expected dividend yield	0%	0%

Black-Scholes requires the use of subjective assumptions which determine the fair value of stock-based awards. These assumptions include:

Expected term—The expected term represents the period that stock-based awards are expected to be outstanding. The expected term for option grants is determined using the simplified method, which is the midpoint between the vesting period and the contractual term of the option.

Expected volatility—Expected volatility is estimated using the Company's stock price since its IPO in October 2019.

Risk-free interest rate—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of a stock-based award.

Expected dividend—The Company has never paid dividends on its common stock and has no plans to pay dividends on its common stock. Therefore, the Company used an expected dividend yield of zero.

Stock-based Compensation

The Company has recorded stock-based compensation in the accompanying statements of operations as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Research and development	$ 3,004	$ 3,317	$ 9,079	$ 9,272
General and administrative	2,260	2,498	6,940	7,409
Total	$ 5,264	$ 5,815	$ 16,019	$ 16,681

As of September 30, 2026, there was $31,668 of unrecognized compensation cost related to unvested option awards, which is expected to be recognized over a weighted-average period of 2.2 years.

2019 Employee Stock Purchase Plan

The 2019 Employee Stock Purchase Plan (2019 ESPP) was approved by the Company's board of directors on October 14, 2019, and became effective on October 23, 2019. A total of 234,229 shares of common stock were initially reserved for issuance under the 2019 ESPP, and such number of shares will be increased each January 1 thereafter through January 1, 2029 by the least of (i) 234,229 shares of common stock, (ii) 1% of the number of shares of the Company's common stock outstanding on the immediately preceding December 31 or (iii) such lesser number of shares determined by the 2019 ESPP's administrator. On January 1, 2026, the total number of shares available under the 2019 ESPP was increased by 234,229 shares pursuant to the 2019 Plan Evergreen Provision. As of September 30, 2026, there were 290,122 shares remaining available for issuance under the 2019 ESPP.

Employee contributions are made through payroll deductions of up to 15% of eligible compensation over the offering period. A participant may not accrue rights to purchase more than $25 worth of the Company's common stock for each calendar year in which such right is outstanding. At the end of each offering period, shares of the Company's common stock may be purchased at 85% of the lesser of the Company's common stock on (i) the first trading day of the relevant offering period and (ii) the last trading day of the relevant offering period. Each offering period will be six months in duration and will commence on each December 1 and June 1.

10. Income Taxes

The Company did not record an income tax benefit in its statements of operations for the three and nine months ended September 30, 2026 and 2025 as it is more likely than not that the Company will not recognize the federal and state deferred tax benefits generated by its losses. The Company has provided a valuation allowance for the full amount of its net deferred tax assets and liabilities as of September 30, 2026 and December 31, 2025, as management has determined it is more likely than not that any future benefit from deductible temporary differences and net operating loss and tax credit carryforwards would not be realized. The Company has not recorded any amounts for unrecognized tax benefits as of September 30, 2026 and December 31, 2025.

11. Net Loss Per Share

The Company calculates basic and diluted net loss per share in conformity with the two-class method required for participating securities. The Company has 6,409,519 authorized shares of non-voting common stock. None of these shares of non-voting common stock have been outstanding since May 2024. Since the rights of the voting and non-voting common stock are identical, except with respect to voting, the undistributed losses of the Company are allocated on a proportionate basis to the two classes in periods when non-voting stock is outstanding. Basic net loss per share of common stock is computed by dividing the net loss per share of common stock by the weighted average number of shares of common stock outstanding for the period. The weighted-average shares of common stock outstanding as of September 30, 2026 and 2025 included outstanding pre-funded warrants to purchase up to an aggregate of 6,000,000 shares of common stock.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026 Voting common stock	2025 Voting common stock	2026 Voting common stock	2025 Voting common stock
Basic and diluted net loss per share:				
Net loss	$ (53,053)	$ (44,866)	$ (147,586)	$ (125,937)
Weighted average number of shares outstanding	186,784,096	102,262,904	150,263,791	71,816,247
Net loss per share, basic and diluted	$ (0.28)	$ (0.44)	$ (0.98)	$ (1.75)

The following outstanding potentially dilutive shares have been excluded from the calculation of diluted net loss per share, as their effect is anti-dilutive:

	Nine Months Ended September 30,	
	2026	2025
Stock options to purchase common stock	18,527,258	13,618,173
Warrants to purchase common stock	—	53,090,190
Total	18,527,258	66,708,363

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

You should read the following discussion and analysis of our financial condition and results of operations together with the section entitled "Risk Factors," and our unaudited interim condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and with our audited financial statements and the notes thereto for the year ended December 31, 2025 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the section entitled "Risk Factors," our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. You should carefully read the section entitled "Risk Factors" to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements.

Our Company

We are a late-stage clinical biotechnology company focused on developing and launching potentially curative targeted cell therapies designed specifically for patients with autoimmune diseases.

Resecabtagene autoleucel

Resecabtagene autoleucel (rese-cel, formerly referred to as CABA-201), our lead product candidate, is an investigational autologous chimeric antigen receptor (CAR) T cell therapy designed specifically for the treatment of patients living with autoimmune diseases. Its CAR construct features a fully-human CD19-binding domain, a CD8 transmembrane domain, a 4-1BB co-stimulatory domain, and a CD3ζ signaling domain. Rese-cel is produced by collecting and engineering a patient's own T cells to express an antibody fragment that recognizes the CD19 receptor expressed on the surface of B cells. The production of rese-cel leverages a standard and well-characterized nine-day manufacturing process which is common across U.S. Food and Drug Administration (FDA)-approved CAR T therapies in oncology. Rese-cel is designed to be administered as a single infusion at a weight-based dose after discontinuing all immunomodulators (IMs). Following treatment, rese-cel induces transient and deep depletion of all CD19-positive B cells, including those that contribute to disease, with subsequent repopulation of non-autoreactive B cells.

Rese-cel has been granted multiple regulatory designations in support of accelerating its clinical development, including: (i) FDA Regenerative Medicine Advanced Therapy designation for myositis, systemic sclerosis (SSc), systemic lupus erythematosus (SLE), lupus nephritis (LN), and generalized myasthenia gravis (gMG); (ii) FDA Orphan Drug designation for myositis, SSc, and gMG; (iii) FDA Fast Track designation for dermatomyositis (DM), SSc, SLE, LN, and gMG; (iv) FDA Rare Pediatric Disease designation for juvenile dermatomyositis (JDM); and (v) European Medicines Agency PRIME scheme access for myositis.

RESET™ Clinical Development Program

We are evaluating rese-cel across the REstoring SElf-Tolerance (RESET™) clinical development program, which includes multiple ongoing company-sponsored clinical trials in rheumatology, neurology, and dermatology with disease-specific cohorts designed to evolve directly into registrational studies. Active clinical trials evaluating rese-cel as a potential treatment for autoimmune diseases within the RESET™ clinical development program include RESET-Myositis® for myositis, RESET-SSc® for SSc, RESET-SLE® for lupus, RESET-MG® for gMG, and RESET-PV® for pemphigus vulgaris (PV).

RESET™ clinical trials have consistent design principles. These include T cell collection via apheresis, a routine and well-characterized nine-day manufacturing process, a standard CAR T preconditioning (PC) regimen of fludarabine and cyclophosphamide intended to reduce the initial B cell target burden, administration of a single, weight-based infusion of rese-cel, and long-term patient follow-up and monitoring. In addition, we are leveraging the design characteristics of rese-cel and in combination with several innovations which, if successful, may broaden and deepen rese-cel's patient reach and impact. These include PC-free treatment with rese-cel dose exploration, automated manufacturing intended to enable scalable and flexible commercial supply, outpatient dosing, pediatric treatment, and use of a whole blood draw for patient T cell collection.

Across its reported RESET™ clinical development program experience, rese-cel has exhibited a predictable translational profile when administered with and without PC, consistent across each indication evaluated, and a generally well-tolerated clinical safety profile. Our reported clinical efficacy and translational data have demonstrated the potential of rese-cel to reset the immune system and result in responses that last throughout follow-up without IMs and/or other chronic therapies and with low-dose or absence of chronic steroids.

Research and Development Updates from RESET™ Trials

We regularly communicate clinical, translational, and scientific data from the RESET™ clinical development program at peer-reviewed scientific and medical conferences and in peer-reviewed publications.

At the American Association of Neuromuscular & Electrodiagnostic Medicine 2026 Annual Meeting, we presented clinical and translational data from the first 14 RESET-MG patients treated with rese-cel and preconditioning. Rese-cel was generally well tolerated, with no cytokine release syndrome in 12 patients and no immune effector cell-associated neurotoxicity syndrome or immune effector cell-associated hemophagocytic lymphohistiocytosis-like syndrome. At 24 weeks, patients who remained off immunomodulators (n=10) had a mean change from baseline of -7.9 on the Myasthenia Gravis Activities of Daily Living scale (MG-ADL) and -7.8 on the Quantitative Myasthenia Gravis score, and 10 of the 14 patients achieved a clinically meaningful MG-ADL improvement as of latest follow-up (median follow-up of 38 weeks) while off immunomodulators.

At the European Society of Gene and Cell Therapy 2026 Annual Meeting, we presented a poster presentation titled, "Differential macrophage responses to CAR T cell produced cytokines across autoimmune diseases may confer differential risk among indications." Data in the presentation indicate the potential relationship between the pro-inflammatory activation of monocyte-derived macrophages in different autoimmune diseases, with a focus on Phase 1/2 dermatomyositis and systemic sclerosis patients treated with rese-cel, and the observation of adverse safety events in autoimmune disease patients. In addition, longer-term Phase 1/2 clinical efficacy data in systemic sclerosis patients treated with rese-cel were shared. At one year and off immunomodulators, the five patients with interstitial lung disease achieved a mean percent-predicted FVC improvement of approximately 9%, and among all systemic sclerosis patients with at least one year follow up, and six of seven (86%) patients achieved rCRISS-25.

At the upcoming American College of Rheumatology Convergence 2026 annual meeting, we will present one oral and three poster presentations. Data to be shared include one-year clinical data from the complete Phase 1/2 DM cohort within RESET-Myositis®, histological remission and response in severe and refractory LN patients after treatment with rese-cel, and aggregate safety data across the RESET™ clinical development program. In addition, we will host an industry-supported innovation theater discussing rese-cel and insights from the RESET™ clinical development program.

RESET-Myositis®

Myositis is an autoimmune disease whereby the immune system attacks muscle and causes muscular inflammation and weakness. It typically affects middle-aged individuals, particularly women. Despite existing therapies, most patients remain refractory and must continue concurrent treatment with IMs. In addition, there are approximately 60,000 adult DM and approximately 15,000 adult antisynthetase syndrome (ASyS) patients in the U.S. who have no or limited FDA-approved treatment options.

Our registrational, single-arm DM/ASyS cohort is open for patient enrollment and includes an outpatient dosing option. The primary endpoint will assess whether a moderate or major Total Improvement Score (TIS) response after discontinuation of all IMs can be achieved at 16 weeks while remaining off IMs and on no or low-dose steroids.

The planned size of 17 patients, comprised of 14 DM patients and 3 ASyS patients, for the registrational cohort is based on the assumed treatment effect of rese-cel in DM/ASyS patients and an estimated background rate. The estimated background rate will be determined from a retrospective analysis of an external myositis patient registry and will include patients with similar inclusion criteria as those in the registrational DM/ASyS cohort. Based on comprehensive literature review, we estimate the likelihood of an active, refractory myositis patient achieving moderate or major TIS response within 16 weeks and concurrently discontinuing all immunomodulators to be less than 10%. Changes in the assumed background rate would result in a change in the number of rese-cel treated patients who would need to achieve the primary endpoint in the registrational cohort.

Based on FDA interactions, we plan to use pooled rese-cel safety data from the entire RESET™ clinical development program to supplement myositis-specific safety data for the Biologics License Application (BLA) submission in myositis. The required safety database is expected to be approximately 100 autoimmune disease patients treated with the same single, weight-based dose of rese-cel. In addition, based on a Type B regulatory interaction with the FDA, we plan to include multi-year Phase 1/2 myositis durability data to support the planned BLA submission. We expect to have three-year durability data from some Phase 1/2 patients at the time of projected launch.

We anticipate reporting registrational myositis topline results in the second half of 2027 to support a potential BLA submission in the first quarter of 2028. At the time of the adult BLA submission, we expect to submit available Phase 1/2 JDM clinical data to support a potential pediatric indication. This strategy may allow for priority review voucher eligibility from the FDA, as rese-cel has been granted Rare Pediatric Disease designation for the treatment of JDM.

RESET-SSc®

SSc is a rare and potentially fatal chronic autoimmune disease characterized by progressive skin and internal organ fibrosis that can be life-threatening, including interstitial lung disease, pulmonary hypertension, cardiac involvement, and scleroderma renal crisis. It affects approximately 90,000 patients in the United States, typically middle-aged women.

Our registrational, single-arm SSc cohort focused on interstitial lung disease has initiated and is open for patient enrollment. The cohort is expected to enroll approximately 25 patients, and the primary endpoint is designed to measure the mean change from baseline in percent-predicted forced vital capacity without any IMs or anti-fibrotic medications and off or on a low-dose of steroids.

RESET-SLE®

As the most common subtype of lupus, SLE is a chronic, potentially severe, autoimmune disease, most commonly impacting young women between the ages of 15 and 40 with higher frequency and more severity in people of color, where the immune system attacks healthy tissue throughout the body. SLE affects an estimated up to 320,000 patients in the United States, with LN as the most common end-organ manifestation, affecting approximately 30-40% of SLE patients.

Our current focus for RESET-SLE® is the evaluation of the PC-free approach with rese-cel dose exploration. PC-free dose exploration is ongoing with higher-dose rese-cel in patients with SLE and LN. We expect to provide an update regarding go-forward clinical development plans for the PC-free approach in the first half of 2027.

In addition, we have the potential to initiate registrational SLE and LN cohorts, each evaluating approximately 25 patients with unique endpoints for each cohort with PC, based on prior regulatory alignment with the FDA. This was based on previously reported clinical data from Phase 1/2 SLE and LN cohorts with preconditioning. We also incorporated adolescent patient enrollment in the Phase 1/2 cohorts with preconditioning.

RESET-MG®

Myasthenia gravis (MG) is a rare autoimmune disease characterized by autoantibodies that interfere with signaling at the neuromuscular junction, leading to potentially life-threatening muscle weakness. Most patients with MG have autoantibodies known to be pathogenic based on their interference with proteins in the neuromuscular junction, of which most target the acetylcholine receptor (AChR). gMG affects approximately 100,000 patients in the United States. Symptoms of gMG include profound muscle weakness throughout the body, disabling fatigue, and potential shortness of breath due to respiratory muscle weakness, with risk for episodes of respiratory failure.

Our current focus for RESET-MG® is the evaluation of the PC-free approach with rese-cel. PC-free dose exploration is ongoing in patients with AChR-positive gMG and AChR-negative gMG. We expect to provide an update regarding go-forward clinical development plans for the PC-free approach in the first half of 2027.

RESET-PV®

PV is an autoimmune disease that occurs when the immune system produces antibodies that attack a protein called desmoglein (DSG). DSG normally enables skin cells and the cells lining the inside of your mouth, nose, throat, eyelids, etc. to bind tightly together. Disruption by the antibodies directed to DSG causes painful blisters and erosions characteristic of PV. Approximately 15,000 patients in the United States are affected by PV.

The Phase 1/2 RESET-PV® trial is designed to evaluate PC-free rese-cel in patients with mucosal pemphigus vulgaris (mPV) and mucocutaneous pemphigus vulgaris (mcPV). We expect to provide an update regarding go-forward clinical development plans for the PC-free approach in the first half of 2027.

Manufacturing Partnerships

Our phase-appropriate manufacturing supply strategy for rese-cel utilizes proven external suppliers, with a philosophy of maintaining redundant supply capability.

Oxford Biomedica (UK) Limited (Oxford) provides supply of lentiviral vector used in the manufacturing process for rese-cel.

Our current manufacturing process, Process B, partners include Lonza Houston Inc. (Lonza) and ElevateBio Basecamp, Inc. (ElevateBio). Process B is partially automated with a commercially scalable process intended for initial commercial launch, and it was implemented prior to the start of our first registrational study following multiple meetings with FDA CMC reviewers to align on comparability strategy with our initial process, Process A, which supplied a subset of Phase 1/2 patients.

We anticipate additional supply from Cellares Corporation (Cellares) as part of Process C, a fully automated version of Process B that has been reviewed by the FDA and verified in a clinical setting. We believe the potential for fully automated manufacturing via Process C complements Process B supply and offers the potential for scalability to produce rese-cel for thousands of patients per year with minimal capital investment by us.

Business Operations and Financing

We were incorporated in April 2017 and started principal operations in August 2018. Our operations to date have been financed primarily by proceeds from the sale of convertible notes and convertible preferred stock prior to our initial public offering, or IPO, and proceeds from the sale of our common stock in public equity offerings, including our IPO, “at-the-market” offerings and follow-on offerings of shares of our common stock and pre-funded warrants. As of September 30, 2026, we had $299.4 million in cash and cash equivalents.

Key Agreements

IASO Agreement

On October 7, 2022, we entered into an Exclusive License Agreement, or the IASO Agreement, with IASO. Pursuant to the IASO Agreement, we received an exclusive, worldwide license under certain IASO intellectual property to use a novel clinical-stage anti-CD19 binder to develop, manufacture, commercialize and otherwise exploit T cell products directed to CD19 for the purpose of diagnosis, prevention or treatment of any autoimmune or alloimmune indications in humans. IASO has the right of first negotiation if we desire to grant a third party an exclusive license to develop, manufacture, commercialize or otherwise exploit the licensed products in the Greater China region. Pursuant to the IASO Agreement, we and IASO have agreed, subject to certain exceptions, to refrain from engaging in certain competitive activities with respect to certain programs. As partial consideration for the exclusive license, IASO received an upfront payment of $2.5 million. IASO is also eligible to receive up to mid double digit millions in milestone payments based upon the achievement of specified pre-clinical, development and regulatory milestones, and up to an additional low triple digit millions in milestone payments based upon achievement of specified sales milestones, for a total consideration, inclusive of the upfront payment, of up to $162 million, along with tiered mid-single digit royalties on future net sales for licensed products that may result from the IASO Agreement. We also may sublicense through multiple tiers the rights granted to it by IASO under the IASO Agreement at any time, however, we must pay IASO a low double-digit percentage of any revenue obtained from sublicenses or options to third parties, subject to certain customary exclusions. The IASO Agreement will continue on a country-by-country, licensed product-by-licensed product basis until the expiration of the royalty term as identified in the IASO Agreement, unless earlier terminated. We and IASO may terminate the IASO Agreement for a material, uncured breach or insolvency of the other party. We may also terminate the IASO Agreement at will upon advance written notice and in the event IASO rejects the IASO Agreement due to bankruptcy-related matters. IASO may also terminate the IASO Agreement if we fail to achieve certain specified diligence milestones in a timely manner and/or if we commence any patent challenges with respect to the patents and patent applications relating to the licensed sequence, in each case upon advance written notice. A milestone payment of $1.5 million was paid to IASO in the first quarter of 2024 after the first patient in a rese-cel trial was dosed. A milestone payment of $2.5 million was paid to IASO in the second quarter of 2026 after the first patient in a rese-cel pivotal trial was dosed.

Oxford Biomedica

In December 2021, we entered into the Licence and Supply agreement, or LSA, with Oxford wherein the LSA grants us a non-exclusive license to Oxford's LentiVector® platform for its application in our DSG3-CAART program and puts in place a multi-year vector supply agreement. Under the terms of the agreement, we were required to pay Oxford an upfront fee, as well as costs associated with initial vector manufacturing activities. Oxford, is eligible to receive regulatory and sales milestones in the low tens of millions and royalties in the low single digits on net sales of products that incorporate the Oxford technology. We can terminate the agreement at will upon advance written notice and subject to certain manufacturing slot cancellation fees. In May 2023, we amended the LSA with Oxford to expand the license to include our rese-cel program for an upfront fee of $0.5 million and in August 2023, we entered into a vector supply agreement with Oxford, and a related second amendment to the LSA, for rese-cel with a total cost of up to approximately $5.0 million under the vector supply agreement. In February 2024, we and Oxford entered into a third amendment to the LSA to update the patent schedule. In June 2024, we and Oxford entered into a fourth amendment to the LSA eliminating royalties on net sales of products that incorporate the Oxford technology if Oxford manufactures the vector. Starting in December 2024, we and Oxford entered into work orders for certain process characterization and process performance qualification activities as part of commercial readiness activities. We can terminate the LSA or any work order under the LSA at will upon advance written notice and subject to certain cancellation fees. A milestone payment of $0.5 million was paid to Oxford in the second quarter of 2026 after the first patient in a rese-cel pivotal trial was dosed.

Lonza Manufacturing Agreement

In December 2024, we entered into a Development and Manufacturing Services Agreement, or the Lonza Agreement, with Lonza to serve as one of our manufacturing partners for the global clinical development of rese-cel in multiple indications, including potential late-stage clinical trials and preparations for commercial readiness. The Lonza Agreement has a term of five years and can be extended for an additional three year term upon notice to Lonza at least 18 months prior to the expiration of the Lonza Agreement. We can terminate the Lonza Agreement at will upon nine months advance written notice to Lonza subject to the terms of the Lonza Agreement. Lonza can terminate the Lonza Agreement at will upon 24 months advance written notice to us subject to the terms of the Lonza Agreement. Under the initial work order, Lonza will perform cell therapy manufacturing activities for our CAR-T cell therapy product, rese-cel, for an initial term of 12 months with the ability to extend the manufacturing period on a rolling basis subject to the terms of the Lonza Agreement.

Cellares Agreement

In January 2026, we entered into a Development and Clinical Manufacturing Services Agreement, or the Cellares Agreement, with Cellares to serve as one of our manufacturing partners for the clinical development of rese-cel in multiple indications, including potential late-stage clinical trials and preparations for commercial readiness. The Cellares Agreement has a term of five years. We can terminate the Cellares Agreement at will by providing a certain advance written notice to Cellares subject to the terms of the Cellares

Agreement. Cellares can terminate the Cellares Agreement at will by providing a certain advance written notice to us subject to the terms of the Cellares Agreement. Under the initial work order, Cellares will perform clinical cell therapy manufacturing activities for our CAR-T cell therapy product, rese-cel.

In April 2026, we announced the execution of a commercial agreement with Cellares to provide future commercial supply of rese-cel, pending FDA approval, using its automated manufacturing and quality control platforms. The agreement facilitates flexible, scalable automated production of rese-cel with minimal capital investment.

Amended and Restated License Agreement with the Trustees of the University of Pennsylvania and the Children's Hospital of Philadelphia

In August 2018, we entered into a license agreement with Penn, which was amended and restated in July 2019 to include CHOP, collectively, the Institutions, and collectively with such amendment, as amended in May 2020 and October 2021, the License Agreement, pursuant to which we obtained (a) a non-exclusive, non-sublicensable, worldwide research license to make, have made and use products in two subfields of use, (b) effective as of October 2018, an exclusive, worldwide, royalty-bearing license, with the right to sublicense, under certain of the Institutions' intellectual property to make, use, sell, offer for sale and import products in the same two subfields of use, and (c) effective as of October 2018, a non-exclusive, worldwide, royalty-bearing license, with limited rights to sublicense, under certain of Penn's know-how to make, have made, use, sell, offer for sale, import and have imported products in the same two subfields of use. Our rights are subject to the rights of the U.S. government and certain rights retained by the Institutions.

Unless earlier terminated, the License Agreement expires on the expiration, abandonment or other termination of the last valid claim in Penn's intellectual property licensed by us. We may terminate the License Agreement at any time for convenience upon 60 days' written notice. In the event of an uncured, material breach, Penn may terminate the License Agreement upon 60 days' written notice.

Components of Operating Results

Revenue

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from the sales of products for several years, if at all. If our development efforts for our current or future product candidates are successful and result in marketing approval, we may generate revenue in the future from product sales. 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.

We may also in the future enter into license or collaboration agreements for our product candidates or intellectual property, and we may generate revenue in the future from payments as a result of such license or collaboration agreements.

Operating Expenses

Research and Development

Our research and development expenses include:

•personnel costs, which include salaries, benefits and stock-based compensation expense;

•expenses incurred under agreements with consultants and third-party contract organizations that conduct research and development activities on our behalf;

•costs related to sponsored research service agreements;

•costs related to production of preclinical and clinical materials, including fees paid to contract manufacturers;

•licensing fees for intellectual property and know-how;

•laboratory and vendor expenses related to the execution of preclinical studies and ongoing and planned clinical trials; and

•laboratory supplies and equipment used for internal research and development activities and related depreciation expense.

We have not reported program costs since inception because historically we have not tracked or recorded our research and development expenses on a pre-clinical program-by-program basis. We use our personnel and infrastructure resources across the breadth of our research and development activities, which are directed toward identifying and developing product candidates.

We expense all research and development costs in the periods in which they are incurred. Costs for certain research and development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and third-party service providers.

We expect our research and development expenses to increase substantially for the foreseeable future as we continue to invest in research and development activities related to developing our product candidates, including investments in manufacturing, as our programs advance and we conduct clinical trials. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain. As a result, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates.

Because of the numerous risks and uncertainties associated with product development, we cannot determine with certainty the duration and completion costs of the current or future preclinical studies and clinical trials or if, when, or to what extent we will generate revenues from the commercialization and sale of our product candidates. We may never succeed in achieving regulatory approval for our product candidates. The duration, costs and timing of preclinical studies and clinical trials and development of our product candidates will depend on a variety of factors, including:

•successful completion of preclinical studies and IND and/or CTA-enabling studies;

•development of chemistry, manufacturing and controls, or CMC, processes and procedures for purposes of IND and/or CTA applications;

•successful patient enrollment in, and the initiation and completion of, clinical trials;

•the impact of any business interruptions to our operations, including the timing and enrollment of patients in our ongoing and planned clinical trials, or to those of our clinical sites, manufacturers, suppliers, or other vendors resulting from public health crises;

•receipt of regulatory approvals from applicable regulatory authorities;

•establishing commercial manufacturing capabilities or arrangements with third-party manufacturers;

•obtaining and maintaining patent and trade secret protection and non-patent exclusivity;

•launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;

•acceptance of our product candidates, if and when approved, by patients, the medical community and third-party payors;

•effectively competing with other therapies and treatment options;

•a continued acceptable safety and efficacy profile following approval;

•enforcing and defending intellectual property and proprietary rights and claims; and

•achieving desirable medicinal properties for the intended indications.

We may never succeed in achieving regulatory approval for any of our product candidates. We may obtain unexpected results from our preclinical studies and clinical trials. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others. A change in the outcome of any of these factors could mean a significant change in the costs and timing associated with the development of our current and future preclinical and clinical product candidates. For example, if the FDA or another regulatory authority, were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development, or if we experience significant delays in execution of or enrollment in any of our preclinical studies or clinical trials, we could be required to expend significant additional financial resources and time on the completion of preclinical and clinical development. We expect our research and development expenses to increase for the foreseeable future as we continue the development of product candidates.

General and Administrative Expenses

Our general and administrative expenses consist primarily of personnel costs, costs related to maintenance and filing of intellectual property, depreciation expense and other expenses for outside professional services, including legal, human resources, information technology, audit and accounting services. Personnel costs consist of salaries, benefits and stock-based compensation expense. We expect our general and administrative expenses to increase over the next several years to support our continued research and development activities, manufacturing activities, increased costs of operating as a public company and the potential commercialization of our product candidates. We anticipate our general and administrative costs will increase with respect to the hiring of additional personnel, developing commercial infrastructure, fees to outside consultants, lawyers and accountants, and increased costs associated with being a public company such as expenses related to services associated with maintaining compliance with Nasdaq listing rules and SEC requirements, insurance and investor relations costs.

Interest Income

Interest income consists of interest earned on our cash, cash equivalents and investments and amortization of bond discount or premium.

Interest Expense

Interest expense consists primarily of interest expense associated with finance lease arrangements.

Other Income (Expense), net

Other income (expense), net primarily consists of foreign currency gains and losses and proceeds received from the sale of our Pennsylvania research and development tax credits.

Results of Operations for the three months ended September 30, 2026 and 2025

The following sets forth our results of operations for the three months ended September 30, 2026 and 2025:

	Three Months Ended September 30, 2026	2025	Change
	(in thousands)		
Statements of Operations Data:			
Operating expenses:			
Research and development	$ 47,144	$ 39,824	$ 7,320
General and administrative	7,563	6,764	799
Total operating expenses	54,707	46,588	8,119
Loss from operations	(54,707)	(46,588)	(8,119)
Other income (expense):			
Interest income	2,144	1,808	336
Interest expense	(511)	(584)	73
Other income, net	21	498	(477)
Net loss	$ (53,053)	$ (44,866)	$ (8,187)

Research and Development

Research and development expenses were $47.1 million for the three months ended September 30, 2026 compared to $39.8 million for the three months ended September 30, 2025. The table below summarizes our research and development expenses:

	Three Months Ended September 30,		
	2026	2025	Change
	(in thousands)		
Manufacturing of preclinical and clinical supplies	$ 17,521	$ 12,997	$ 4,524
Clinical trials	13,362	10,872	2,490
Personnel	13,125	11,700	1,425
Development services	2,379	3,677	(1,298)
Other research and development costs	757	578	179
	$ 47,144	$ 39,824	$ 7,320

Specific changes in our research and development expenses year over year include a:

- $4.5 million increase in manufacturing costs primarily due to expanded cell processing capabilities, including those for commercial readiness;
- $2.5 million increase in clinical trial costs primarily due to higher enrollment and clinical trial sites across multiple clinical studies for rese-cel;
- $1.4 million increase in personnel costs primarily driven by an increase in headcount to support overall growth related to our rese-cel program; partially offset by a
- $1.3 million decrease in development services due to lower spend on research lab consumables and external research activities.

General and Administrative

General and administrative expenses were $7.6 million for the three months ended September 30, 2026 compared to $6.8 million for the three months ended September 30, 2025. The increase of $0.8 million in our general and administrative expenses includes:

- $0.5 million higher personnel related costs due to increased headcount; and a
- $0.3 million increase in administrative costs primarily due to increased spend for commercial readiness activities.

Interest Income

Interest income increased by $0.3 million for the three months ended September 30, 2026 compared to the three months ended September 30, 2025, primarily due to higher cash, cash equivalents and investment balances earning interest during 2026 due to the proceeds from sales of common stock pursuant to the 2025 ATM Program, proceeds from the exercise of common stock warrants and proceeds from the May 2026 financing.

Other Income, net

Other income, net decreased by $0.5 million for the three months ended September 30, 2026 compared to the three months ended September 30, 2025, primarily due to proceeds received from the sale of our Pennsylvania research and development tax credits in 2025.

Results of Operations for the nine months ended September 30, 2026 and 2025

The following sets forth our results of operations for the nine months ended September 30, 2026 and 2025:

	Nine Months Ended September 30, 2026	2025	Change
	(in thousands)		
Statements of Operations Data:			
Operating expenses:			
Research and development	$ 128,927	$ 106,480	$ 22,447
General and administrative	22,097	23,150	(1,053)
Total operating expenses	151,024	129,630	21,394
Loss from operations	(151,024)	(129,630)	(21,394)
Other income (expense):			
Interest income	4,824	4,705	119
Interest expense	(1,664)	(1,449)	(215)
Other income, net	278	437	(159)
Net loss	$ (147,586)	$ (125,937)	$ (21,649)

Research and Development

Research and development expenses were $128.9 million for the nine months ended September 30, 2026 compared to $106.5 million for the nine months ended September 30, 2025. The table below summarizes our research and development expenses:

	Nine Months Ended September 30, 2026	2025	Change
	(in thousands)		
Manufacturing of preclinical and clinical supplies	$ 42,169	$ 29,639	$ 12,530
Clinical trials	35,795	28,453	7,342
Personnel	38,323	35,066	3,257
License of intellectual property	3,000	—	3,000
Development services	6,913	11,442	(4,529)
Other research and development costs	2,727	1,880	847
	$ 128,927	$ 106,480	$ 22,447

Specific changes in our research and development expenses year over year include a:

- $12.5 million increase in manufacturing costs primarily due to expanded cell processing capabilities, including those for commercial readiness;
- $7.3 million increase in clinical trial costs primarily due to higher enrollment and clinical trial sites across multiple clinical studies for rese-cel;
- $3.3 million increase in personnel costs primarily driven by an increase in headcount to support overall growth related to our rese-cel program;
- $3.0 million increase in license of intellectual property costs due to a $2.5 million milestone payment to IASO and $0.5 million milestone payment to Oxford after the first patient in a rese-cel pivotal trial was dosed;
- $0.9 million increase in other research and development costs primarily due to company growth and related expenses; partially offset by a
- $4.5 million decrease in development services due to lower spend on research lab consumables and external research activities.

General and Administrative

General and administrative expenses were $22.1 million for the nine months ended September 30, 2026 compared to $23.1 million for the nine months ended September 30, 2025. The decrease of $1.0 million in our general and administrative expenses includes:

•$1.7 million decrease in personnel related costs due to lower average headcount; partially offset by a

•$0.7 million increase in administrative costs primarily due to increased spend for commercial readiness activities.

Interest Expense

Interest expense increased by $0.2 million for the nine months ended September 30, 2026 as compared to the nine months ended September 30, 2025, as a result of finance lease arrangements from embedded leases within our manufacturing agreements with Minaris and Lonza.

Other Income, net

Other income, net decreased by $0.2 million for the nine months ended September 30, 2026 as compared to the nine months ended September 30, 2025, primarily due to proceeds received from the sale of our Pennsylvania research and development tax credits in 2025.

Liquidity and Capital Resources

From our inception in April 2017 to the time of our initial public offering, or IPO, our operations were financed by proceeds of $86.4 million from the sale of convertible notes and our convertible preferred stock and proceeds of $71.0 million from the sale of common stock in our IPO. Since our IPO and through September 30, 2026, we have generated cash from public offerings of our common stock and pre-funded warrants to purchase our common stock, and from the exercise of common stock warrants, resulting in aggregate net proceeds of approximately $688.0 million. Our cash and cash equivalents balance of $299.4 million as of September 30, 2026, should enable us to fund our operations and capital expenditures into the first quarter of 2028. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation.

We have incurred losses since our inception and, as of September 30, 2026, we had an accumulated deficit of $664.5 million. Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures, and to a lesser extent, general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding prepaid expenses and other current assets, accounts payable and accrued expenses.

Any product candidates we may develop may never achieve commercialization and we anticipate that we will continue to incur losses for the foreseeable future. We expect that our research and development expenses, general and administrative expenses, and capital expenditures will continue to increase. As a result, until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements. Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, third-party clinical research, manufacturing and development services, office and laboratory, laboratories and manufacturing facility, license payments or milestone obligations that may arise, laboratory and related supplies, clinical costs, manufacturing costs, legal and other regulatory expenses and general overhead costs.

As disclosed in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2026, we had previously identified conditions that raised substantial doubt about our ability to continue as a going concern. During the quarter ended September 30, 2026, we raised additional funds through the exercise of common stock warrants for proceeds of $115.0 million and sold 1.9 million shares pursuant to the 2025 ATM Program for net proceeds of $6.0 million. As a result of these cash raises, the conditions that previously raised substantial doubt are no longer present. We expect that our cash and cash equivalents as of September 30, 2026, will be sufficient to fund our projected operations for at least 12 months following the date we file this Quarterly Report on Form 10-Q with the Securities and Exchange Commission (“SEC”).

We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. We will continue to require additional financing to advance our current product candidates through clinical development, to develop, acquire or in-license other potential product candidates and to fund operations for the foreseeable future. We will continue to seek funds through equity offerings, debt financings or other capital sources, including potentially collaborations, licenses and other similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders’ rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our

ability to pursue our business plans and strategies. If we are unable to raise capital, we will need to delay, reduce or terminate planned activities to reduce costs.

At-The-Market Offering Sales Agreement

On March 31, 2025, we converted the Form S-3ASR to a Form S-3 (File No. 333-278126) by post-effective amendments. This Form S-3 was declared effective on March 31, 2025. We had a Sales Agreement with TD Securities (USA) LLC, as successor to Cowen and Company, LLC, or TD Cowen, to provide for the offering, issuance and sale of up to an aggregate amount of $200.0 million of common stock from time to time in "at-the-market" offerings, or the 2024 ATM Program, pursuant to its S-3, and subject to the limitations thereof. On June 11, 2025, the 2024 ATM Program with TD Cowen was terminated. Prior to termination, we sold an aggregate of 2,609,865 shares pursuant to the 2024 ATM Program for total net proceeds of $7.7 million, consisting of $5.1 million in 2024 and $2.6 million in 2025.

On August 7, 2025, we filed a Registration Statement (File No. 333-289339) with the SEC, which was declared effective on August 15, 2025, or the 2025 Shelf Registration Statement, in relation to the registration of common stock, preferred stock, debt securities, warrants and/or units of any combination thereof for the purposes of selling, from time to time, our common stock, debt securities or other equity securities in one or more offerings. We also simultaneously entered into a Sales Agreement with TD Cowen to provide for the offering, issuance and sale of up to an aggregate amount of $150.0 million of our common stock from time to time in "at-the-market" offerings, or the 2025 ATM Program, under the 2025 Shelf Registration Statement and subject to the limitations thereof, or the 2025 Sales Agreement. During the year ended December 31, 2025, we sold 4,160,176 shares pursuant to the 2025 ATM Program for net proceeds of $10.2 million. During the nine months ended September 30, 2026, we sold 12,057,202 shares, for net proceeds of $34.7 million.

May 2026 Financing

In May 2026, we issued 51,725,000 shares of our common stock at a price of $2.90 per share pursuant to a prospectus supplement dated May 4, 2026 to our shelf registration statement on Form S-3 (File No. 333-278126). The offering was underwritten by TD Securities (USA) LLC, Guggenheim Securities, LLC and Cantor Fitzgerald & Co., as joint book-running managers, and H.C. Wainwright & Co., LLC, as lead manager. Aggregate net proceeds were approximately $140.2 million after deducting underwriting discounts and commissions and offering expenses.

June 2025 Financing

In June 2025, we issued (i) 39,200,000 shares of our common stock and accompanying warrants to purchase an aggregate of 39,200,000 shares of common stock (or pre-funded warrants in lieu thereof) and (ii) in lieu of common stock, to certain investors, pre-funded warrants to purchase an aggregate of up to 10,800,000 shares of our common stock and accompanying warrants to purchase an aggregate of 10,800,000 shares of common stock (or pre-funded warrants in lieu thereof), at an exercise price of $0.00001 per pre-funded warrant. The combined offering price of each share of common stock and accompanying common stock warrant was $2.00. The combined offering price of each pre-funded warrant and accompanying common stock warrant was $1.99999. The pre-funded warrants were exercisable immediately. The common stock and pre-funded warrants were sold in combination with an accompanying common stock warrant to purchase one share of common stock (or a pre-funded warrant in lieu thereof) for each share of common stock or pre-funded warrant sold. Each common stock warrant has an exercise price per share of $2.50. The common stock warrants are immediately exercisable from the date of issuance and expired fifteen months from the date of issuance. Aggregate net proceeds were $93.6 million after deducting underwriting discounts and commissions and offering expenses. As of September 30, 2026, 4,800,000 pre-funded warrants had been exercised and 6,000,000 remain outstanding. In addition, as of September 30, 2026, 51,287,000 common stock warrants were exercised for proceeds of $128.2 million. The remaining common stock warrants expired and no common stock warrants remain outstanding.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, progress, results and costs of researching, developing and manufacturing our lead product candidates or any future product candidates, and conducting preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals or clearances for our lead product candidates or any future product candidates;
- the impact of any business interruptions to our operations or to those of our clinical sites, manufacturers, suppliers, or other vendors resulting from public health crises;
- the number and characteristics of any additional product candidates we develop or acquire;
- the timing of any cash milestone payments if we successfully achieve certain predetermined milestones;

•the cost of manufacturing our lead product candidate or any future product candidates and any products we successfully commercialize, including costs associated with building-out our manufacturing capabilities;

•our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of any such agreements that we may enter into;

•the expenses needed to attract and retain skilled personnel;

•the costs associated with being a public company; and

•the timing, receipt and amount of sales of any future approved or cleared products, if any.

Further, our operating plans may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials and other research and development activities. We currently have no credit facility or committed sources of capital. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated product development programs.

Cash Flows

The following table summarizes our cash flows for the periods indicated:

	Nine Months Ended September 30,	
	2026	2025
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (126,819)	$ (95,737)
Investing activities	50,818	(100,061)
Financing activities	292,440	92,015
Effect of exchange rate changes on cash and cash equivalents	(38)	27
Net increase (decrease) in cash and cash equivalents	$ 216,401	$ (103,756)

Operating Activities

During the nine months ended September 30, 2026, cash used in operating activities of $126.8 million was attributable to our net loss of $147.6 million, partially offset by non-cash charges of $30.3 million for stock-based compensation charges, amortization of finance lease, non-cash operating lease expense, depreciation, accretion of operating lease liabilities and foreign currency exchange rates and further increased by a net change of $9.5 million in our net operating assets and liabilities.

During the nine months ended September 30, 2025, cash used in operating activities of $95.7 million was attributable to our net loss of $125.9 million, partially offset by non-cash charges of $29.0 million for stock-based compensation charges, amortization of finance lease, non-cash operating lease expense, depreciation, accretion of operating lease liabilities and foreign currency exchange rates and a net change of $1.2 million in our net operating assets and liabilities.

Investing Activities

During the nine months ended September 30, 2026, cash provided by investing activities of $50.8 million was attributable to $51.0 million from the maturity of short-term investments, partially offset by $0.2 million of purchases of property and equipment.

During the nine months ended September 30, 2025, cash used in investing activities of $100.0 million was attributable to $99.0 million of purchases of investments and $1.0 million of purchases of property and equipment.

Financing Activities

During the nine months ended September 30, 2026, cash provided by financing activities of $292.4 million was attributable to $140.2 million in sales of common stock, net of issuance costs paid, $128.2 million from the exercise of common stock warrants, $34.7 million in sales of common stock under our 2025 ATM Program, net of sales agent commission and fees, $0.2 million from the purchases of shares under our 2019 Employee Stock Purchase Plan, or 2019 ESPP and $0.2 million from the exercise of employee stock options, offset by $11.0 million in principal payments on finance leases.

During the nine months ended September 30, 2025, cash provided by financing activities of $92.0 million was attributable to $93.5 million in sales of common stock, warrants and pre-funded warrants to purchase common stock, net of issuance costs paid, $2.6 million in sales of common stock from our ATM offering, net of sales agent commission and fees and $0.2 million from the purchases of shares under our 2019 ESPP, offset by $4.3 million in principal payments on finance leases.

Contractual Obligations and Commitments

For a discussion of contractual obligations and other commitments affecting us, see the discussion under the heading "Management Discussion and Analysis of Financial Condition and Results of Operations – Contractual obligations and other commitments" included in our Annual Report on Form 10-K for the year ended December 31, 2025, as filed with the SEC on March 23, 2026.

There have been no material changes to the Company's contractual obligations and other commitments since December 31, 2025.

Critical Accounting Policies and Significant Judgments and Estimates

The Critical Accounting Policies and Significant Judgments and Estimates included in our Annual Report on Form 10-K for the year ended December 31, 2025, as filed with the SEC on March 23, 2026, have not materially changed.

Smaller Reporting Company Status

We are a "smaller reporting company," as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended. We would cease to be a smaller reporting company if we have a public float in excess of $250 million, or have annual revenues in excess of $100 million and a public float in excess of $700 million, determined on an annual basis. This status allows us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

Recently Issued Accounting Pronouncements

For a discussion of recently issued accounting pronouncements please read Note 2, Summary of Significant Accounting Policies, to our unaudited condensed consolidated financial statements included in this report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. We held cash and cash equivalents of $299.4 million as of September 30, 2026. We generally hold our cash in interest-bearing money market treasury fund accounts. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term maturities of our cash equivalents, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents. Declines in interest rates, however, would reduce future investment income.

We do not have any foreign currency or derivative financial instruments. Inflation generally affects us by increasing our cost of labor and program costs. Although we do not believe that inflation has had a material impact on our financial position or results of operations to date, we may experience some effect in the near future (especially if inflation rates continue to rise) due to an impact on the costs to conduct clinical trials, labor costs we incur to attract and retain qualified personnel, and other operational costs. Inflationary costs could adversely affect our business, financial condition and results of operations.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of the end of the period covered by this report. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this report were effective at a reasonable assurance level in ensuring that information required to be disclosed by us in reports that we file or submit under the Exchange Act (i) is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely discussions regarding required disclosure. We believe that a control system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the control system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) of the Exchange Act) that occurred during the fiscal quarter ended September 30, 2026 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, our company may become involved in litigation or legal proceedings. While the outcome of any such proceedings cannot be predicted with certainty, as of September 30, 2026, we are not involved in any material litigation or legal proceedings that we would expect to have a material adverse impact on our financial position, results of operations, or cash flows.

Item 1A. Risk Factors.

Our business involves material and other risks, some of which are summarized and described below. You should carefully consider the risks and uncertainties described below, together with all of the other information contained in this Quarterly Report on Form 10-Q, including "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the condensed consolidated financial statements and the related notes. If any of the following risks actually occur, it could harm our business, prospects, operating results and financial condition and future prospects. In such event, the market price of our common stock could decline and you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. This Quarterly Report on Form 10-Q also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this Quarterly Report.

The risk factors denoted with a "", if any, are newly added or have been materially updated from our Annual Report on Form 10-K for the year ended December 31, 2025.*

Risks Related to Our Business, Technology and Industry

Risks Related to Clinical Development

We are early in our development efforts. If we are unable to advance our product candidates through clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

We are early in our development efforts and we have not yet completed any clinical trials. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of one or more of our product candidates. Even if we are able to develop and commercialize a marketable product, we may face challenges generating revenue from product sales. The success of our product candidates will depend on several factors, including the following:

- successful completion of preclinical studies resulting in data that is supportive of advancing to an investigational new drug, or IND, or clinical trial application, or CTA submission;
- successful submission and acceptance of INDs, CTAs or comparable applications;
- successful initiation of clinical trials;
- demonstration of adequate safety to progress to a therapeutic dose level;
- successful patient enrollment in and completion of clinical trials;
- receipt and related terms of regulatory and marketing approvals and licensures from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers for clinical supply and commercial manufacturing of our product candidates;
- making arrangements with various medical divisions across hospitals for administration of our product candidates, including with cancer treatment centers to conduct leukapheresis and with the relevant hospital divisions to perform infusion;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- establishing sales, marketing and distribution and patient administration capabilities and launching commercial sales of our products, if and when licensed, whether alone or in collaboration with others;
- acceptance of our products, if and when licensed, by patients, the medical community and third-party payors;

•effectively competing with established and emerging therapies targeting the same indications as our product candidates;

•obtaining and maintaining third-party coverage and adequate reimbursement; and

•maintaining a continued acceptable safety profile of our products following licensure.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or be unable to successfully commercialize our product candidates, which would materially harm our business. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations.

Cellular therapies, including our engineered chimeric antigen receptor T cell, or CAR T, chimeric autoantibody receptor T cell, or CAAR T, product candidates, represent a novel approach to the treatment of autoimmune diseases, which creates significant challenges for us. Negative perception or increased regulatory scrutiny of any product candidates that we develop could adversely affect our ability to conduct our business or obtain regulatory approvals for such product candidates.

Cellular therapies are a novel approach to the treatment of autoimmune diseases, and negative perception or increased regulatory scrutiny of any product candidates that we develop could adversely affect our ability to conduct our business or obtain regulatory approvals for such product candidates. There are no cellular immunotherapies licensed to date in the United States or the European Union to treat autoimmune diseases or alloimmune responses. CAR T or CAAR T cell therapies for autoimmune or alloimmune diseases may not gain the acceptance of the public or the medical community. For example, CAR Ts and other cellular therapies have in some cases caused severe side effects, including death, and their broader use may therefore be limited. In the future, in the event such severe side effects are observed with other CAR T therapies (including those with a CD19 binder), it may increase negative perception of, and regulatory scrutiny on, our product candidates. For example, in November 2023, the FDA announced that it would be conducting an investigation into reports of T cell malignancies following treatment with BCMA-directed or CD19-directed autologous CAR T cell immunotherapies. The FDA also stated that patients and clinical trial participants receiving treatment with such approved products should be monitored life-long for new malignancies. In January 2024, the FDA determined that new safety information related to T cell malignancies should be included in the labeling with boxed warning language on these malignancies for all BCMA- and CD19-directed genetically modified autologous T cell immunotherapies. Public perception may be influenced by claims that gene therapy, including the insertion of a transgene, is unsafe, and products incorporating gene therapy may not gain the acceptance of the public or the medical community. The patient populations targeted by our product candidates are also typically not at risk of near-term death, even if they may suffer life-threatening symptoms, so patients will need to deem the benefits of cell therapy to be worth the risk of unknown potential adverse side effects. Our success will depend upon physicians who specialize in the treatment of autoimmune diseases targeted by our product candidates prescribing treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments with which they are more familiar and for which greater clinical data may be available. Adverse events in clinical trials of our product candidates, in clinical trials of others developing similar products or in the post-approval setting and the resulting publicity, as well as any other adverse events in the field of cellular therapies, could result in a decrease in demand for any product that we may develop. For example, in August 2026, after reports of immune effector cell-associated hemophagocytic syndrome resulting in three patient deaths in clinical trials, Novartis announced suspension of trials of a CAR T candidate in development for treatment of autoimmune conditions. Bristol Myers Squibb similarly paused enrollment in autoimmune trials of a CAR T candidate after noting "transient and reversible inflammatory events." These types of adverse events associated with CAR T product candidates in the autoimmune setting may result in additional scrutiny of our approach from regulators, healthcare providers, and patients.

We are developing a pipeline of CAR T and CAAR T product candidates that are intended for use in treating individuals with autoimmune diseases. Advancing these novel product candidates creates significant challenges for us, including:

•manufacturing our product candidates to our specifications and in a timely manner to support our clinical trials, and, if licensed, commercialization;

•sourcing clinical and, if licensed, commercial supplies for the materials used to manufacture our product candidates;

•understanding and addressing variability in the quality and quantity of a subject's T cells, which could ultimately affect our ability to manufacture clinical supply and, if licensed, commercial supply of our product candidates in a reliable and consistent manner;

•educating medical personnel regarding the potential side effect profile of our product candidates, if licensed, such as the potential adverse side effects related to worsening of systemic lupus erythematosus, or SLE, idiopathic inflammatory myopathy (IIM), or myositis, systemic sclerosis, or SSc, muscle-specific kinase myasthenia gravis, or MuSK MG, generalized myasthenia gravis, or gMG, pemphigus vulgaris, or PV, adverse effects related to infusion of activated T cells or medication taper, including cytokine release syndrome, or CRS, immune effector cell-associated neurotoxicity syndrome, or ICANS, or other unexpected adverse effects of therapy with our product candidates or potential class-wide side effects, such as those related to CD19-directed autologous CAR T cell immunotherapies;

•facilitating patient access to the limited number of facilities able to administer our product candidates, if licensed;

•using medicines to manage adverse side effects of our product candidates that may not adequately control the side effects and/or may have a detrimental impact on the efficacy of the treatment;

•utilizing preconditioning agents in patients to enhance engraftment in advance of administering our product candidates, which may increase the risk of adverse side effects and potentially reduce the population eligible for therapy;

•obtaining and maintaining regulatory approval for our product candidates, as the FDA and other regulatory authorities have limited or no experience with development of engineered T cell therapies for the treatment of autoimmune diseases where B cells may play a role in initiating or maintaining disease;

•establishing sales and marketing capabilities upon obtaining any regulatory approval to gain market acceptance of a novel therapy; and

•managing costs of inputs and other supplies while scaling production.

In addition, preclinical murine and other animal models may not exist or be adequate for some or all of the autoimmune diseases where B cells may play a role in initiating or maintaining disease we choose to pursue in our programs, and because we are early in the clinical development process, we are unable to predict whether there may be short-term or long-term effects from treatment with any product candidates that we develop. In developing our product candidates, we have not exhaustively explored different options in the method for manufacturing CAR T or CAAR T cells. We may find our existing manufacturing process may be substantially improved with future design or process changes, necessitating further clinical testing, delaying commercial launch of our first products, and causing us to incur additional expenses. For example, while we have used a lentiviral vector in our manufacturing process, we may in the future find that another viral vector or non-viral vector-based process offers advantages. Switching from one lentiviral vector to another or switching from lentiviral to another delivery system would necessitate additional process development and clinical testing, and this may delay the development of existing product candidates.

In addition, for certain RESET™ trials, we do not know the doses to be evaluated in pivotal trials or, if licensed, commercially. Finding a suitable dose may delay our anticipated clinical development timelines, and we may elect to pause clinical trials to find a suitable dose or make assessments ahead of continuing a trial. Our expectations with regard to our scalability and costs of manufacturing may vary significantly as we develop our product candidates and understand these critical factors. We may experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners, which may prevent us from completing our clinical studies or commercializing our product candidates on a timely or profitable basis, if at all.

Moreover, our product candidates may not perform successfully in clinical trials or may be associated with adverse events that distinguish them from the CAR T therapies that have previously been licensed. For instance, subjects in our CAAR T clinical trials have been infused with our proposed therapies, and may possess strongly activating soluble antibodies, which are not present in oncology patients, and when they interact with our infused product candidates, could result in potential adverse side effects, such as CRS or ICANS, which have been observed in our clinical trials. Additionally, adverse side effects caused by even one of our CAR T or CAAR T product candidates could negatively affect our ability to develop future product candidates based on our CABA® platform. Unexpected side effects or clinical outcomes from any of our product candidates would significantly impact our business.

Further, the clinical study requirements of the FDA, the European Medicines Agency, or EMA, and other regulatory agencies and the criteria they use to determine the safety, potency and purity of a product candidate are determined according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates such as ours is less clear, and can be more complex and consequently have higher development risk, be more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates. Approvals by the FDA for existing cell therapies treating B cell-mediated diseases, such as Kymriah (Novartis Pharmaceuticals Corporation) and Yescarta® (Gilead Sciences, Inc.) in oncology indications, may not be indicative of what the FDA may require for approval of our therapies in autoimmune indications. Approvals by any regulatory agency may not be indicative of what any other regulatory agency may require for approval or what such regulatory agencies may require for approval in connection with new product candidates. As we advance our product candidates, we will be required to consult with these regulatory agencies and comply with applicable requirements and guidelines. If we fail to do so, we may be required to delay or discontinue development of such product candidates. These additional processes may result in a review and approval process that is longer than we otherwise would have expected. More restrictive statutory regimes, government regulations or negative public opinion would have an adverse effect on our business, financial condition, results of operations and prospects and may delay or impair the development and commercialization of our product candidates or demand for any products we may develop.

In addition, responses by agencies at the federal and state level to negative public perception or ethical concerns may result in new legislation or regulations that could limit our ability to develop or commercialize any product candidates, obtain or maintain regulatory approval or otherwise achieve profitability. The FDA has expressed interest in further regulating biotechnology products, such as cellular therapies. Agencies at both the federal and state level in the United States, as well as the U.S. Congressional committees and other government entities or governing agencies have also expressed interest in further regulating the biotechnology industry. Such action may delay or prevent commercialization of some or all of our product candidates. Adverse developments in clinical trials of cellular therapy products conducted by others or in the post-approval setting may cause the FDA or other oversight bodies to change the

requirements for approval of any of our product candidates. These regulatory review agencies and committees and the new requirements or guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies or trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions.

Patients receiving T cell-based immunotherapies, such as our product candidates, have in the past and may in the future experience serious adverse events, including ICANS, CRS and killing of cells other than the intended B cells that express the autoantibodies. If our product candidates are revealed to have high and unacceptable severity and/or prevalence of side effects or unexpected characteristics, their clinical development, regulatory approval, and commercial potential will be negatively impacted, which will significantly harm our business, financial condition and prospects.

Our product candidates are CAR T or CAAR T cell-based immunotherapies. In our clinical trials and clinical trials of other similarly designed cellular immunotherapies to treat cancer, there have been life threatening events related to ICANS and/or CRS requiring intense medical intervention, such as intubation or medications to support blood pressure, and in several cases in clinical trials of other similarly situated clinical trials and of other similarly designed immunotherapies to treat cancer resulted in death. We have observed events of CRS and ICANS in our ongoing rese-cel REstoring SElf-Tolerance, or RESET, trial. ICANS is a condition that is currently defined clinically by cerebral edema, confusion, drowsiness, speech impairment, tremors, seizures or other central nervous system side effects, when such side effects are serious enough to lead to intensive care. CRS is a condition that is currently defined clinically by certain symptoms related to the release of cytokines, which can include fever, chills and low blood pressure, when such side effects are serious enough to lead to intensive care with mechanical ventilation or significant medications to support blood pressure. There is a possibility that our product candidates could have similarly life threatening serious adverse side effects, such as ICANS and CRS.

Our product candidates may have serious and potentially fatal consequences due to the targeting of cells within the body due to unexpected protein interactions with the CAR or CAAR. Although we have completed multiple preclinical studies designed to screen for toxicity caused by unintended off-target recognition by the cell binding domain of the DSG3 CAAR, MuSK CAAR and rese-cel and intend to screen future CAR candidates not yet tested in patients through preclinical studies, our product candidates may still recognize and react with one or more proteins unrelated to the intended surface immunoglobin target protein to which it is designed to link. If unexpected binding occurs in normal tissue, our product candidates may target and kill the normal tissue in a patient, leading to serious and potentially fatal adverse events, undesirable side effects, toxicities or unexpected characteristics. Detection of any unexpected targeting may halt or delay any ongoing clinical trials for our product candidates and prevent or delay regulatory approval. While we have developed a preclinical screening process to identify cross-reactivity of our product candidates, we cannot be certain that this process will identify all potential tissue that our product candidates may target. For example, a membrane protein array with DSG3-CAART yielded one weak signal against a protein that is designed to bind to glycoproteins and which was detected in both the test and control conditions. Further analysis of this protein in confirmatory cell-based assays repeatedly demonstrated that DSG3-CAART does not recognize nor activate against this protein. We performed similar preclinical studies for rese-cel and did not observe any confirmed off target activity for rese-cel. However, this further analysis may prove to be inaccurate. Any unexpected targeting that impacts patient safety could materially impact our ability to advance our product candidates into clinical trials or to proceed to marketing approval and commercialization. Furthermore, in the event subjects are re-treated, they may respond differently than other subjects given the same dose, and may not tolerate the dose or develop safety concerns.

Results of our studies could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory agencies. Our clinical trials of rese-cel represent the first evaluation of this product candidate in patients and rese-cel is directed against all B cells expressing CD19; therefore, there is a risk for prolonged B cell aplasia and/or hypogammaglobulinemia, which may predispose patients to infections. Given that the autoimmune and alloimmune diseases we are seeking to treat are, in some cases, less serious than the later stage cancers being treated with other immunotherapy products, we believe the FDA and other regulatory authorities likely will apply a different benefit-risk assessment thresholds such that even if our product candidate demonstrated a similar safety profile as current CAR T therapies, the FDA may ultimately determine that the harmful side effects outweigh the benefits and require us to cease clinical trials or deny approval of our product candidates. We believe tolerance for adverse events in the patient population being pursued with our CAAR T and CAR T cell therapies in autoimmune and alloimmune indications will be lower than it is in oncology, and the risks of negative impact from these toxicities may therefore be higher for us than for CAR T programs in oncology.

Furthermore, treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the studies or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from T cell-based immunotherapies are not normally encountered in routine medical care. Medical personnel may need additional training regarding T cell-based immunotherapy product candidates to understand their side effects. Inadequate training in recognizing or failure to effectively manage the potential side effects of T cell-based immunotherapy product candidates could result in patient deaths. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition to side effects caused by our product candidates, any preconditioning, administration process or related procedures, which we evaluate from time to time as part of our process improvement and optimization efforts, may also cause adverse side effects. For example, prolonged or persistent cytopenias and ICANS have been noted to be associated with the use of certain lymphodepleting regimens and CAR T therapies.

Preconditioning regimens, as currently implemented in several of our clinical trials, may increase the risk of adverse side effects and impact our ability to accurately assess the efficacy of our product candidates.

In oncology patients receiving CAR T cell therapy, a lymphodepleting preconditioning regimen is typically used to condition the patient prior to CAR T cell infusion in order to improve tumor immunogenicity and to promote the expansion of the infused CAR T cells. Together, these effects have been shown to enhance the clinical activity of CAR T cells in oncology patients. These regimens often include cyclophosphamide and fludarabine and are usually administered within the week prior to infusion of CAR T cells. We implemented a preconditioning regimen in the DesCAARTes™ trial where certain subjects were pre-treated with IVIg and cyclophosphamide, and other patients were pre-treated with IVIg, cyclophosphamide, and fludarabine prior to DSG3-CAART infusion, have included planned dosing cohorts in the MusCAARTes™ trial where subjects were pre-treated with fludarabine and cyclophosphamide prior to MuSK-CAART infusion, and we have incorporated a lymphodepleting preconditioning regimen of fludarabine and cyclophosphamide in our RESET™ clinical trials. We are evaluating rese-cel without preconditioning in our RESET-PV® trial in patients with mPV and mcPV, as well as in a subset of patients enrolled in our RESET-SLE® trial. Serious adverse events have been observed in some patients following CAR T cell infusion, and these include infection, cytokine release syndrome and ICANS. The lymphodepleting and immunomodulatory preconditioning regimen may contribute to the occurrence and severity of these adverse events due to its role in inducing leukopenia, or low levels of white blood cells in the blood, including lymphopenia, or low levels of lymphocytes in the blood, and regulating the activation and effector functions of other immune cells and antibodies, and enhanced CAR T cell activity.

In addition, a lymphodepleting regimen may eliminate pathogenic B cells targeted by our CAAR T cell product candidates. As a result, any lymphodepleting regimen for preconditioning that we use may delay or otherwise adversely affect our ability to use DSG3 or MuSK autoantibody titers, a standard clinical assay, to assess the activity of DSG3-CAART and MuSK-CAART, respectively. An inability to use DSG3 or MuSK autoantibody levels to demonstrate the specific activity of our CAAR T cell product candidates may require us to rely on the subjective measurement of blister formation in patients in the DesCAARTes™ trial or muscle weakness in the MusCAARTes™ trial, which can be a less sensitive and accurate measurement of CAAR T cell activity. This therefore could delay a signal of potential biologic activity attributable to CAAR and therefore may slow clinical development. We are not actively enrolling patients in the MusCAARTes™ trial at this time.

In addition to lymphodepleting preconditioning, other preconditioning regimens with immunomodulatory effects may be considered to prepare the body for CAR T or CAAR T infusion. For example, if autoantibody is found to reduce or inhibit function of CAAR T in the body, then pretreatment of patients with antibody reducing therapies, such as FcRN inhibitors, IVIg, plasmapheresis, or treatment of post rituximab patients may be considered. Some of these types of preconditioning are standard of care for this autoimmune population and therefore are already considered to have a beneficial risk profile in this patient population. These other preconditioning regimens may cause serious adverse events, including hypotension, thromboembolism, and opportunistic infections.

Subjects in our RESET™ trials, except for our RESET-PV® trial and a subset of patients enrolled in our RESET-SLE® trial, will be treated with a standard preconditioning regimen consisting of fludarabine and cyclophosphamide prior to rese-cel infusion. In addition, the lymphodepleting regimen may eliminate some of the pathogenic B cells targeted by rese-cel. As a result, the lymphodepleting regimen may contribute to the initial clinical response that may be observed after rese-cel, which may make interpretation of early efficacy difficult to assess and may also delay our ability to characterize the activity of rese-cel independent of the effects of fludarabine and cyclophosphamide. We intend to evaluate this potential impact of preconditioning in our CAAR and rese-cel studies, through the comparison to non-lymphodepletion arms.

Our clinical patients may experience increased or more severe adverse effects specifically related to the preconditioning regimens, such as severe allergic reactions, difficulty breathing, severe headaches, fevers and chills, serious infections, low blood counts, inflammation of the colon with bleeding, bladder irritation, blood clots, development of certain cancers, damage to the heart, lung or kidneys, and even death. These undesirable side effects, whether associated with the preconditioning regimen alone or in combination with our CAR T cell product candidates or CAAR T cell product candidates, could cause delays in patient enrollment in our clinical trials, could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a change to our clinical trial design, a more restrictive label or the delay or denial of regulatory approval by the FDA. Any of the foregoing may increase the duration

and expense of the clinical development of our product candidates or limit market acceptance of such product candidates, if approved, any of which could have a material adverse effect on our business and financial condition.

Our business is highly dependent on the success of our initial product candidates targeting autoimmune diseases where B cells may play a role in initiating or maintaining disease. All of our product candidates will require significant additional preclinical and/or clinical development before we can seek regulatory approval for and launch a product commercially.

Our business and future success depend on our ability to obtain regulatory approval of, and then successfully launch and commercialize our initial product candidates targeting autoimmune diseases where B cells may play a role in initiating or maintaining disease. There is no guarantee that we will be able to advance our product candidates through clinical development or obtain marketing approval for any of our product candidates. The process for obtaining marketing approval for any product candidate is very long and risky and there will be significant challenges for us to address in order to obtain marketing approval as planned, if at all.

The initial clinical results we have observed may not be predictive of results of subsequent cohorts in this clinical trial, or of any future clinical trials. Because rese-cel is the first CAR T product candidate that we are testing in the clinic, we may experience preliminary complications surrounding trial design, protocol establishment and execution, establishing trial protocols, patient recruitment and enrollment, quality and supply of clinical doses, or safety issues.

Additionally, a failure of our rese-cel RESET™ clinical trial could influence physicians' and regulators' opinions with regard to the viability of our CABA® platform more broadly, particularly if treatment-related side effects are observed. The occurrence of any of these risks could significantly harm our development plans and business prospects. If treatment-related side effects are observed with the administration of rese-cel, or if they are viewed as less safe, potent or pure than other therapies, our ability to develop other CAR T cell therapies may be significantly harmed.

We have never successfully completed any clinical trials, and we may be unable to do so for any product candidates we develop.

We have not yet demonstrated our ability to successfully complete any clinical trials, including large-scale, pivotal clinical trials, obtain regulatory approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Although our key employees have significant experience in leading clinical development programs, our experience conducting clinical trials with our product candidates is limited. We may not be able to file INDs or CTAs for any of our other product candidates on the timelines we expect, if at all. For example, we cannot be certain that the IND-enabling or CTA-enabling studies for our future product candidates will be completed in a timely manner or be successful or that the manufacturing process will be validated in a timely manner. Even if we submit an IND or CTA for a future product candidate, the FDA, the EMA, or other foreign regulatory authorities may not clear the IND or CTA and allow us to begin clinical trials in a timely manner or at all. The timing of submissions on future product candidates will be dependent on further preclinical and manufacturing success. Moreover, we cannot be sure that submission of an IND or a CTA will result in the FDA or other foreign regulatory authorities allowing further clinical trials to begin, or that, once begun, issues will not arise that require us to suspend or terminate clinical trials. Commencing each of these clinical trials is subject to finalizing the trial design based on discussions with the FDA and other foreign regulatory authorities. Any guidance we receive from the FDA or other foreign regulatory authorities is subject to change. These regulatory authorities could change their position, including, on the acceptability of our trial designs or selection of comparator or clinical endpoints, which may require us to complete additional clinical trials or impose stricter approval conditions than we currently expect. If the FDA disagrees with, or subsequently revises or withdraws its prior feedback regarding our clinical endpoints or how to measure clinically meaningful significance, then even if we meet clinical endpoints we may be prevented or delayed in obtaining marketing approval for such product candidates.

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

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- be subject to post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

Our registrational trials may rely on a single-arm design and an external control; if regulatory authorities determine that the external control is unsuitable, we may be unable to obtain approval on our anticipated timelines, or at all.

We plan to conduct registrational trials using an open-label, single-arm design with an external comparator(s) rather than a blinded, randomized controlled trial. As a result, data generated from these studies may be subject to heightened FDA scrutiny regarding potential bias, confounding variables, and the overall reliability of treatment-effect estimates. In externally controlled trials, outcomes for patients who receive the investigational therapy according to the trial protocol are compared with outcomes from individuals who did not receive the investigational therapy and who are external to the trial. External controls may be historical (from an earlier time period) or concurrent (collected during the same time period in a different setting), and may be derived from real-world data sources such as patient registries, electronic health records, or medical claims. For example, in our RESET-Myositis® program for rese-cel, we intend to conduct a single-arm registrational trial in patients with dermatomyositis or antisynthetase syndrome evaluating a 16-week primary endpoint—defined as achievement of a moderate or major Total Improvement Score while off immunomodulators and on no or low-dose steroids—and we intend to rely on a retrospective analysis of a myositis patient registry to estimate control response rates.

Use of a registry dataset introduces risks, including whether the dataset is sufficiently comparable to our trial population and whether key clinical and demographic variables are assessed consistently. If the FDA disagrees with, or subsequently revises or withdraws its prior feedback regarding the suitability of our trial design, analytical methods, or the external control dataset, the FDA may require additional data, extended follow-up, alternative endpoints, or a randomized controlled trial. Any of these outcomes could substantially delay or prevent regulatory approval. The FDA has highlighted multiple risks associated with the use of external controls, including the potential for confounding and bias arising from, among other factors: temporal changes in standard of care; geographic differences in treatment practices or access to care; heterogeneity in diagnostic criteria; differences in prognostic indicators; variations in background therapies; differing clinical characteristics and responses to standard of care among patients with different disease subtypes; differing assessment schedules or endpoint definitions; missing data; and selection bias in the external dataset. The FDA also generally expects patient-level access to external datasets and robust, pre-specified statistical analysis plans. Even with such plans, as well as propensity methods and sensitivity analyses, these approaches may insufficiently mitigate confounding and bias in the view of the FDA.

If our external control dataset, its pre-specification, or our planned analyses are viewed as inadequate, the FDA may determine that our single-arm registrational trial does not constitute an "adequate and well-controlled" investigation under applicable regulations, and may make such determination even where we believe that we have previously aligned with the FDA on the design of the registrational trial. The FDA may also determine that any patient registry we use—including the myositis registry supporting our RESET-Myositis® cohort—is unsuitable as an external control. In March 2026, FDA noted that concerns with the use of a registry include potential differences between the enrolled study population and registry population for the RESET-Myositis® cohort (e.g. diagnosis classification and refractory definition) and missing data as well as other criteria established by FDA guidance for industry, and that such details are needed in order to assess suitability of the proposed registry as an external control. In addition, FDA has recently issued Complete Response Letters or changed its feedback to sponsors in pre-BLA meetings citing concerns with external controls such as potential bias and design flaws, including eligibility criteria, endpoints, and timing of assessments not being closely aligned between trial population and the external dataset. If the FDA reaches similar conclusions in our case, it could reject our comparative analyses, request confirmatory data, or require a randomized trial, resulting in significant delays, increased costs, or failure to obtain approval.

Even if our clinical data and statistical analyses comparing our data to an external control—such as a myositis registry—demonstrate favorable evidence of the investigational candidate's effectiveness, the FDA may still determine that such evidence is insufficient to support approval. This could occur for a variety of reasons, including unfavorable interpretation of comparative analyses, perceived differences between the clinical and external datasets, questions regarding the adequacy of our sensitivity analyses, or concerns about the absence of additional control sources.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- inability to bring our product candidates to the market;
- decreased demand for our product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;

•initiation of investigations by regulators;

•costs to defend the related litigation;

•a diversion of management's time and our resources;

•substantial monetary awards to trial participants or patients;

•product recalls, withdrawals or labeling, marketing or promotional restrictions;

•loss of revenue;

•exhaustion of any available insurance and our capital resources;

•the inability to commercialize any product candidate; and

•a decline in our share price.

Since we have not yet commenced marketing of any products, we do not yet hold product liability insurance for commercialization of our product candidates. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with corporate collaborators. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. Assuming we obtained clinical trial insurance for our clinical trials, we may have to pay amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

Risks Related to the Industry

Our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.

Undesirable or unacceptable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other foreign regulatory authorities. Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of subjects and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the drug. Undesirable side effects could also result in an expansion in the size of our clinical trials, increasing the expected costs and timeline of our clinical trials. Additionally, results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics.

Licensed CAR T cell therapies and those under development have shown frequent rates of CRS and ICANS, and adverse events have resulted in the death of patients. Similar adverse events have occurred and could occur during treatment with our current or future CAR T or CAAR T cell product candidates. For example, activation of CAAR T cells by patient autoantibodies or alloantibodies could stimulate CRS. When CAAR T cells are infused and the CAAR binds to soluble antibodies in the blood or tissues of treated patients, these soluble antibodies may cause the CAAR T cells to proliferate, resulting in an activation of the immune system that is too high, leading to CRS. Further, it is possible that patients will exhibit acute rejection of the CAAR T cells because of preexisting immunity to the antigen within the CAAR. This could render our product candidates ineffective.

If unacceptable toxicities or health risks, including risks inferred from other unrelated immunotherapy trials, arise in the development of our product candidates, we could suspend or terminate our trials or the FDA, the Safety Monitoring Boards for our trials (e.g. Data Safety Monitoring Board, or DSMB, or Independent Data Safety Monitoring Committee, or IDMC), or local regulatory authorities such as institutional review boards, or IRBs, or independent ethics committees, or IECs, as applicable, could recommend or order us to cease clinical trials. Regulatory authorities, such as the FDA, could also deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from T cell therapy are not normally encountered in the general patient population and by medical personnel. We expect to have to train medical personnel using CAR T or CAAR T cell product candidates to understand the side effect profile of our product candidates for both our preclinical studies and clinical trials and upon any commercialization of any of our product candidates, if licensed. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient deaths. Any of these occurrences may harm our business, financial condition and prospects significantly.

Our preclinical studies and clinical trials may fail to demonstrate the safety, potency and purity of any of our product candidates, which would prevent or delay regulatory approval and commercialization.

Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are safe, potent and pure for use in each target indication. Clinical trials are expensive and can take many years to complete, and their outcomes are inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials, including in any post-approval studies of our product candidates. In addition, initial success in any clinical trials may not be indicative of results obtained when such trials are completed. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety, potency and purity profile despite having progressed through preclinical studies and initial clinical trials. Similarly, while we believe rese-cel has a similar overall design to the construct used for the patients in the *Nature Medicine, Lancet, Annals of Rheumatic Diseases, and Rheumatology* publications, those studies involved a small number of patients, and a different product candidate, and the initial clinical results observed in those studies may not be predictive of clinical trial results with rese-cel or any of our other product candidates. Additionally, because those studies are not our own, we may not have access to accurate follow-up information or peer-reviewed results.

A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of potency or efficacy, insufficient durability of potency or efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical and other nonclinical findings made while clinical trials were underway, or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA or European Commission approval. Most product candidates that commence clinical trials are never approved as products.

Any preclinical studies or clinical trials that we may conduct may not demonstrate the safety, potency and purity necessary to obtain regulatory approval to market our product candidates. If the results of our ongoing or future preclinical studies and clinical trials are inconclusive with respect to evaluations of efficacy, the safety, potency and purity of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may be prevented or delayed in obtaining marketing approval for such product candidates. In some instances, there can be significant variability in evaluations of efficacy, safety, potency or purity results between different preclinical studies and clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. For example, because our CAAR T cell product candidates only target approximately 0.01% to 1% of the B cells in a patient, they may not engage enough of the target to achieve adequate engraftment necessary for elimination of all pathogenic B cells. Insufficient safety or potency in clinical trials may delay product development to enable time to modify the product candidate for next generation approaches or make manufacturing changes or may lead us to discontinue development of the product candidate.

Additionally, our ongoing clinical trials utilize, and our planned trials may utilize, an "open-label" trial design. An "open-label" clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an active drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a "patient bias" where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open-label trial may not be predictive of future clinical trial results with any of our product candidates for which we include an open-label clinical trial when studied in a controlled environment with a placebo or active control.

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

In order to market any product outside of the United States, a company must also comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of products. Whether or not it obtains FDA approval for a product, an applicant must obtain the necessary approvals by the comparable foreign regulatory authorities before commencing clinical trials or marketing of the product in those countries or jurisdictions. For example, the process governing approval of medicinal products in the European Union generally follows the same lines as in the United States but can differ in significant ways. It entails the satisfactory completion of preclinical studies and adequate and well-controlled clinical trials to establish the safety and efficacy of the product for each proposed indication. It also requires the submission of a marketing authorization application to the EMA (for products within the scope of the centralized marketing authorization procedure) and the granting of a marketing authorization by the European Commission before the product can be marketed and sold in the European Union.

Interim, topline or preliminary data from any preclinical studies or clinical trials that we conduct may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data.

Our RESET^{TM} trials in SLE, myositis, SSc, gMG and PV are designed as open-label trials. From time to time, we may publicly disclose interim, preliminary or topline data from our preclinical studies and clinical trials, including safety data and evaluations of efficacy, which will be based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following our receipt of additional data or a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data.

As a result, the 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. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from planned interim analyses in our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or our competitors, or by patients or caregivers who are aware that a patient is receiving investigational product, due to the open-label design of the trial, could result in volatility in the price of our common stock.

Regulatory agencies, including the FDA or other foreign regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general.

If the interim, topline or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

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

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

We may encounter substantial delays in our clinical trials or may not be able to conduct our trials on the timelines we expect or at all.

Clinical testing is expensive, time consuming and subject to uncertainty. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. Even if these trials begin as planned, issues may arise that could suspend or terminate such clinical trials. A failure of one or more clinical trials can occur at any stage of testing, and our ongoing and future clinical trials may not be successful. Events that may prevent successful or timely completion of clinical development include:

- inability to generate sufficient preclinical, toxicology or other in vivo or in vitro data to support the initiation of clinical trials;
- delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for clinical trials;
- delays in developing suitable assays for screening patients for eligibility for clinical trials with respect to certain product candidates;
- delays in reaching a consensus with the FDA and other regulatory agencies on trial design;
- delays in reaching agreement on acceptable terms with prospective CMOs, CROs and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CMOs, CROs and clinical trial sites;
- delays in obtaining required IRB approval at each clinical trial site;
- imposition of a temporary or permanent clinical hold by regulatory agencies for a number of reasons, including after review of an IND submission or amendment, or equivalent application or amendment; as a result of a new safety finding that presents unreasonable risk to clinical trial participants; a negative finding from an inspection of our clinical study operations or study sites; developments on trials conducted by competitors for related technology or by those that rely on a similar construct, design and/or third-party research that raise FDA or other foreign regulatory authorities concerns about risk to patients of the technology or construct broadly, and/or negative public perception of the same; or if FDA or other foreign regulatory authorities find that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- delays in recruiting eligible patients to participate in our clinical trials, including pediatric patients who need parental consent;
- delays in treating one or more patients, once enrolled, due to a patient's inability to accommodate parts of the complex study procedures schedule;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, other third parties or us to adhere to clinical trial requirements and the potential termination of ongoing agreements with our CROs;
- failure to perform in accordance with the FDA's Good Clinical Practice, or GCP, requirements or applicable regulatory guidelines in other countries;
- transfer of manufacturing processes to any new CMO or our own manufacturing facilities or any other development or commercialization partner for the manufacture of product candidates;

•delays in having patients complete participation in a trial or return for post-treatment follow-up;

•patients dropping out of a trial;

•occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;

•changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;

•changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;

•the cost of clinical trials of our product candidates being greater than we anticipate;

•clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon product development programs;

•delays or failure to secure supply agreements with suitable raw material suppliers, or any failures by suppliers to meet our quantity or quality requirements for necessary raw materials; and

•delays in manufacturing or inability to manufacture sufficient clinical supply (for example, due to capacity constraints, supply interruption, or the need to engineer the process to meet higher dose requirements), testing, releasing, validating or importing/exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue. If we make manufacturing or formulation changes to our product candidates, we may be required to, or we may elect to, conduct additional trials to bridge our modified product candidates to earlier versions. Clinical trial delays could also shorten any periods during which our product candidates and products, if licensed, have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

We could also encounter delays if a clinical trial is suspended or terminated by us, the FDA or other regulatory authority, or if the IRBs of the institutions in which such trials are being conducted suspend or terminate the participation of their clinical investigators and sites subject to their review. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Delays in the initiation, conduct or completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. In the event we identify any additional product candidates to pursue, we cannot be sure that submission of an IND or comparable foreign regulatory submission will result in the FDA or other foreign regulatory authorities allowing clinical trials to begin in a timely manner, if at all.

In addition, from time to time, we may publicly announce the expected timing of various scientific, clinical, regulatory, manufacturing and other product development milestones. These milestones may include the commencement, completion or development of data from our preclinical studies and clinical trials or the submission of regulatory filings, such as an IND or a CTA. All of these milestones are, and will be, based on a variety of assumptions. If any of the foregoing events impact our ability to meet the publicly announced timing of our milestones, we may experience adverse effects on our business, financial condition and prospects and the price of our common stock could decline.

Monitoring safety of patients receiving our product candidates will be challenging, which could adversely affect our ability to obtain regulatory approval and commercialize our product candidates.

For our RESET™ and other planned clinical trials, we expect to continue to contract with academic medical centers and hospitals experienced in the assessment and management of toxicities arising during clinical trials. In the future, we may also contract with non-academic medical centers and hospitals with similar capabilities. Nonetheless, these centers and hospitals may have difficulty observing patients, including due to failure by patients to comply with post-clinical trial follow-up programs, and treating toxicities, which may be more challenging due to personnel changes, inexperience, inadequate institutional safety procedures, shift changes, house staff coverage or related issues. This could lead to more severe or prolonged toxicities or even patient deaths, which could result in us or the FDA delaying, suspending or terminating one or more of our clinical trials, and which could jeopardize regulatory approval. We also expect the centers using rese-cel and our other product candidates, if licensed, on a commercial basis could have similar difficulty in managing adverse events. Medicines used at centers to help manage adverse side effects of rese-cel, DSG3-CAART, MuSK-CAART

and our other product candidates may not adequately control the side effects and/or may have a detrimental impact on the efficacy of the treatment.

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

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. The enrollment of patients depends on many factors, including:

- the size and nature of the patient population;
- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- recruiting an adequate number of suitable patients to participate in a clinical trial;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;
- obtaining IRB and other required reviewing body approval at each clinical trial site;
- the proximity of patients to trial sites;
- the design of the trial and whether the FDA or other foreign regulatory authorities agree to the design and implementation of the trial;
- our ability to identify clinical trial sites and recruit clinical trial investigators with the appropriate capabilities, competencies and experience;
- clinicians', patients' and parents' (for juvenile patients) perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating, or with CAR T cell therapies broadly following the FDA's investigation into reports of T cell malignancies for approved BCMA- and CD19-directed CAR T cell immunotherapies;
- the occurrence of dose-limiting toxicity in the clinical trial;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- our ability to obtain and maintain patient consents;
- the risk that patients enrolled in clinical trials will drop out of the trials before the infusion of our product candidates or trial completion; and
- the ability of patients to meet the complex follow-up requirements of the clinical trial.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, some of our clinical trial sites may also be used by some of our competitors, which may reduce the number of patients who are available for our clinical trials in that clinical trial site.

Moreover, because our product candidates represent a departure from more commonly used methods for autoimmune diseases where B cells may play a role in initiating or maintaining disease treatment, potential patients and their doctors may be inclined to use conventional therapies, such as corticosteroids or systemic immunosuppressive medications, rather than enroll patients in our clinical trial. Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our ongoing and planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

Our RESET™ trials in SLE, myositis, SSc, gMG and PV and any additional expected clinical trials for each of our product candidates will enroll a limited number of patients. The activity and toxicity data from these clinical trials of our product candidates may differ from future results of subsequent clinical trials that enroll a larger number of patients. Since the number of patients that we plan to dose in our RESET™ trials in SLE, myositis, SSc, gMG and PV is small, and the number of patients in clinical trials for any future product candidates may be small, the results from such clinical trials, once completed, may be less reliable than results achieved in larger clinical trials, which may hinder our efforts to obtain regulatory approval for our product candidates. In a subset of our RESET-SLE® trial and our RESET-PV® trial, we plan to evaluate the toxicity profile of our product candidates and establish the recommended dose for the next clinical trial. The preliminary results of clinical trials with smaller sample sizes, such as our RESET™ trials, as well as any clinical trials for future product candidates, can be disproportionately influenced by various biases associated with the conduct of small clinical trials, such as the potential failure of the smaller sample size to accurately depict the features of the broader patient population, which limits the ability to generalize the results across a broader community, thus making the clinical trial results less reliable than clinical trials with a larger number of patients. As a result, there may be less certainty that such product candidates would achieve a statistically significant effect in any future clinical trials. If we conduct any future clinical trials of rese-cel, we may not achieve a statistically significant result or the same level of statistical significance, if any, that we might have anticipated based on the results observed in our RESET™ trials.

Risks Related to Sales, Marketing and Competition

The market opportunities for our product candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small.

Our projections of both the number of people who have autoimmune diseases where B cells may play a role in initiating or maintaining disease we are targeting, as well as the subset of people with these diseases in a position to receive second or later lines of therapy and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these autoimmune diseases where B cells may play a role in initiating or maintaining disease. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates.

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

The biopharmaceutical and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong focus on intellectual property. We face competition from many different players, including large and specialty pharmaceutical and biotechnology companies, academic research organizations and governmental agencies. Any therapeutic candidates we successfully develop and commercialize will compete with the existing standard of care as well as novel therapies that may gain regulatory approval in the future. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations and well-established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. We are one of several companies developing CAR T drug candidates for the treatment of autoimmune diseases where B cells may play a role in initiating or maintaining disease. Additionally, despite the significant differences in discovery, development and target populations between oncology and autoimmune targets, we recognize that companies with an investment and expertise in CAR T cell development for oncology indications could also attempt to leverage their expertise into autoimmune diseases where B cells may play a role in initiating or maintaining disease affected populations. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products.

We are aware of several other biopharmaceutical companies developing therapies for SLE, myositis, SSc, gMG and PV. Some product candidates may be directly competitive to our product candidates, such that even if we obtain regulatory approval of our product candidates, the availability and price of these other products, whether directly competitive or not, could limit the demand and the price we are able to charge for our product candidates. We may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances.

Even if we obtain regulatory approval of our product candidates, the products may not gain the market acceptance among physicians, patients, hospitals, treatment centers and others in the medical community necessary for commercial success.

The use of engineered T cells as a potential treatment for B cell-mediated autoimmune diseases is a recent development and may not become broadly accepted by physicians, patients, hospitals, treatment centers and others in the medical community. We expect physicians to be particularly influential and we may not be able to convince them to use our product candidates for many reasons. Additional factors will influence whether our product candidates are accepted in the market, including:

- the clinical indications for which our product candidates are licensed;
- physicians, hospitals, treatment centers and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA or other regulatory authorities;
- the timing of market introduction of our product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement and pricing by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage and adequate reimbursement by third-party payors and government authorities;
- relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and
- the effectiveness of our sales and marketing efforts.

The product candidates we plan to develop and commercialize are premised on offering a potential cure for autoimmune diseases where B cells may play a role in initiating or maintaining disease, which may result in a high degree of uncertainty related to pricing and long-term demand for our product. Our target patient populations are relatively small. Because of this pricing and demand for our product candidates, if licensed, may not be adequate to support an extended period of commercial viability, which could adversely affect our continued ability to successfully produce and market our product or any follow-on products.

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

Risks Related to Business Development

We may not be successful in our efforts to identify additional product candidates. Due to our limited resources and access to capital, we must prioritize development of certain product candidates, which may prove to be wrong and may adversely affect our business.

Although we intend to explore other therapeutic opportunities, in addition to the product candidates that we are currently developing, we may fail to identify viable new product candidates for clinical development for a number of reasons. If we fail to identify additional potential product candidates, our business could be materially harmed.

Research programs to pursue the development of our existing and planned product candidates for additional indications and to identify new product candidates and disease targets require substantial technical, financial and human resources whether or not they are ultimately successful. Our research programs may initially show promise in identifying potential indications and/or product candidates, yet fail to yield results for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying potential indications and/or product candidates;
- potential product candidates may be identified but may not be able to be expressed on T cells in a manner that enables product activity;
- potential product candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective drugs; or
- it may take greater human and financial resources than we will possess to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, thereby limiting our ability to develop, diversify and expand our product portfolio.

Because we have limited financial and human resources, we intend to initially focus on research programs and product candidates for a limited set of indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities.

Accordingly, there can be no assurance that we will ever be able to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, which could materially adversely affect our future growth and prospects. We may focus our efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful.

If we fail to develop additional product candidates, our commercial opportunity will be limited.

One of our core strategies is to pursue clinical development of additional product candidates beyond rese-cel. Developing, obtaining regulatory approval and commercializing additional product candidates will require substantial additional funding and is prone to the risks of failure inherent in medical product development. We cannot provide you any assurance that we will be able to successfully advance any of these additional product candidates through the development process.

Even if we receive FDA or other foreign regulatory authority approval to market additional product candidates for the treatment of autoimmune diseases where B cells may play a role in initiating or maintaining disease, we cannot assure you that any such product candidates will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. If we are unable to successfully develop and commercialize additional product candidates, our commercial opportunity will be limited. Moreover, a failure in obtaining regulatory approval of additional product candidates may have a negative effect on the approval process of any other, or result in losing approval of any approved, product candidate.

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

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific, and medical personnel, including our Chief Executive Officer and President, our Scientific Advisory Board members, our President, Science and Technology, our Chief Medical Officer, our Chief Financial Officer and our Chief Commercial Officer. The loss of the services of any of our executive officers, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements could result in delays in product development and harm our business.

Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain “key person” insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel.

We expect to grow the size of our organization, and we may experience difficulties in managing this growth.

As our development and commercialization plans and strategies develop, and as we continue to broaden our operational capabilities, we expect to expand our employee base and continue to add managerial, operational, sales, research and development, marketing, financial and other personnel. Current and future growth imposes significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, retaining and motivating additional employees in an increasingly competitive, inflationary market;
- managing our internal development efforts effectively, including the clinical and FDA or other regulatory authority review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize our product candidates will depend, in part, on our ability to effectively manage our growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including certain research and development as well as general and administrative support, pursuant to agreements which expire after a certain period of time. There can be no assurance that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, or if we are not able to raise sufficient funds in the future to support our hiring efforts beyond our research and development personnel, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

****Business disruptions, including due to natural disasters, global conflicts or political unrest, could seriously impact our operations, research and trials and harm our future revenue and financial condition.***

Our operations, Lonza Houston Inc., or Lonza's, operations, Cellares Corporation, or Cellares, and those of any CMOs, CROs and other contractors and consultants that we may engage could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. Further, global conflicts or political unrest, such as the ongoing military conflict between Russia and Ukraine and the escalating conflict in the Middle East, including the ongoing U.S.-Israel military conflict with Iran and related hostilities involving other regional actors, may disrupt our global clinical trials and increase the likelihood of supply interruptions. These conflicts have contributed to heightened geopolitical tensions, volatility in energy prices and costs, disruptions to global supply chains and transportation networks, and the expansion of sanctions by the United States and other governments to additional sectors, any of which could increase our costs or impair our ability to source materials and conduct our clinical programs. Additionally, the effect of global financial and economic conditions and geopolitical events, including the consequences of the current administration in the United States, events or changes related thereto, including reductions in force at administrative agencies and tariffs, or political unrest or otherwise, or similar events, may have an impact on our business. Sanctions imposed by the U.S. and other countries in response to geopolitical events and conflicts may also adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. The occurrence of any of these business disruptions could seriously harm our research, clinical trials, operations and financial condition and increase our costs and expenses. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

There are also geopolitical tensions with China. For example, in December, 2025, the National Defense Authorization Act for Fiscal Year 2026, or the NDAA, was enacted, which includes Section 851, commonly referred to as the “BIOSECURE Act.” The BIOSECURE Act restricts U.S. government agencies from procuring biotechnology equipment or services from, or entering into contracts with, entities that use biotechnology equipment or services from, designated “biotechnology companies of concern”, or BCCs, and from expending federal loan or grant funds for such equipment or services. If our current or future vendors with which we work are designated as BCCs in the future, or if our collaborators, customers, investors, or future commercial partners become subject to

BIOSECURE-related restrictions as a result of their relationships with such vendors, we could be required to terminate or restructure existing arrangements, transition manufacturing or other services to alternative suppliers, or delay or suspend development activities, subject to a grace period of 5 years during which time a company could continue to work with such restricted vendor. Any such transition could involve significant cost, operational complexity, regulatory risk, and delays, and alternative suppliers may not be available on acceptable terms or at all.

In addition, the increased prevalence of personnel working from home may negatively impact productivity, or disrupt, delay, or otherwise adversely impact our business operations. Further, this could increase our cyber security risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations or delay necessary interactions with local and federal regulators, ethics committees, manufacturing sites, research or clinical trial sites and other important agencies and contractors.

Risks Related to Our Financial Condition and Capital Requirements

Risks Related to Past Financial Condition

We have incurred net losses in every period since our inception and anticipate that we will incur substantial net losses over the next several years, and may never achieve or maintain profitability.

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products licensed for commercial sale, and we will continue to incur significant research and development and other expenses related to our ongoing operations. Our net losses may fluctuate significantly from quarter to quarter and year to year. We have to date financed our operations primarily through private placements of our preferred stock, the sale of common stock in our initial and secondary public offerings and sales of our common stock from time to time in "at-the-market" offerings.

As a result, we are not profitable and have incurred net losses in each period since our inception. For the nine months ended September 30, 2026 and 2025, we recorded net losses of $147.6 million and $125.9 million, respectively. As of September 30, 2026, we had an accumulated deficit of $664.5 million. We expect to incur significant losses for the foreseeable future, and we expect these losses to increase substantially if, and as, we:

- continue our research and development efforts and submit additional INDs and/or CTAs for our product candidates;
- conduct preclinical studies and clinical trials for our current and future product candidates;
- further develop our product candidate platform;
- continue to discover and develop additional product candidates;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, scientific manufacturing and commercial personnel;
- establish a commercial manufacturing source and secure supply chain capacity sufficient to provide commercial quantities of any product candidates for which we may obtain regulatory approval, whether through a CMO or through a manufacturing facility that we establish;
- acquire or in-license other product candidates and technologies, including advanced manufacturing and translational capabilities that we will need for the further development and possible commercialization of our product candidates;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure to support the sales and marketing of any product candidates for which we may obtain marketing approvals; and
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts, as well as to support our operations as a public company.

To become and remain profitable, we must succeed in developing, and eventually commercializing, a product or products that generate significant revenue. The ability to achieve this success will require us to be effective in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, discovering additional product candidates, obtaining regulatory approval for these product candidates and manufacturing, marketing and selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of most of these activities and have not yet demonstrated our ability to successfully develop any product candidate, obtain regulatory approvals, manufacture a commercial scale product or arrange for a

third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. We may never be able to develop, manufacture or commercialize a marketable product.

Even if we are able to succeed in these activities, we may never generate revenues that are significant enough to achieve profitability. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Our expenses will increase if, among other things:

•there are any delays in completing our clinical trials or the development of any of our product candidates;

•we are required by the FDA or other regulatory authorities to perform trials or studies in addition to, or different than, those expected; or

•there are any third-party challenges to our intellectual property or we need to defend against any intellectual property-related claim.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses we will incur or when, if ever, we will be able to achieve profitability. Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop, seek regulatory approval for and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

We have a limited operating history, which may make it difficult to evaluate the success of our business to date and to assess our future viability, and we may face significant challenges and expense as we test our product candidates and build our capabilities.

We were incorporated in 2017 and initially acquired rights to license certain patent rights from Penn in August 2018, and acquired rights to license certain patent rights from Nanjing IASO Biotherapeutics Co., Ltd., or IASO, in October 2022. All of our product candidates are still in the preclinical development or clinical stage. We have not yet demonstrated our ability to successfully complete any clinical trials, including large-scale, pivotal clinical trials, obtain marketing approvals, manufacture clinical and commercial scale therapeutics, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Our ability to generate product revenue or profits, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates, which may never occur. We may never be able to develop or commercialize a marketable product.

Our limited operating history, particularly in light of the rapidly evolving cell therapy field, may make it difficult to evaluate our current business and predict our future performance. Our relatively short history as an operating company makes any assessment of our future success or viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by clinical-stage companies in rapidly evolving fields. If we do not address these risks successfully, our business will suffer. Similarly, we expect that our financial condition and operating results will continue to fluctuate from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. As a result, our shareholders should not rely upon the results of any quarterly or annual period as an indicator of future operating performance.

We currently do not have in-house resources sufficient to enable the development of our product candidates, including our CAR T and CAAR T cell platforms. We were reliant on Minaris manufacturing services for rese-cel in multiple indications through a Development, Manufacturing and Testing Services Agreement, or the Minaris Agreement. Our ability to rely on services from Minaris was limited to a specified period of time, to specific capabilities, and is subject to Minaris' right to terminate these services with or without cause. We are also reliant on Lonza manufacturing services for rese-cel in multiple indications through a Development and Manufacturing Services Agreement, or the Lonza Agreement. Our ability to rely on services from Lonza is limited to a specified period of time, to specific capabilities, and is subject to Lonza's right to terminate these services with or without cause. If we are unable to establish necessary relationships with third party partners and/or build our own capabilities, our operating and financial results could differ materially from our expectations, and our business could suffer. As we build our own capabilities, and enter into agreements with third parties, we expect to encounter risks and uncertainties frequently experienced by growing companies in new and rapidly evolving fields, including the risks and uncertainties described herein.

All of our programs require additional preclinical research and development, clinical development, regulatory approval in multiple jurisdictions, obtaining manufacturing supply, capacity and expertise, building of a commercial organization, substantial investment and significant marketing efforts before we generate any revenue from product sales. Other programs of ours require additional discovery research and then preclinical and clinical development. In addition, our product candidates must be licensed for marketing by the FDA or other foreign regulatory authorities before we may commercialize any product.

We have not generated any revenue from our product candidates and our ability to generate revenue from product sales and become profitable depends significantly on our success in a number of areas.

To become and remain profitable, we or any potential future collaborator must develop and eventually commercialize products with significant market potential at an adequate profit margin after cost of goods sold and other expenses. All of our product candidates are in the early stages of development and we will require additional preclinical studies, clinical development, regulatory review and approval, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. Our ability to generate revenue depends on a number of factors, including, but not limited to:

- timely completion of our preclinical studies and clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party academic and commercial contractors;
- our ability to complete IND-enabling studies and successfully submit INDs or comparable applications;
- whether we are required by the FDA or other foreign regulatory authorities to conduct additional clinical trials or other studies beyond those planned to support the licensure and commercialization of our product candidates or any future product candidates;
- our ability to demonstrate to the satisfaction of the FDA or other foreign regulatory authorities, the safety, potency, purity and acceptable risk to benefit profile of our product candidates or any future product candidates;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates or future product candidates, if any;
- the cost of manufacturing and processing our product candidates being greater than we anticipate;
- the timely receipt of necessary marketing approvals from the FDA or other foreign regulatory authorities;
- the willingness of physicians, operators of clinics and patients to utilize or adopt any of our product candidates or future product candidates to treat autoimmune diseases where B cells may play a role in initiating or maintaining disease;
- our ability and the ability of third parties with whom we contract to manufacture adequate clinical and commercial supplies of our product candidates or any future product candidates, remain in good standing with regulatory authorities and develop, validate and maintain commercially viable manufacturing processes that are compliant with FDA's current Good Manufacturing Practices, or cGMP;
- our ability to successfully develop a commercial and competitive strategy and thereafter commercialize our product candidates or any future product candidates in the United States or other countries, if licensed for marketing, reimbursement, sale and distribution, whether alone or in collaboration with others;
- patient demand for our product candidates and any future product candidates, if licensed; and
- our ability to establish and enforce intellectual property rights in and to our product candidates or any future product candidates.

Many of the factors listed above are beyond our control and could cause us to experience significant delays or prevent us from obtaining regulatory approvals or commercialize our product candidates. Even if we are able to commercialize our product candidates, we may not achieve profitability soon after generating product sales, if ever. If we are unable to generate sufficient revenue through the sale of our product candidates or any future product candidates, we may be unable to continue operations without continued funding.

If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Additionally, even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to research, develop and market additional product candidates. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company also could cause you to lose all or part of your investment.

We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

Risks Related to Future Financial Condition

We will require substantial additional financing to develop and commercialize our product candidates and implement our operating plans. If we fail to obtain additional financing or cannot obtain financing at the levels we require, we may be forced to delay, reduce or discontinue our plans and operations or unable to complete the development and commercialization of our product candidates.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to continue the preclinical and clinical development of our product candidates, including our RESET™ trials, and our research and development, preclinical studies and clinical trials for any future product candidates, to seek regulatory approvals for our product candidates, to enable commercial production of our products, if licensed, and to initiate and complete registration trials for multiple products. From our inception in April 2017 to the time of our initial public offering, or IPO, our operations were financed by proceeds of $86.4 million from the sale of convertible notes and our convertible preferred stock and proceeds of $71.0 million from the sale of common stock in our IPO. Since our IPO and through September 30, 2026, we have generated cash from public offerings of our common stock and pre-funded warrants to purchase our common stock, and from the exercise of common stock warrants, resulting in aggregate net proceeds of approximately $688.0 million. As of September 30, 2026, we had $299.4 million of cash and cash equivalents. We currently expect our existing cash and cash equivalents as of September 30, 2026, to be sufficient to fund our operations into the first quarter of 2028, which includes our plans to fund the expanded clinical development of rese-cel in multiple indications with and/or without preconditioning, including the ongoing myositis registrational study and initiation of additional potentially registrational studies, and to further advance our manufacturing capabilities in preparation for commercial readiness of rese-cel. We expect to require significant additional financing to complete these clinical trials and any future clinical trials of these and our other product candidates. Further, if marketing approval is received, we will require significant additional amounts of cash to launch and commercialize our product candidates. However, we have based this estimate on assumptions that may prove to be wrong. Additionally, changing circumstances may cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We may require substantial additional capital for the further development and commercialization of our product candidates, including funding our internal manufacturing capabilities, and may need to raise additional funds sooner if we choose to expand more rapidly than we presently anticipate. Because the length of time and activities associated with development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and commercialization activities. Our future funding requirements, both near- and long-term, will depend on many factors, including, but not limited to:

- the initiation, progress, timing, costs and results of preclinical studies and clinical trials for our product candidates;
- the clinical development plans we establish for these product candidates;
- the number and characteristics of product candidates that we may develop or in-license;
- the terms of any collaboration agreements we may choose to conclude;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA or other foreign regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us or our product candidates;
- the effect of competing technological and market developments;
- the costs of establishing and maintaining a supply chain for the development and manufacture of our product candidates;
- the cost and timing of establishing, expanding and scaling manufacturing capabilities;
- the cost of maintaining the amount of patient data for which we would be responsible following commercialization of one or more of our product candidates; and
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own.

We cannot be certain that additional funding will be available on acceptable terms, or at all. As widely reported, global credit and financial markets have experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, inflation, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Until we are able to generate sufficient revenue to finance our cash requirements, we will need to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue our research and development initiatives and clinical development plans. We could be required to seek collaborators for our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to our product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

We expect that significant additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our common stock.

Subsequently, we issued (i) 39,200,000 shares of our common stock and accompanying warrants to purchase an aggregate of 39,200,000 shares of common stock (or pre-funded warrants in lieu thereof) and (ii) in lieu of common stock, to certain investors, pre-funded warrants to purchase an aggregate of up to 10,800,000 shares of our common stock and accompanying warrants to purchase an aggregate of 10,800,000 shares of common stock (or pre-funded warrants in lieu thereof), at an exercise price of $0.00001 per pre-funded warrant, or the 2025 Offering. The combined offering price of each share of common stock and accompanying common stock warrant was $2.00. The combined offering price of each pre-funded warrant and accompanying common stock warrant was $1.99999. The accompanying warrant has an exercise price of $2.50 per share, is immediately exercisable from the date of issuance and expired on September 12, 2026, fifteen months from the date of issuance. Aggregate net proceeds were $93.6 million after deducting underwriting discounts and commissions and offering expenses. As a result of this offering, our stockholders experienced significant dilution. Sales of common stock, debt securities or other equity securities by us may represent a significant percentage of our common stock currently outstanding. If we sell, or the market perceives that we intend to sell, substantial number of additional shares of our common stock under the 2025 Shelf Registration Statement or otherwise, the market price of our common stock could decline significantly.

On August 7, 2025, we filed the 2025 Registration Statement (File No. 333-289339) with SEC, which was declared effective on August 15, 2025, in relation to the registration of common stock, preferred stock, debt securities, warrants and/or units of any combination thereof for the purposes of selling, from time to time, our common stock, debt securities or other equity securities in one or more offerings. We also simultaneously entered into the 2025 Sales Agreement with TD Cowen to provide for the offering, issuance and sale of up to an aggregate amount of $150.0 million of our common stock from time to time in "at-the-market" offerings, or 2025 ATM Program, under the 2025 Shelf Registration Statement and subject to the limitations thereof. During the year ended December 31, 2025, we sold 4,160,176 shares pursuant to the 2025 ATM Program for net proceeds of $10.2 million. During the nine months ended September 30, 2026, we sold 12,057,202 shares, for net proceeds of $34.7 million.

In addition, as of September 30, 2026, we had outstanding pre-funded warrants to purchase 6,000,000 shares of our common stock. If some or all of these warrants are exercised, our stockholders could experience substantial dilution and may cause the market price of our stock to decline.

In May 2026, the Company issued 51,725,000 shares of common stock at a price of $2.90 per share. Aggregate net proceeds were approximately $140.2 million after deducting underwriting discounts and commissions and offering expenses.

We have also filed registration statements on Form S-8 to register shares issued or reserved for issuance under our equity compensation plans and will file additional registration statements on Form S-8 to register additional shares pursuant to the "evergreen" provisions under our equity compensation plans, the Plan Amendment and any subsequent amendments to our equity compensation plans. Shares registered under these registration statements on Form S-8 can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates and the lock-up agreements described above. If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline.

Pursuant to our equity incentive plans, our management is authorized to grant stock options to our employees, directors and consultants. Additionally, the number of shares of our common stock reserved for issuance under the 2019 Stock Option and Incentive

Plan, or the 2019 Plan, automatically increased on January 1, 2026 and will automatically increase each January 1 thereafter through and including January 1, 2029, by 4% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors. Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause our stock price to fall. In addition, on April 7, 2023, our board of directors adopted, and at our 2023 annual meeting our stockholders approved, an amendment to the 2019 Plan, or the Plan Amendment, to increase the aggregate number of shares authorized for issuance under the 2019 Plan by 3,000,000 shares, subject to adjustment.

In addition, certain of our employees, executive officers, and directors may enter into Rule 10b5-1 trading plans providing for sales of shares of our common stock from time to time. Under a Rule 10b5-1 trading plan, a broker executes trades pursuant to parameters established by the employee, director, or officer when entering into the plan, without further direction from the employee, officer, or director. A Rule 10b5-1 trading plan may be amended or terminated in some circumstances. Our employees, executive officers, and directors also may buy or sell additional shares outside of a Rule 10b5-1 trading plan when they are not in possession of material, nonpublic information.

Future issuances of our common stock or other equity securities, or the perception that sales of this nature may occur, could adversely affect the trading price of our common stock, and impair our ability to raise capital through future offerings of shares or equity securities. No prediction can be made as to the effect, if any, that future sales of common stock or the availability of common stock for future sales will have on the trading price of our common stock.

Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

We will not receive any meaningful amount of additional funds upon the exercise of the pre-funded warrants; however, any exercise would increase the number of shares of our common stock eligible for future resale in the public market and result in dilution to our stockholders.

In the 2025 Offering, we issued and sold pre-funded warrants to purchase up to 10,800,000 shares of our common stock. As of September 30, 2026, 4,800,000 pre-funded warrants had been exercised and 6,000,000 remain outstanding. Each pre-funded warrant is exercisable until it is fully exercised and by means of payment of the nominal cash purchase price upon exercise or by means of a "cashless exercise" according to a formula set forth in the pre-funded warrant. Accordingly, we will not receive any meaningful additional funds upon the exercise of the pre-funded warrants. To the extent such pre-funded warrants are exercised, additional shares of common stock will be issued for nominal or no additional consideration, which will result in dilution to the then existing holders of our common stock and will increase the number of shares eligible for resale in the public market.

Risks Related to Our Intellectual Property

We rely heavily on certain in-licensed patent and other intellectual property rights in connection with our development of our product candidate and, if we fail to comply with our obligations under our existing and any future intellectual property licenses with third parties, we could lose license rights that are important to our business.

Our ability to develop and commercialize our product candidate is heavily dependent on in-licenses to patent rights and other intellectual property granted to us by third parties. For example, we depend on our Exclusive License Agreement with IASO, which was entered into in October 2022, pursuant to which we obtained a worldwide, exclusive license under certain intellectual property to develop, manufacture, commercialize and otherwise exploit T cell products directed to CD19 for the purpose of diagnosis, prevention or treatment of an autoimmune or alloimmune indication in humans, or the IASO Agreement. We may enter into additional license agreements in the future. Our license agreement with IASO imposes, and we expect that future license agreements will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with our obligations under these licenses, our licensors, including IASO may have the right to terminate these license agreements, in which event we might not be able to market our product candidate. Termination of any of our license agreements or reduction or elimination of our licensed rights may also result in our having to negotiate new or reinstated licenses with less favorable terms.

We may need to obtain additional licenses from third parties to advance our research or allow commercialization of our product candidate, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected product candidate, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current product candidate or future products, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

Furthermore, in many cases, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we in-license from third parties. For example, pursuant to our IASO Agreement, IASO controls such activities for the patent rights licensed to us under such agreement. Therefore, although we provide input to IASO on these activities, we cannot be certain that these patents will be prosecuted, maintained and enforced in a manner consistent with the best interests of our business. If our current or future licensors or collaboration partners fail to obtain, maintain or protect any patents or patent applications licensed to us, our rights to such patents and patent applications may be reduced or eliminated and our right to develop and commercialize any of our product candidate that are the subject of such licensed rights could be adversely affected.

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

- the scope of rights granted under the IASO Agreement and other interpretation-related issues;
- whether we have breached the IASO Agreement and whether any such breach is subject to a cure period;
- 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 patent and other rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidate, and what activities satisfy those diligence obligations; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

Furthermore, disputes may arise between us and our current or future licensors regarding the ownership of intellectual property developed by us, such that we may be required to assign or otherwise transfer such intellectual property to such licensor. In the event that the assigned or transferred intellectual property is covered by an existing license agreement with such licensor we may be required to make additional royalty or milestone payments, or both, to such licensor. If the assigned or transferred intellectual property is not covered by an existing license agreement, then we may be required to enter into an additional license agreement to advance our research or allow commercialization of our product candidate, which may not be available on commercially reasonable terms or at all.

If disputes over intellectual property that we have licensed, or license in the future, prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidate.

If our efforts to protect the proprietary nature of the intellectual property related to our current and any future product candidates are not adequate, we may not be able to compete effectively in our market.

Our success depends in large part on our ability to obtain and maintain intellectual property protection in the United States and other countries with respect to our product candidates. If we do not adequately protect or enforce our intellectual property rights, competitors may be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. To protect our proprietary position, we have filed and in-licensed patent rights in the United States and abroad relating to the product candidates that are important to our business. The patent application and approval process is expensive, complex and time-consuming. We or our licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. In addition, the determination of patent rights with respect to biological and pharmaceutical products commonly involves complex legal and factual questions, which has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the United States, the first to invent was entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or our licensors were the first to make the inventions claimed in the patents or pending patent applications, or that we and our licensors were the first to file for patent protection of such inventions.

Moreover, because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, the patents or pending patent applications that we own or in-license may be challenged in the courts or patent offices in the United States and abroad. For example, we may be subject to a third party preissuance submission of prior art to the U.S. Patent and Trademark Office, or USPTO,

or become involved in post-grant review procedures, derivation proceedings, reexaminations, or *inter partes* review in the United States, or oppositions and other comparable proceedings in foreign jurisdictions, challenging our patent rights or the patent rights of others. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized.

Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of the patents we in-license or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent or in the same manner as the laws of the United States. For example, European patent law is more restrictive than U.S. patent law in connection with the patentability of methods of treatment of the human body and Chinese bankruptcy law may not provide a licensee the same protections as U.S. bankruptcy law. This could impact our in-license under the IASO Agreement with IASO, a China-based company, if IASO declared bankruptcy, and could have a material adverse effect on the development of rese-cel.

A European Unified Patent Court, or the UPC, came into force during 2023. The UPC is a common patent court to hear patent infringement and revocation proceedings effective for member states of the European Union. This could enable third parties to seek revocation of our European patents in a single proceeding at the UPC rather than through multiple proceedings in each of the jurisdictions in which the European patent is validated. 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 our European patents. Although we have decided, and may continue to decide, to opt out certain of our European patents and patent applications from the UPC, if certain formalities and requirements are not met, then our European patents and patent applications could be challenged for non-compliance and brought under the jurisdiction of the UPC. Thus, we cannot be certain that our European patents and patent applications will avoid falling under the jurisdiction of the UPC.

We cannot predict whether the patent applications that we own or in-license will issue as patents, whether the claims of any patent that has or may issue will provide us with a competitive advantage or prevent competitors from designing around the claims to develop competing technologies in a non-infringing manner, or whether we or our licensors will be able to successfully pursue patent applications in the future relating to our current product candidates or future products and product candidates. Moreover, the patent application and approval process is expensive and time-consuming. We or our licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Furthermore, we, or any future partners, collaborators, or licensees, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to seek additional patent protection.

It is possible that defects of form in the preparation or filing of patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If there are material defects in the form, preparation, prosecution or enforcement of the patents or patent applications we in-license, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

Even if the patent applications we own or in-license issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patent rights by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may also seek approval to market their own products similar to or otherwise competitive with our product candidates. Alternatively, our competitors may seek to market generic versions of any approved products by submitting abbreviated BLAs to the FDA during which process they may claim that our owned or in-licensed patents are invalid, unenforceable or not infringed. In these circumstances, we may need to defend or assert our intellectual property rights, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find the patents we own or in-license invalid or unenforceable, or that our competitors are competing in a non-infringing manner. Thus, even if we own or in-license valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

In the future, we likely will need to expand our patent portfolio to pursue patent coverage for new product candidates that we wish to develop. The patent prosecution process is competitive, and other companies, some which may have greater resources than we do in this area, may also be pursuing intellectual property rights that we may consider necessary or attractive in order to develop and commercialize future product candidates.

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

Filing, prosecuting, maintaining, defending and enforcing patents on our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States. Although our IASO Agreement grants us worldwide rights, there can be no assurance that we will obtain or maintain patent rights in or outside the United States under any future license agreements. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States even in jurisdictions where we and our licensors pursue patent protection. Consequently, we and our licensors may not be able to prevent third parties from practicing our inventions in all countries outside the United States, even in jurisdictions where we and our licensors pursue patent protection, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we and our licensors have not pursued and obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we and our licensors have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates and the patents we in-license or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of the patents we in-license or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights, even if obtained, in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put the patents we in-license at risk of being invalidated or interpreted narrowly and the patent applications we own or in-license at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

We or our licensors may be subject to claims challenging the inventorship or ownership of the patents and other intellectual property that we own or license.

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an ownership interest in the patents and intellectual property that we own or in-license or that we may own or in-license in the future. While it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own or such assignments may not be self-executing or may be breached. Our licensors may face similar obstacles. We or our licensors could be subject to ownership disputes arising, for example, from conflicting obligations of employees, consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against any claims challenging inventorship or ownership. If we or our licensors fail in defending any such claims, we may have to pay monetary damages and may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property, which could adversely impact our business, results of operations and financial condition.

Some intellectual property which we have in-licensed was discovered through government funded programs and thus is subject to federal regulations such as "march-in" rights, certain reporting requirements, and a preference for U.S. industry. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-U.S. manufacturers.

Certain of the intellectual property rights we have licensed were generated through the use of U.S. government funding and may therefore be subject to certain federal laws and regulations. As a result, the U.S. government has certain rights to intellectual property embodied in our DSG3-CAART product candidate and may have rights in future product candidates pursuant to the Bayh-Dole Act of 1980. These U.S. government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations, also referred to as "march-in rights". The U.S. government also has the right to take title to these inventions if we, or the applicable licensor, fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us or the applicable licensor to expend substantial resources. In addition, the U.S. government requires that products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to

manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. manufacturers may limit our ability to contract with non-U.S. product manufacturers for product candidates covered by such intellectual property.

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

Competitors may infringe, misappropriate or otherwise violate patents, trademarks, copyrights or other intellectual property that we own or in-license. To counter infringement, misappropriation or other unauthorized use, we may be required to file claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived violators could provoke these parties to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their intellectual property, in addition to counterclaims asserting that the patents we in-license are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent we own or in-license is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. In the U.S., grounds for a validity challenge in a court proceeding could be an alleged failure to meet one or more statutory requirements for patentability, including, for example, lack of novelty, obviousness, lack of written description or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Additionally, third parties are able to challenge the validity of issued patents through administrative proceedings in the patent offices of certain countries, including the USPTO and the European Patent Office.

Even if the validity of a patent is upheld during a court proceeding, there is a risk that the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that the patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving the patents we own or in-license could limit our ability to assert the patent against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition.

Even if we establish infringement, misappropriation or another violation of our intellectual property rights, the court may decide not to grant an injunction against the offender and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our shares. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings. Any of the foregoing may have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Changes in either the patent laws or the interpretation of the patent laws in the United States or other jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. When implemented, the Leahy-Smith Act included several significant changes to U.S. patent law that impacted how patent rights could be prosecuted, enforced and defended. In particular, the Leahy-Smith Act also included provisions that switched the United States from a "first-to-invent" system to a "first-to-file" system, allowed third-party submission of prior art to the USPTO during patent prosecution and set forth additional procedures to attack the validity of a patent by the USPTO administered post grant proceedings. Under a first-to-file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The USPTO developed new regulations and procedures governing the administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, became effective on March 16, 2013. It remains unclear what impact, if any, the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of the patent applications we in-license and the enforcement or defense of the issued patents we in-license, all of which could have a material adverse effect on our business.

The patent positions of companies engaged in the development and commercialization of biologics are particularly uncertain. For example, the Supreme Court of the United States issued its decision in Association for Molecular Pathology v. Myriad Genetics, Inc., or Myriad, a case involving patent claims held by Myriad Genetics, Inc. relating to the breast cancer susceptibility genes BRCA1 and

BRCA2. Myriad held that an isolated segment of naturally occurring DNA, such as the DNA constituting the BRCA1 and BRCA2 genes, is not patent-eligible subject matter, but that complementary DNA, which is an artificial construct that may be created from RNA transcripts of genes, may be patent-eligible. Thereafter, the USPTO issued a guidance memorandum instructing USPTO examiners on the ramifications of the Prometheus and Myriad rulings and apply the Myriad ruling to natural products and principles including all naturally occurring nucleic acids. Certain claims of our owned and in-licensed patent applications contain, and any future patents we may obtain may contain, claims that relate to specific recombinant DNA sequences that are naturally occurring at least in part and, therefore, could be the subject of future challenges made by third parties.

We cannot assure you that our efforts to seek patent protection for one or more of our product candidates will not be negatively impacted by this Supreme Court decision, rulings in other cases or changes in guidance or procedures issued by the USPTO. We cannot fully predict what impact the Supreme Court's decisions in Myriad may have on the ability of life science companies to obtain or enforce patents relating to their products in the future. These decisions, the guidance issued by the USPTO and rulings in other cases or changes in USPTO guidance or procedures could have a material adverse effect on our existing patent rights and our ability to protect and enforce our intellectual property in the future.

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

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect certain proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce, and any other elements of our product candidate discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect and some courts inside and outside the United States are less willing or unwilling to protect trade secrets. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors, and contractors. We cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach.

In addition, our trade secrets may otherwise become known or be independently discovered by competitors. Competitors and other third parties could infringe, misappropriate or otherwise violate our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If our trade secrets are not adequately protected or sufficient to provide an advantage over our competitors, our competitive position could be adversely affected, as could our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating our trade secrets.

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

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, which is limited to the approved indication (or any additional indications approved during the period of extension). However, a patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of the product's approval by the FDA, only one patent applicable to an approved drug is eligible for the extension, and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. In the future, if and when our product candidates receive FDA approval, we plan to apply for patent term extensions on patents covering those product candidates in any jurisdiction where these are available. However, 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 the patents we own or in-license, or may grant more limited extensions than we request. Moreover, we may not receive an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

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

Certain of our employees, consultants or advisors are currently, or were previously, employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management. Our licensors may face similar risks, which could have an adverse impact on intellectual property that is licensed to us.

We may become subject to claims that we are infringing certain third-party patents or other third-party intellectual property rights, any of which may prevent or delay our development and commercialization efforts and have a material adverse effect on our business.

Our commercial success depends in part on avoiding infringing, misappropriating and otherwise violating the patents and other intellectual property and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, and administrative proceedings such as interferences, *inter partes* review and post grant review proceedings before the USPTO and opposition proceedings before foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned or controlled by third parties, including our competitors, exist in the fields in which we are pursuing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we or our licensors are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, methods of manufacture or methods for treatment relating to our product candidates and, because patent applications can take many years to issue, there may be currently pending third party patent applications which may later result in issued patents, in each case that our product candidates, their manufacture or use may infringe or be alleged to infringe. We may fail to identify potentially relevant patents or patent applications, incorrectly conclude that a patent is invalid or does not cover our activities, or incorrectly conclude that a patent application is unlikely to issue in a form of relevance to our activities.

Parties making patent infringement claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, including demonstrating non-infringement, invalidity or unenforceability of the respective patent rights in question, regardless of their merit, is time-consuming, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. For example, in order to successfully challenge the validity of any U.S. patent in federal court, we would need to overcome a presumption of validity. This is a high burden requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, and we can provide no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. We may not have sufficient resources to bring these actions to a successful conclusion. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our shares.

In the event that a holder of any such patents seeks to enforce its patent rights against us with respect to one or more of our product candidates, and our defenses against the infringement of such patent rights are unsuccessful, we may be precluded from commercializing our product candidates, even if approved, without first obtaining a license to some or all of these patents, which may not be available on commercially reasonable terms or at all. Moreover, we may be required to pay significant fees and royalties to secure a license to the applicable patents. Such a license may only be non-exclusive, in which case our ability to stop others from using or commercializing technology and products similar or identical to ours may be limited. Furthermore, we could be liable for damages to the holder of these patents, which may be significant and could include treble damages if we are found to have willfully infringed such patents. In the event that a challenge to these patents were to be unsuccessful or we were to become subject to litigation or unable to obtain a license on commercially reasonable terms with respect to these patents, it could harm our business, financial condition, results of operations and prospects.

We are aware of third-party U.S. patents relating to the lentiviral vectors which may be used in the manufacture or use of our product candidates. We are also aware of a patent family that includes granted U.S. and European patent rights directed to methods using, and compositions containing, genetically engineered T cells that may be relevant to our rese-cel product candidate. If these patent rights were enforced against us, we believe that we have defenses against any such action, including that these patents would not be infringed by our product candidates and/or that these patents are not valid. However, if these patents were enforced against us and defenses to such enforcement were unsuccessful, unless we obtain a license to these patents, which may not be available on commercially reasonable terms, or at all, we could be liable for damages and precluded from commercializing any product candidates that were ultimately held to infringe these patents, which could have a material adverse effect on our business, financial condition, results of operations and prospects. Furthermore, even if our arguments are successful, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could significantly harm our business and operating results.

Even in the absence of a finding of infringement, we may need or may choose to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, or at all. In that event, we would be unable to further develop and commercialize our product candidates. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. Any of the foregoing could materially adversely affect our business, results of operations and financial condition.

Intellectual property rights do not necessarily address all potential threats.

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

- others may be able to make products that are similar to our product candidates or utilize similar cell therapy technology but that are not covered by the claims of our current or future patent portfolio;
- we, or our current or future licensors or collaborators, might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own or license now or that we may own in the future;
- we, or our current or future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights;
- it is possible that our current or future owned or licensed patent applications will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business;
- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such intellectual property; and

•third-party patents may issue with claims covering our activities; we may have infringement liability exposure arising from such patents.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Our Reliance on Third Parties

We currently, and will likely continue to, rely on third parties to conduct our clinical trials. If these third parties do not 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 depend and will continue to depend upon third parties, including independent investigators and collaborators, such as universities, medical institutions, CROs and strategic partners, to conduct our preclinical studies and clinical trials under agreements with us. Specifically, we depend on clinical trial sites to enroll patients and conduct the RESET™ trials in a timely and appropriate manner. If our clinical trial sites do not conduct the trials on the timeline we expect or otherwise fail to support the trials, our clinical trial results could be significantly delayed, thereby adversely impacting our leadership position in the autoimmune cell therapy space and our ability to progress additional product candidates. As we open additional clinical trial sites, we expect to have to negotiate budgets and contracts with CROs and study sites, which may result in delays to our development timelines and increased costs.

We will rely heavily on these third parties to conduct our manufacturing, and as a result, will have limited control over pace at which these activities are carried out. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with FDA's GCPs which are regulations and guidelines enforced by the FDA for product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications. We cannot provide assurance that, upon inspection, such regulatory authorities will not determine that some or all of our clinical trials do not fully comply with the GCP requirements. For any violations of laws and regulations during the conduct of our clinical trials, we could be subject to untitled and warning letters or enforcement action that may include civil penalties up to and including criminal prosecution. In addition, our clinical trials must be conducted with biologic product produced under cGMPs and will require a large number of test patients. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

As widely reported, global credit and financial markets have experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. Regional or single-source dependencies may in some cases accentuate these risks. For example, the pharmaceutical industry in general, and in some instances we or our collaborators or other third parties on which we or they rely, depend on China-based suppliers or service providers for certain raw materials, products and services, or other activities, Our ability or the ability of our collaborators or such other third parties to continue to engage these China-based suppliers or service providers for certain preclinical research programs and clinical development programs could be restricted due to geopolitical developments between the United States and China.

There have been, and may continue to be, significant changes to U.S. trade policies, sanctions, legislation, treaties and tariffs, including, but not limited to, trade policies and tariffs affecting products from outside of the U.S. The legal basis for U.S. tariffs has continued to evolve during 2026: the U.S. Supreme Court invalidated tariffs imposed under the International Emergency Economic Powers Act, or IEEPA, with related tariff refunds subsequently ordered by the U.S. Court of International Trade; the global 10% surcharge imposed under Section 122 of the Trade Act of 1974, which applied from February 24, 2026 through July 24, 2026, has since expired; and tariffs of 10% to 12.5% imposed under Section 301 of the Trade Act of 1974 took effect on July 24, 2026 and remain subject to ongoing litigation. The U.S. government has indicated that it may pursue further or replacement tariffs under other statutory authorities, and other countries may respond with retaliatory measures. The extent and duration of increased tariffs and the resulting impact on general economic conditions and on our business are uncertain and depend on various factors, such as negotiations between the U.S. and affected countries, the responses of other countries or regions, exemptions or exclusions that may be granted, the outcome of pending tariff litigation, the availability and cost of alternative sources of supply, and demand in affected markets. Supply chain disruptions and delays as a result of any new, replacement or retaliatory tariff policies or trade restrictions could increase our cost of materials and disrupt our manufacturing processes. If we or our current or future service providers, manufacturers and other partners are unable to obtain materials in sufficient quantity and in a timely manner due to disruptions in the global supply chain caused by macroeconomic events and conditions, the development and testing of our current and any future product candidates, including our clinical trials, may be delayed or become infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business.

Further, in the event that one or more of our current or future service providers, manufacturers and other partners do not successfully carry out their contractual duties, meet expected deadlines, or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, due to the economic downturn, the enactment of legislative proposals or for any other reasons, then we may not be able to obtain, or may be delayed in obtaining, marketing approvals for any product candidates we may develop and will not be able to, or may be delayed in our efforts to, successfully commercialize our medicines. Our failure or the failure of these third parties to comply with applicable regulatory requirements or our stated protocols could also subject us to enforcement action. 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 or not they devote sufficient time and resources to our ongoing preclinical and clinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies or other drug development activities, which could affect their performance on our behalf. 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. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

If any of our relationships with trial sites, or any CRO that we may use in the future, terminates, we may not be able to enter into arrangements with alternative trial sites or CROs or do so on commercially reasonable terms. Switching or adding third parties to conduct our clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is often a natural transition period when a new third party commences work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar 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.

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

We intend to rely on third parties to manufacture our clinical product supplies, and we may have to rely on third parties to produce and process our product candidates, if licensed.

Although we may eventually secure our own clinical manufacturing facility for any late phase clinical development that we undertake, we currently rely on third parties to manufacture our product candidates, and we intend in the future to continue to rely on CMOs. In the case of any manufacturing performed for us by third parties, the services performed for us risk being delayed because of the competing priorities that such parties have for utilization of their manufacturing resources and any capacity issues that thereby arise.

We do not yet have sufficient information to reliably estimate the cost of the manufacturing and processing of our product candidates in clinical quantity or commercial quantity, and the actual cost to manufacture and process our product candidates could ultimately materially and adversely affect the commercial viability of our product candidates. As a result, we may never be able to develop a commercially viable product.

In addition, our anticipated reliance on a limited number of third-party manufacturers exposes us to the following risks:

•We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA may have questions regarding any replacement contractor. This may require new testing and regulatory interactions. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA questions, if any.

•Our third-party manufacturers might be unable to timely formulate and manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any.

•Contract manufacturers may not be able to execute our manufacturing procedures appropriately.

•Any contract manufacturers that we engage may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our product candidates.

•Manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP and other government regulations. We do not have control over third-party manufacturers' compliance with these regulations and standards.

•We may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our product candidates.

•Our third-party manufacturers could breach or terminate their agreement with us.

Furthermore, all of our contract manufacturers are engaged with other companies to supply and/or manufacture materials or products for such companies, which exposes our manufacturers to regulatory risks related to the production of such materials and products. As a result, failure to meet the regulatory requirements for the production of those materials and products may affect the regulatory clearance of our contract manufacturers' facilities generally. If the FDA does not approve these facilities for the manufacture of our product candidates or if any agency withdraws its approval in the future, we may need to find alternative manufacturing facilities, which would negatively impact our ability to develop, obtain regulatory approval for or market our product candidates, if licensed.

Our contract manufacturers would also be subject to the same risks we face in developing our own manufacturing capabilities, as described above. Each of these risks could delay our clinical trials, the approval, if any of our product candidates by the FDA or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenue. In addition, we will rely on third parties to perform release tests on our product candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm.

For more information, see "Risk Factors—Risks Related to Manufacturing and Supply".

We may form or seek strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements.

We may form or seek strategic alliances, create joint ventures or collaborations or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. 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 stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety, potency and purity. Any delays in entering into new strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following a strategic transaction or license, we will achieve the results, revenue or specific net income that justifies such transaction.

We may not realize the benefits of acquired assets or other strategic transactions, including any transactions whereby we acquire or license manufacturing and other advanced technologies.

In October 2022, we entered into the IASO Agreement, pursuant to which we were granted worldwide license under certain intellectual property to develop, manufacture, commercialize and otherwise exploit T cell products directed to CD19 for the purpose of diagnosis, prevention or treatment of an autoimmune or alloimmune indication in humans.

We actively evaluate various strategic transactions on an ongoing basis. We may acquire other businesses, products or technologies as well as pursue joint ventures or investments in complementary businesses. The success of our strategic transactions, including the License Agreement, and any future strategic transactions depends on the risks and uncertainties involved including:

•unanticipated liabilities related to acquired companies or joint ventures;

•difficulties integrating acquired personnel, technologies and operations into our existing business;

•retention of key employees;

•diversion of management time and focus from operating our business to management of strategic alliances or joint ventures or acquisition integration challenges;

•increases in our expenses and reductions in our cash available for operations and other uses;

•disruption in our relationships with collaborators or suppliers as a result of such a transaction; and

•possible write-offs or impairment charges relating to acquired businesses or joint ventures.

If any of these risks or uncertainties occur, we may not realize the anticipated benefit of any acquisition or strategic transaction. Additionally, foreign acquisitions and joint ventures are subject to additional risks, including those related to integration of operations across different cultures and languages, currency risks, potentially adverse tax consequences of overseas operations and the particular economic, political, legal and regulatory risks associated with specific countries. For example, IASO is based in China and we may not receive the same protections under Chinese law, including with respect to applicable bankruptcy, insolvency, liquidation, arrangement, moratorium or similar laws relating to or affecting our rights.

Future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write-offs of goodwill, any of which could harm our financial condition.

Risks Related to Manufacturing and Supply

We are reliant on Lonza for our current manufacturing activities and termination would disrupt normal business operations, and we intend to continue to rely on other third parties for our future manufacturing needs prior to establishing our own manufacturing facility.

We are reliant on Lonza for our current manufacturing activities for our preclinical and clinical research. If Lonza were to fail to perform their obligations in accordance with the terms of the Lonza Agreement or terminate the Lonza Agreement, we may have difficulty continuing our normal business operations and our business prospects, financial condition and results of operations could be harmed. We continue to expand our agreements for manufacturing operations within the industry, including Cellares.

There are also current geopolitical tensions with China. These tensions and the related risks are described in the Risk Factor in this Report titled, “Risks Related to Business Development – Business disruptions, including due to natural disasters, global conflicts or political unrest, could seriously impact our operations, research and trials and harm our future revenue and financial condition.”

The CARTA Services Agreement is scheduled to expire on the completion of all research and development projects, and unless the CARTA Services Agreement is amended, Penn will not be obligated to provide any further services under the CARTA Services Agreement after that time. In addition, Penn has the right to terminate the CARTA Services Agreement in whole at any time with 180 days’ notice. From time to time, we may enter into further addenda to the CARTA Services Agreement that provide Penn with the right to terminate such addenda with limited notice periods. If we do not have adequate personnel and capabilities at the time that we assume responsibilities for such services, we may not be successful in effectively or efficiently transitioning these services from Penn, which could disrupt our business and have a material adverse effect on our financial condition and results of operations. Even if we are able to successfully transition these services, they may be more expensive or less efficient than the services we are receiving from Penn during the transition period.

The Lonza Agreement has an initial five year term with the ability to extend subject to the terms. Under the Lonza Agreement, Lonza will serve as one of our manufacturing partners for the global clinical development of rese-cel in multiple indications, including potential late-stage clinical trials and preparations for commercial readiness. Lonza has the right to terminate the Lonza Agreement in whole at any time with written notice including a three month ramp down period. If Lonza were to fail to perform their obligations in accordance with the terms of the Lonza Agreement or terminate the Lonza Agreement, our clinical trials and commercial readiness may be adversely impacted which could in turn materially and adversely affect our business, results of operations and prospects.

Further, we may not be able to achieve clinical manufacturing and cell processing through our CMOs or on our own on a timely basis. While our current manufacturing process is similar to the well-established process developed at Penn for CD19 CAR-T, or CART19, which was later commercialized, we have limited experience as an organization in managing the CAR-T engineering process at commercial scale. Finally, because clinical manufacturing and cell processing is highly complex and patient donor material is inherently variable, we cannot yet be sure that our manufacturing process, will consistently result in product that meets specifications for release. Success in manufacturing in smaller early phase clinical trials may not predict the frequency of success at larger late phase clinical trials, or success at the commercial phase production until process qualification and validation is completed and submitted for BLA filing.

Changes in manufacturers or manufacturing processes for rese-cel, including process optimization and scale-up for commercial production, present significant risks. If we cannot establish comparability, validate our processes and methods (including for critical materials such as lentiviral vector), and/or if our CMO(s) fails pre-approval inspection, the initiation or completion of pivotal studies, regulatory approval and commercialization could be delayed or prevented.

Cell therapy products like rese-cel are complex and sensitive to changes in materials, equipment, sites, and processes. The physical and chemical properties of cell therapies such rese-cel generally cannot be fully characterized, and regulators expect robust process

controls and phase-appropriate but maturing analytical methods to assure identity, quality, purity, and strength. As a result, assays of the finished product may not be sufficient to ensure that the product will perform in the intended manner. Accordingly, we employ multiple steps to control our manufacturing process to assure that the product candidate is made strictly and consistently in compliance with the applicable quality standards. We may encounter problems achieving adequate quantities and quality of clinical materials that meet FDA, or other applicable foreign standards or specifications. Manufacturing deviations or seemingly minor process changes can alter critical quality attributes, leading to lot failures, supply interruptions, or additional investigations, any of which can delay clinical timelines or regulatory submissions.

Challenges complying with cGMP requirements and other quality issues could arise during efforts to increase manufacturing capacity, optimize manufacturing and scale up production. In addition, in order to obtain regulatory approval of our product candidates (and in order to release our products for commercial use), our manufacturing processes and analytical methods, including with respect to certain raw materials used in the manufacturing of our product candidates, such as lentiviral vector, must be validated in accordance with regulatory guidelines. Failure to successfully validate, or maintain validated state of our manufacturing processes and analytical methods for the product candidates or certain raw materials used in the manufacturing of our product candidates, such as lentiviral vector, in a timely or cost-effective manner, or at all, may undermine our clinical development timelines or delay, or prevent, our ability to obtain regulatory approval of our product candidates. Any process performance qualification (PPQ) campaign for rese-cel must show that the commercial process can consistently produce product meeting predefined specifications under normal variability, including variability of critical materials such as lentiviral vector, or LVV. Regulators may question PPQ approaches that rely on limited or single lots of critical inputs to establish consistency, and may expect a risk assessment, process characterization, and evidence that input material specifications are representative of intended commercial supply. If our PPQ design or results are deemed insufficient, we could be required to perform additional PPQ runs, repeat validation activities, adjust specifications, or conduct further studies, which could be costly and delay our BLA or other regulatory approval.

LVV is a critical manufacturing input for CAR T-cell products. FDA guidance highlights expectations for vector manufacturing and testing, including identity, purity, functional (e.g., potency-related) characteristics, and safety testing. Regulators also emphasize having an appropriately qualified potency strategy in place as development progresses, and they may expect potency-relevant assays for critical components used to support pivotal study supplies, or, if not available at the time of manufacture, a risk-based justification with follow-up testing. Challenges in qualifying or validating vector-related assays, securing vector supply, or meeting evolving specifications could delay batch release, clinical milestones, or approval.

Transferring processes, methods, and know-how to a new manufacturers or manufacturing site is complex and time-consuming, may necessitate method bridging/transfer, and can introduce site-specific changes in equipment, raw materials, or procedures. As is customary, we have been, and may continue, optimizing and scaling manufacturing for later-stage development and potential commercialization, and we have transferred, and may in the future transfer, manufacturing to one or more contract manufacturers or additional manufacturing sites. Regulators expect sponsors to demonstrate comparability—analytically, and when needed via nonclinical or clinical bridging—between products made before and after process changes and across manufacturing sites. If our manufacturers fail to demonstrate adequate comparability on the expected timelines and at the required quality, and/or if FDA or other applicable foreign regulators do not agree with our proposed plans for demonstrating the comparability of the two processes, it may require us to incur additional costs or delay initiation or completion of clinical trials, complete additional pre-clinical studies and/or clinical trials, develop additional assays, or modify release specifications, and/or could delay or prohibit regulatory approval, including regulatory approval of certain manufacturing sites or processes.

Reliance on third parties for manufacture of our product candidates and raw materials utilized in manufacturing our product candidates entails certain risks, including reliance on the third party for regulatory compliance and quality assurance, the possibility that the third-party manufacturer does not maintain the financial, personnel or other resources to meet its obligations, the possibility that the third party fails to manufacture such components, or our product candidates or any products we may eventually commercialize, in accordance with our specifications, misappropriation of our proprietary information, including our trade secrets and know-how, and the possibility of termination of our manufacturing relationship by the third party, based on its own business priorities, at a time that is costly or damaging to us. In addition, the FDA and other regulatory authorities require that our product candidates and any products that we may eventually commercialize be manufactured according to cGMP and similar jurisdictional standards. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. The FDA or similar foreign regulatory agencies may also implement new standards at any time, or change their interpretations and enforcement of existing standards for manufacture, packaging or testing of products. We have little control over our manufacturers' compliance with these regulations and standards.

In some cases, the technical skills required to manufacture our product candidates may be unique or proprietary to a particular CMO, and we may have difficulty, or there may be contractual restrictions prohibiting us from transferring such skills to a back-up or alternate supplier if needed, or we may be unable to transfer such skills at all.

Our product candidates are uniquely manufactured. If we or any of our third-party manufacturers encounter difficulties in manufacturing our product candidates, our ability to provide supply of our product candidates for clinical trials or, if licensed, for commercial sale, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

The manufacturing process used to produce our product candidates is complex and novel, and it has not yet been validated for commercial production. The manufacture of our product candidates includes harvesting white blood cells from each patient, stimulating certain T cells from the white blood cells and thereby causing them to activate and proliferate, combining patient T cells with lentiviral delivery vector through a process known as transduction, expanding the transduced T cells to obtain the desired dose, formulating and freezing the cell product, and ultimately infusing the modified T cells back into the patient's body. Because of the bespoke nature of this product for patients, the cost to manufacture our product candidates is higher than traditional small molecule chemical compounds and monoclonal antibodies. Furthermore, our manufacturing process development and scale-up is at an early stage, and evaluation of cost at large scale has not yet been finalized. The actual cost to manufacture and process our product candidates could be greater than we expect and could materially and adversely affect the commercial viability of our product candidates.

Our manufacturing process may be susceptible to technical and logistics delays or failures due to the fact that each patient is an independent manufacturing lot, and also due to unique supply chain requirements. These include the collection of white blood cells from patients' blood, variability in the quality of white blood cells collected from patients' blood, cryopreservation of the white blood cells collected, packaging and shipment of frozen white blood cells to the manufacturing site in order to enable multi-site studies, procurement of lentiviral vectors that meet potency and purity requirements and shipment to the product candidate manufacturing site, shipment of the final product to clinical centers, manufacturing issues associated with interruptions in the manufacturing process, scheduling constraints for cell manufacturing slots, process contamination, equipment or reagent failure or supply shortage(s)/interruption(s), improper installation or operation of equipment, vendor or operator error, and inconsistency in cell growth. Even minor deviations from normal manufacturing processes could result in reduced production yields, lot failures, product defects, product recalls, product liability claims and other supply disruptions. If microbial, viral, or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, production at such manufacturing facilities may be interrupted for an extended period of time to investigate and remedy the contamination. Further, as product candidates are developed through preclinical studies to late-stage clinical trials toward approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes may result in the need to enroll additional patients or to conduct additional clinical studies to evaluate the impact of changes on product safety and efficacy. Penn has informed us that it will be unable provide clinical supply for any late-phase or non-U.S. clinical trials of our product candidates that we may conduct. Therefore, we will need to maintain and/or add new agreements with additional CMOs to produce clinical supply of our product candidates for late-phase clinical trials and at the necessary scale. We cannot guarantee that we will be able to enter into such agreements on commercially acceptable terms, if at all. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of ongoing and planned clinical trials or other future clinical trials.

Although we continue to optimize our manufacturing process for our product candidates, doing so is a difficult and uncertain task, and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, lot consistency and timely availability of reagents and/or raw materials. If we are unable to adequately scale-up the manufacturing process for our product candidates with Lonza, we may need to transfer to another manufacturer and/or our own facility, which can be lengthy. If we are able to adequately establish and scale-up the manufacturing process for our product candidates with an alternative manufacturer, we will still need to negotiate with such manufacturer an agreement for commercial supply and it is not certain we will be able to come to agreement on terms acceptable to us. This may impact our cost of goods and thus commercial viability and/or competitiveness.

In addition, many of the components which are required to support our cell manufacturing process, such as equipment, media, growth factors and disposables, are highly specialized and it is possible that the supply chain for these materials may be interrupted. If we are unable to promptly remedy such interruption, then there may be delays to our clinical development efforts.

The manufacturing process for any products that we may develop is subject to the FDA approval process, and we will need to contract with manufacturers who can meet all applicable FDA requirements on an ongoing basis.

The manufacturing process for any products that we may develop is subject to the FDA approval process, and we will need to contract with manufacturers who can meet all applicable FDA requirements on an ongoing basis. If we or our CMOs are unable to reliably produce products to specifications acceptable to the FDA, we may not obtain or maintain the approvals we need to commercialize such products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our CMOs will be able to manufacture the approved product in accordance with requirements from the FDA, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, suspension of production or recalls of the product candidates or marketed biologics, operating restriction and criminal prosecutions, delay approval of our product candidates, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations and growth prospects. Our future success depends on our ability to manufacture our products, if licensed, on a timely basis with acceptable manufacturing costs, while at the same time maintaining good quality control and complying with applicable regulatory requirements, and an inability to do so could have a material adverse effect on our business, financial condition, and results of operations. In addition, we could incur higher manufacturing costs if manufacturing processes or standards change, and we could need to replace, modify, design, or build and install equipment, all of which would require additional capital expenditures. Specifically, because our product candidates may have a higher cost of goods than conventional therapies, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater.

The manufacture of viral vectors is complex and variable, and there are a limited number of manufacturers able to supply us with viral vectors.

Our rese-cel product candidates utilize a lentiviral delivery vector and some or all of our other product candidates may require a lentiviral delivery vector, a key drug substance that delivers the CAR to the target T cells. We do not have the capability to manufacture lentiviral vector and plan to obtain the vector we require from third parties. The manufacturing process for lentiviral vector is variable and still evolving. It is not uncommon for manufacturing runs to fail, whether due to contamination, supplier error, or equipment failure, or to be delayed. To the extent our product candidates use a lentiviral delivery vector, a lack of vector supply will cause us to be unable to manufacture our CAR T cells as well as a delay in patient enrollment, which may have a negative impact on our ability to successfully develop our product candidates.

Further, there are a limited number of manufacturers capable of producing lentiviral vectors. It can be challenging to secure a relationship with any of these manufacturers, and the manufacturing and release process can take a significant amount of time. We have secured a supply of lentiviral vector from CAROT and Oxford for the patients we plan to enroll in our RESET™ clinical trials. In December 2021, as amended in May 2023, February 2024 and May 2024, we secured a license and supply agreement with Oxford to establish a process and supply lentiviral vector for the clinical and commercial development of our rese-cel candidate. There is no assurance that we will be able to continue to secure adequate and timely supply of lentiviral vector. Moreover, we cannot be certain that our CAR T cell product candidates produced with lentiviral vector from different manufacturers will be comparable or that results of clinical trials will be consistent if conducted with lentiviral vector from different manufacturers.

Vector production also requires the production of high-quality DNA plasmids, for which there is also a limited number of suppliers. Although we have established relationships with suppliers for lentiviral vector and plasmids, we do not yet have our own clinical-scale manufacturing facility established, and are therefore highly dependent on the ability of these suppliers to manufacture necessary materials and to deliver these materials to us on a timely and reliable basis.

If we are to operate our own manufacturing facility, significant resources will be required and we may fail to successfully operate our facility, which could adversely affect our clinical trials and the commercial viability of our product candidates.

If we establish our own manufacturing facility, our operations will be subject to review and oversight by the FDA and the FDA could object to our use of our manufacturing facility. We must first receive approval from the FDA prior to licensure to manufacture our product candidates, which we may never obtain. Even if licensed, we would be subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMPs and other government regulations. Our license to manufacture product candidates will be subject to continued regulatory review. Our cost of goods development is at an early stage. The actual cost to manufacture and process our product candidates at a manufacturing facility of our own could be greater than we expect and could materially and adversely affect the commercial viability of our product candidates.

The manufacture of biopharmaceutical products is complex and requires significant expertise, and can be impacted by resource constraints, labor disputes and workforce limitations.

The manufacture of biopharmaceutical products is complex and requires significant expertise, including the development of advanced manufacturing techniques and process controls. Manufacturers of cell therapy products often encounter difficulties in production, particularly in scaling out and validating initial production and ensuring the absence of contamination. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if contaminants are discovered in our supply of product candidates or in the manufacturing facilities upon which we currently or will rely, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any stability or other issues relating to the manufacture of our product candidates, whether by Lonza, or other third-party CMOs, or at any manufacturing facility that we may establish, will not occur in the future.

Lonza, or other third-party CMOs that we engage, or we may fail to manage the logistics of storing and shipping our product candidates. Storage failures and shipment delays and problems caused by us, our vendors or other factors not in our control, such as weather, could result in loss of usable product or prevent or delay the delivery of product candidates to patients.

Lonza, or other third-party CMOs that we engage, or we may also experience manufacturing difficulties due to resource constraints, labor disputes or workforce limitations arising from the expanding need for manufacturing in the cell therapy field and the limited number of training programs for technical staff. If we were to encounter any of these difficulties, our ability to provide our product candidates to patients would be jeopardized.

We are dependent upon the availability of specialty raw materials and the production capabilities of small manufacturers to source the components of our product candidates.

Our product candidates require many specialty raw materials, some of which are manufactured by small companies with limited resources and experience to support a commercial product, and the suppliers may not be able to deliver raw materials to our specifications. In addition, those suppliers generally do not have the capacity to support commercial products manufactured under cGMP by biopharmaceutical firms. The suppliers may be ill-equipped to support our needs, especially in non-routine circumstances like an FDA inspection or medical crisis, such as widespread contamination. We also do not have contracts with many of these suppliers, and we may not be able to contract with them on acceptable terms or at all. Accordingly, we may experience delays in receiving key raw materials to support clinical or commercial manufacturing.

In addition, some raw materials are currently available from a single supplier, or a small number of suppliers. We cannot be sure that these suppliers will remain in business or that they will not be purchased by one of our competitors or another company that is not interested in continuing to produce these materials for our intended purpose. In addition, the lead time needed to establish a relationship with a new supplier can be lengthy, and we may experience delays in meeting demand in the event we must switch to a new supplier. The time and effort to qualify a new supplier could result in additional costs, diversion of resources or reduced manufacturing yields, any of which would negatively impact our operating results. Further, we may be unable to enter into agreements with a new supplier on commercially reasonable terms, which could have a material adverse impact on our business. We are also unable to predict how changing global economic conditions or global health concerns will affect our third-party suppliers and manufacturers. Regional or single-source dependencies may in some cases accentuate these risks. For example, the pharmaceutical industry generally, and in some instances our Company or our collaborators or other third parties on which we rely, depend on China-based suppliers or service providers for certain raw materials, products and services, or other activities. Our ability or the ability of our collaborators or such other third parties to continue to engage these China-based suppliers or service providers for certain preclinical research programs and clinical development programs could be restricted due to geopolitical developments between the United States and China, including as a result of the escalation of tariffs or other trade restrictions or due to the enactment of the NDAA, which includes Section 851, commonly referred to as the "BIOSECURE Act.". Any negative impact of such matters on our third-party suppliers and manufacturers may also have an adverse impact on our results of operations or financial condition.

We may encounter difficulties in production, particularly with respect to process development or scaling up of our manufacturing capabilities. If we encounter such difficulties, our ability to provide supply of our CAR T cells for clinical trials or for commercial purposes could be delayed or stopped.

Establishing clinical and commercial manufacturing and supply is a difficult and uncertain task, and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including, among others, increased costs, potential problems with process scale-out, process reproducibility, stability issues, lot consistency, and timely availability of reagents or raw materials. For example, we may find it difficult to establish a manufacturing process that is consistent. If this occurs, we may need to complete more than one manufacturing run for each treated patient, which would impact the availability of adequate coverage and reimbursement from third-party payors. Competitors that have developed CAR T cell therapies have had difficulty reliably producing engineered T cell therapies in the commercial setting. If we experience similar challenges manufacturing product candidates to approved specifications, this may limit our product candidates' utilization and our ability to receive payment for these product candidates once licensed. Alternatively, these challenges may require changes to our manufacturing processes, which could require us to perform additional clinical studies, incurring significant expense. We may ultimately be unable to reduce the expenses associated with our product candidates to levels that will allow us to achieve a profitable return on investment.

If we or our third-party suppliers use hazardous, non-hazardous, biological or other materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials. We and our suppliers are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that we and our suppliers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we and our suppliers cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

Changes in product candidate manufacturing or formulation may result in additional costs or delay, which could adversely affect our business, results of operations and financial condition.

As product candidates are developed through preclinical studies to later-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods or formulation, are altered along the way in an effort to optimize processes and results. Any of these changes could cause our product candidates to perform differently and affect the results of ongoing and planned clinical trials or other future clinical trials conducted with the altered materials or with materials made with the altered methods. Such changes may also require additional testing, or notification to, or approval by the FDA or other regulatory authorities. This could delay completion of clinical trials, require the conduct of bridging clinical trials or studies, require the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and/or jeopardize our ability to commence product sales and generate revenue.

Risks Related to Government Regulation

The regulatory approval process is lengthy and time-consuming, and we may experience significant delays in the clinical development and regulatory approval of our product candidates.

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

We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. For example, to our knowledge, the FDA has not previously reviewed regulatory applications for marketing authorization of CAR T cells for treatment of autoimmune disease or CAAR T cells for treatment of pemphigus, and there is no cell therapy currently approved by the FDA for the treatment of mPV, MuSK myasthenia gravis, SLE, myositis, SSc or gMG. Because of this, we have little guidance as to which endpoints will be accepted, how many clinical trials we may expect to conduct, and whether open-label clinical trials will be deemed acceptable, among other things. We may also request regulatory approval of future CAR T or CAAR T cell-based product candidates by target, regardless of disease type or origin, which the FDA may have difficulty accepting if our clinical trials only involved diseases of certain origins. The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety, potency and purity data to support licensure. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain licensure of the product candidates based on the completed clinical trials, as the FDA often adheres to the Advisory Committee's recommendations. Further, given the rapidly evolving landscape of cell therapy, we could encounter a significant change in the regulatory environment for our product candidates once we have already begun one or more lengthy and expensive clinical trials for our product candidates. For example, the U.S. Supreme Court's July 2024 decision to overturn prior established case law giving deference to regulatory agencies' interpretations of ambiguous statutory language has introduced uncertainty regarding the extent to which FDA's regulations, policies, and decisions may become subject to increasing legal challenges, delays, and/or changes. Moreover, the current U.S. administration may propose policy changes that create additional uncertainty for our business and may result in increased regulatory uncertainty, judicial interpretations overturning precedent and other impacts to the agency rulemaking process. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and approval may not be obtained.

We may also experience delays in completing ongoing and planned clinical trials for a variety of reasons, including delays related to:

- obtaining regulatory authorization to begin a trial, if applicable;
- the availability of financial resources to commence and complete the planned trials;
- reaching agreement on acceptable terms with prospective 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;
- obtaining approval at each clinical trial site by an independent IRB;
- recruiting suitable patients to participate in a trial;
- having patients complete a trial, including having patients enrolled in clinical trials dropping out of the trial before the product candidate is manufactured and returned to the site, or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- addressing any patient safety concerns that arise during a trial;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of qualified materials under cGMPs and applying them on a patient by patient basis for use in clinical trials.

We could also encounter delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. If we experience delays in the completion of, any future clinical trial of our product candidates, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may ultimately lead to the denial of regulatory approval of our product candidates.

We expect the product candidates we develop will be regulated as biological products, or biologics, and therefore they may be subject to competition.

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, was enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to a licensed biologic. Under the BPCIA, an application for a biosimilar product cannot be licensed by the FDA until 12 years after the reference product was licensed under a BLA. The law is complex and is still being interpreted and implemented by the FDA.

We believe that any of the product candidates we develop that is licensed in the United States as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider the subject product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once licensed, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

In the European Union, there is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product. For such products, the results of appropriate preclinical or clinical trials must be provided in support of an application for market authorization. Guidelines from the EMA detail the type and quantity of supplementary data to be provided for different types of biological product.

The regulatory landscape that will govern our product candidates is uncertain; regulations relating to more established cell therapies and other therapies for autoimmune diseases where B cells may play a role in initiating or maintaining disease are still developing, and changes in regulatory requirements could result in delays or discontinuation of development of our product candidates or unexpected costs in obtaining regulatory approval.

Because we are developing novel CAR T and CAAR T cell product candidates that are unique biological entities, the regulatory requirements that we will be subject to are not entirely clear. Even with respect to more established products that fit into the categories of gene therapies or cell therapies, the regulatory landscape is still developing. For example, regulatory requirements governing gene therapy products and cell therapy products have changed frequently and may continue to change in the future. Moreover, there is substantial, and sometimes uncoordinated, overlap in those responsible for regulation of existing gene therapy products and cell therapy products. For example, in the United States, the FDA established the Office of Tissues and Advanced Therapies, or OTAT, in 2016, within its Center for Biologics Evaluation and Research, or CBER, to consolidate the review of gene therapy and related products, and the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. In September 2022, the FDA announced retitling of OTAT to the Office of Therapeutic Products, or OTP, and elevation of OTP to a "Super Office" to meet its growing cell and gene therapy workload. In addition, under guidelines issued by the National Institutes of Health, or NIH, gene therapy clinical trials are also subject to review and oversight by an institutional biosafety committee, or IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. Before a clinical trial can begin at any institution, that institution's IRB and its IBC assesses the safety of the research and identifies any potential risk to public health or the environment. While the NIH guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them. Although the FDA decides whether individual gene therapy protocols may proceed, review process and determinations of other reviewing bodies can impede or delay the initiation of a clinical study, even if the FDA has reviewed the study and approved its initiation. Conversely, the FDA can place an IND application on clinical hold even if such other entities have provided a favorable review. Furthermore, each clinical trial must be reviewed and approved by an independent IRB at or servicing each institution at which a clinical trial will be conducted. In addition, adverse developments in clinical trials of gene therapy products conducted by others or in the post-approval context may cause the FDA or other regulatory bodies to change the requirements for approval of any of our product candidates. For example, after the FDA's November 2023 announcement of its investigation into reports of T cell malignancies for BCMA- and CD19-directed CAR T cell immunotherapies, the FDA informed us that, based on those reports, patients receiving rese-cel in our clinical trials will require life-long monitoring for new malignancies.

Complex regulatory environments exist in other jurisdictions in which we might consider seeking regulatory approvals for our product candidates, further complicating the regulatory landscape. For example, in the European Union, a special committee called the Committee for Advanced Therapies was established within the EMA in accordance with Regulation (EC) No 1394/2007 on advanced-therapy medicinal products, or ATMPs, to assess and provide an opinion on the quality, safety and efficacy of ATMPs, which are the subject of a marketing authorization application, and to follow scientific developments in the field. ATMPs include gene therapy products as well as somatic cell therapy products and tissue engineered products. These various regulatory review committees and advisory groups and new or revised guidelines that they promulgate from time to time may lengthen the regulatory review process,

require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. Because the regulatory landscape for our CAR T and CAAR T cell product candidates is new, we may face even more cumbersome and complex regulations than those emerging for gene therapy products and cell therapy products. Furthermore, even if our product candidates obtain required regulatory approvals, such approvals may later be withdrawn because of changes in regulations or the interpretation of regulations by applicable regulatory agencies. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient product revenue to maintain our business.

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.

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 are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States. Before we can commercialize any of our product candidates, we must obtain marketing approval. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction and it is possible that none of our product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval. We, as a company, have no experience in filing and supporting the applications necessary to gain regulatory approvals and expect to rely on third-party CROs and/or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the drug candidate's safety, potency and purity.

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. 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 marketing approval or prevent or limit commercial use.

The process of obtaining regulatory approvals is expensive, may take many years if additional clinical trials are required, 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. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted IND, BLA or comparable application types in other countries, may cause delays in the approval or rejection of an application. The FDA and 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 studies. Our product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including the following:

- the FDA or other 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 that a drug candidate is safe, potent and pure for its proposed indication or a related companion diagnostic is suitable to identify appropriate patient populations;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or other foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or other foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an BLA, or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or other foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications, or facilities that we may establish or of third-party manufacturers with which we may contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or other foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of drugs in development, only a small percentage successfully complete the FDA approval process 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. Although we have discussed the designs of our trials for rese-cel with the FDA to align on the key aspects of the studies, the FDA may not ultimately agree that the data from such trials supports regulatory approval. For example, in March 2026, the FDA noted that details are needed in order for the FDA to assess suitability of the proposed registry as an external control, including information on potential baseline differences between the enrolled study population and registry population (e.g., diagnosis classification and refractory definition) and the risk of missing or unavailable data, as well as other criteria established by FDA guidance for industry.

We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. As a result, our ability to develop product candidates and obtain regulatory approval may be significantly impacted. For example, the general approach for FDA approval of a new biologic or drug is for sponsors to seek licensure or approval based on dispositive data from well-controlled, Phase 3 clinical trials of the relevant product candidate in the relevant patient population. Phase 3 clinical trials typically involve hundreds of patients, have significant costs and take years to complete. We believe that we may be able to utilize the FDA's Regenerative Medicine Advanced Therapy designation for our product candidates given the limited alternatives for treatments for certain rare diseases and autoimmune diseases where B cells may play a role in initiating or maintaining disease, but the FDA may not agree with our plans.

Moreover, approval of genetic or biomarker diagnostic tests may be necessary to advance some of our product candidates to clinical trials or potential commercialization. In the future, regulatory agencies may require the development and approval of such tests. Accordingly, the regulatory approval pathway for such product candidates may be uncertain, complex, expensive and lengthy, and approval may not be obtained.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, if licensed, 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. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

Even though we may apply for orphan drug designation for our product candidates, we may not be able to obtain orphan drug marketing exclusivity.

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 in the United States, or a patient population of 200,000 or more in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. In order to obtain orphan drug designation, the request must be made before submitting a BLA. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval of that particular product for the use or indication for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a BLA, to market the same biologic (meaning, a product with the same principal molecular structural features) for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan drug exclusivity or if FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. As a result, even if one of our product candidates receives orphan exclusivity, the FDA can still approve other biologics that do not have the same principal molecular structural features for use in the same indication or the same biologic for a different indication during the exclusivity period. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product or if a subsequent applicant demonstrates clinical superiority over our product.

We have obtained from the FDA orphan drug designation for DSG3-CAART for the treatment of pemphigus vulgaris, for MuSK-CAART for the treatment of MuSK MG and for rese-cel for the treatment of IIM (myositis) and systemic sclerosis. We may seek orphan drug designation for certain other of our product candidates, but may be unable to obtain orphan drug designation for some or all of our product candidates in specific orphan indications in which we believe there is a medically plausible basis for the use of these products. Even if we obtain orphan drug designation, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition, or if a subsequent applicant demonstrates clinical superiority over our products, if licensed. Although we may seek orphan drug designation for other product candidates, we may never receive such designations. In addition, the FDA may further reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

The FDA has granted rare pediatric disease designation to rese-cel for the treatment of juvenile dermatomyositis. However, a marketing application for rese-cel or any other product candidate, if approved, may not meet the eligibility criteria for a priority review voucher.

The FDA has granted rare pediatric disease designation to rese-cel for the treatment of juvenile dermatomyositis. Designation of a drug or biological product as a drug for a rare pediatric disease does not guarantee that an NDA or BLA for such drug or biological product will meet the eligibility criteria for a rare pediatric disease priority review voucher at the time the application is approved. Under the FDCA, we will need to request a rare pediatric disease priority review voucher in our original BLA for rese-cel. The FDA may determine that a BLA for rese-cel, if approved, does not meet the eligibility criteria for a priority review voucher, including for the following reasons:

- juvenile dermatomyositis no longer meets the definition of a rare pediatric disease;
- the BLA contains an active ingredient that has been previously approved by the FDA;
- the BLA does not rely on clinical data derived from studies examining a pediatric population and dosages of the drug intended for that population (that is, if the BLA does not contain sufficient clinical data to allow for adequate labeling for use by the full range of affected pediatric patients); or
- the BLA is approved for a different adult indication than the rare pediatric disease for which rese-cel is designated.

The Rare Pediatric Disease Priority Review Voucher program was reauthorized in February 2026. Under the current statutory sunset provisions, the FDA may not award rare pediatric disease priority review vouchers after September 30, 2029. The current sunset provisions do not provide a separate deadline by which a product must have received rare pediatric disease designation in order to be eligible for a voucher. Nevertheless, the program remains subject to statutory requirements and future legislative action, and Congress may amend, curtail, or decline to further reauthorize the program in the future.

Accordingly, even though rese-cel has received rare pediatric disease designation for the treatment of juvenile dermatomyositis, we may not receive a rare pediatric disease priority review voucher if a BLA for rese-cel is approved. In addition, absent further reauthorization or extension of the program, if a BLA for rese-cel is approved after September 30, 2029, the FDA would not be permitted to award a rare pediatric disease priority review voucher, regardless of whether rese-cel otherwise satisfies the criteria for such a voucher, although FDA's authority to do so could be extended by Congress in the future.

A fast track designation by the FDA, even if granted, may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our current product candidate and any future product candidates will receive marketing approval.

If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA fast track designation for a particular indication. Fast track is a process designed to facilitate the development, and expedite the review of drugs to treat serious or life-threatening conditions and address an unmet medical need. We have received fast track designation for DSG3-CAART for improving healing of mucosal blisters in patients with mPV, for MuSK-CAART for improving activities of daily living and muscle strength in patients with MuSK antibody-positive myasthenia gravis and for rese-cel, designed to deplete CD19-positive B cells and improve disease activity in patients with SLE, LN and the myositis subtype of dermatomyositis and for the treatment of patients with systemic sclerosis to improve associated organ dysfunction. We may also apply for fast track designation for certain of our other product candidates, but there is no assurance that the FDA will grant this status to any of our other current or future product candidates. Marketing applications filed by sponsors of products in fast track development may qualify for priority review under the policies and procedures offered by the FDA, but the fast track designation does not assure any such qualification or ultimate marketing approval by the FDA. The FDA has broad discretion whether or not to grant fast track designation, so even if we believe a particular product candidate is eligible for this designation, there

can be no assurance that the FDA would decide to grant it. Even though we have received fast track designation for certain of our product candidates, we may not experience a faster development process, regulatory review or approval for these product candidates as compared to conventional FDA procedures, and receiving a fast track designation does not provide assurance of ultimate FDA approval. In addition, the FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program. In addition, the FDA may withdraw any fast track designation at any time.

Although we may pursue expedited regulatory approval pathways for a product candidate, it may not qualify for expedited development or, if it does qualify for expedited development, it may not actually lead to a faster development or regulatory review or approval process.

Although we believe there may be an opportunity to accelerate the development of certain of our product candidates through one or more of the FDA's expedited programs, such as fast track, breakthrough therapy, Regenerative Medicine Advanced Therapy, accelerated approval or priority review, we cannot be assured that any of our product candidates will qualify for such programs.

For example, we may seek a Regenerative Medicine Advanced Therapy, or RMAT, designation for some of our product candidates. We have received RMAT designation for our myositis and systemic sclerosis programs. An RMAT is defined as cell therapies, therapeutic tissue engineering products, human cell and tissue products, and combination products using any such therapies or products. Gene therapies, including genetically modified cells that lead to a durable modification of cells or tissues may meet the definition of a Regenerative Medicine Therapy. The RMAT program is intended to facilitate efficient development and expedite review of RMATs, which are intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition. A new drug application or a BLA for an RMAT may be eligible for priority review or accelerated approval through (1) surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit or (2) reliance upon data obtained from a meaningful number of sites. Benefits of such designation also include early interactions with FDA to discuss any potential surrogate or intermediate endpoint to be used to support accelerated approval. A Regenerative Medicine Therapy that is granted accelerated approval and is subject to post-approval requirements may fulfill such requirements through the submission of clinical evidence, clinical studies, patient registries, or other sources of real world evidence, such as electronic health records; the collection of larger confirmatory data sets; or post-approval monitoring of all patients treated with such therapy prior to its approval. Although RMAT designation or access to any other expedited program may expedite the development or approval process, it does not change the standards for approval. If we apply for RMAT designation or any other expedited program for our product candidates, the FDA may determine that our proposed target indication or other aspects of our clinical development plans do not qualify for such expedited program. Even if we are successful in obtaining a RMAT designation or access to any other expedited program, we may not experience faster development timelines or achieve faster review or approval compared to conventional FDA procedures. Access to an expedited program may also be withdrawn by the FDA if it believes that the designation is no longer supported by data from our clinical development program. Additionally, qualification for any expedited review procedure does not ensure that we will ultimately obtain regulatory approval for such product candidate.

Disruptions at the FDA, the USPTO, the SEC and other government agencies, including from government shutdowns, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, substantial changes in leadership and shifting policy priorities as a result of the current presidential administration and its appointees tasked to oversee the agency, 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, patent offices in the United States and abroad and other agencies – including as a result of reductions in force, significant organizational changes, substantial leadership departures, and policy changes – may also slow the time necessary for new drugs or biologics to be reviewed or for patent applications to be examined and granted, which would adversely affect our business. Changes and cuts in FDA staffing have also been reported by some within the pharmaceutical industry as creating instances of in delays in the FDA's responsiveness or in its ability to review IND submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion. In addition, over the past decade, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. Specifically, in October 2025, the U.S. federal government entered a shutdown suspending services deemed non-essential as a result of the failure by Congress to enact regular appropriations for the 2026 fiscal year. Federal government operations are currently funded under a continuing resolution that expires on December 11, 2026. If Congress does not enact full-year appropriations or a further continuing resolution before that date, the federal government could again shut down, and agencies such as the FDA and the SEC could again furlough employees and suspend non-essential activities, which could delay review of our regulatory submissions, meetings with

the FDA and review of our public filings. In addition, the U.S. government has issued certain policies and executive orders directed towards reducing the employee headcount and costs associated with U.S. administrative agencies, including the FDA, and it remains unclear the degree to which these efforts may limit or otherwise adversely affect the FDA's ability to conduct routine activities. If a prolonged government shutdown, such as the one that occurred in October 2025, or if funding shortages or staffing limitations hinder or prevent the FDA, the SEC or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, including formal and informal interactions with product developers, it could significantly affect the ability of the FDA or other such regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns or other substantial disruptions at other government agencies, such as the SEC, may also impact our business by delaying review of our public filings, which in turn could delay or frustrate our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Significant political, trade, regulatory developments, and other circumstances beyond our control, could have a material adverse effect on our financial condition or results of operations.

We operate beyond the United States and, if approved, we may sell our products in countries throughout the world. Significant political, trade, or regulatory developments in the jurisdictions in which we may sell our products, such as those stemming from the change in U.S. federal administration, are difficult to predict and may have a material adverse effect on us. Similarly, changes in U.S. federal policy that affect the geopolitical landscape could give rise to circumstances outside our control that could have negative impacts on our business operations. For example, certain governments (including the United States and other countries) have imposed or may impose tariffs on a wide range of products, raw materials, and intermediate goods. Additional tariffs, or retaliatory measures by other countries in response, may be implemented at any time. Historically, tariffs have led to increased trade and political tensions, between not only the U.S. and China, but also between the U.S. and other countries in the international community. 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. Any changes in political, trade, regulatory, and economic conditions, including U.S. trade policies, could have a material adverse effect on our financial condition or results of operations. Until we know what policy changes are made, whether those policy changes are challenged and subsequently upheld by the court system and how those changes impact our business and the business of our competitors over the long term, we will not know if, overall, we will benefit from them or be negatively affected by them.

Risks Related to Ongoing Regulatory Obligations

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

Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety, potency and purity of the product candidate. We believe it is likely that the FDA will require a Risk Evaluation and Mitigation Strategy, or REMS, in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any BLA, other marketing application and previous responses to inspectional observations. Additionally, manufacturers and manufacturers' facilities are required to comply with extensive FDA, and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations and applicable product tracking and tracing requirements. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. In addition, the FDA could require us to conduct another study to obtain additional safety or biomarker information. Additionally, under the Food and Drug Omnibus Reform Act of 2022, or FDORA, sponsors of approved drugs and biologics must provide six months' notice to the FDA of any changes in marketing status, such as the withdrawal of a drug, and failure to do so could result in a letter citing such failure to comply and public posting of such letter and redacted company response, which could damage the company's reputation.

Further, we will be required to comply with FDA promotion and advertising rules, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved uses (known as "off-label use"), limitations on industry-sponsored scientific and educational activities and requirements for promotional activities involving the internet and social media. Later discovery of previously unknown problems with our product candidates through follow-up programs with our clinical trial patients, including adverse events of unanticipated severity or frequency, or with our third-party suppliers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post-market studies or clinical studies to assess new safety risks, or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action. If these executive actions impose restrictions on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability.

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 research and development activities involve the use of biological and hazardous materials and produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. 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 production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Although we maintain workers' compensation insurance to cover us for costs and expenses, we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological waste or hazardous waste insurance coverage, workers compensation or property and casualty and general liability insurance policies that include coverage for damages and fines arising from biological or hazardous waste exposure or contamination.

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

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with the laws of the FDA, provide true, complete and accurate information to the FDA, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws, or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs.

Risks Related to Healthcare

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

Successful commercialization of our product candidates, if licensed, will depend in part on the extent to which reimbursement for those drug products will be available from government health administration authorities, private health insurers, and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drug products they will pay for and establish reimbursement levels. The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford a drug product. Sales of drug products depend substantially, both domestically and abroad, on the extent to which the costs of drugs products are paid for by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. Any product candidate for which we seek regulatory approval and reimbursement will need to meet or surpass our target product profile, or TPP, to be deemed a viable alternative to currently approved therapies. In addition, because our product candidates represent new approaches to the treatment of autoimmune diseases where B cells may play a role in initiating or maintaining disease, we cannot accurately estimate the potential revenue from our product candidates. For more information, see the section titled "Business—Government regulation—Pricing and Reimbursement" included in our Annual Report on Form 10-K for the year ended December 31, 2025.

Obtaining coverage and reimbursement of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide the payor with supporting scientific, clinical and cost-effectiveness data for the use of our products, if licensed. In the United States, the principal decisions about reimbursement for new drug products are typically made by the Centers for Medicare and Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS. CMS decides whether and to what extent a new drug product will be covered and reimbursed under Medicare, and private payors tend to follow CMS to a substantial degree. However, no uniform policy of coverage and reimbursement for drug products exists among third-party payors and coverage and reimbursement levels for drug products can differ significantly from payor to payor. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

Even if we obtain coverage for a given product, if the resulting reimbursement rates are insufficient, hospitals may not approve our product for use in their facility or third-party payors may require co-payments that patients find unacceptably high. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates. Separate reimbursement for the product itself may or may not be available. Instead, the hospital or administering physician may be reimbursed only for providing the treatment or procedure in which our product is used. Further, from time to time, CMS revises the reimbursement systems used to reimburse health care providers, including the Medicare Physician Fee Schedule and Outpatient Prospective Payment System, which may result in reduced Medicare payments. In some cases, private third-party payors rely on all or portions of Medicare payment systems to determine payment rates. Changes to government healthcare programs that reduce payments under these programs may negatively impact payments from private third-party payors, and reduce the willingness of physicians to use our product candidates.

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

Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations.

In the United States, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay regulatory approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain regulatory approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and in additional downward pressure on the price that we, or any collaborators, may receive for any approved products. For more information, see the section titled "Business—Government regulation—Current and Future Legislation" included in our Annual Report on Form 10-K for the year ended December 31, 2025.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. For instance, multiple executive actions in the first half of 2025 signaled the federal government's increasing focus on lowering prescription drug prices, adding to the uncertainty surrounding future drug pricing and reimbursement frameworks. For example:

- On May 12, 2025, President Trump signed the executive order titled "Delivering Most-Favored-Nation Prescription Drug Pricing," which directs the Secretary of HHS to identify and communicate most-favored-nation, or MFN, price targets for prescription drugs and to propose a rulemaking plan to impose such pricing if "significant progress" is not made. The order also directs the federal government to explore regulatory pathways that would facilitate direct-to-patient sales for manufacturers that meet these price targets. Additionally, it signals potential further action against manufacturers that fail to offer MFN pricing, including evaluating whether to modify or rescind marketing approvals or allow individual drug importation waivers. Notably, a similar rule promulgated during President Trump's first term would have tied Medicare Part B reimbursement rates to the lowest price available for a drug in certain foreign countries. That rule was subject to litigation and ultimately rescinded by the Biden Administration in August 2021. In a related development, FDA Commissioner Makary announced in July 2025 that the agency is considering a new fast-track priority review voucher program for manufacturers that commit to pricing drugs in line with those in economically comparable countries. The implementation timeline and commercial implications of these proposals remain uncertain.

- On April 15, 2025, President Trump issued the executive order "Lowering Drug Prices by Once Again Putting Americans First," which contains a broad set of directives aimed at reducing drug costs. Among other actions, the order directs HHS to revise guidance under the Inflation Reduction Act of 2022, or the IRA, to eliminate the so-called "pill penalty," which currently subjects small molecule drugs to Medicare price negotiation four years earlier than biologics. The order also calls for a comprehensive evaluation of the role played by pharmacy benefit managers, or PBMs, in drug pricing and market access.

Further, the Medicare Drug Price Negotiation Program, administered by CMS as part of the IRA, may apply to our products if they are selected for negotiation, which could materially reduce the amount of revenue we can generate from our products if they are approved. Prior to the enactment of the One Big Beautiful Bill Act of 2025, or the OBBBA, orphan drugs were exempt from Medicare price negotiation under the IRA only if they had received a single orphan designation and were approved solely for the corresponding rare disease or condition. The OBBBA amended this exemption to apply more broadly: now, any orphan-designated drug is exempt from price negotiation, regardless of the number of orphan designations it has received, provided the drug's approved indications are exclusively for those rare diseases. The OBBBA also included significant reforms to Medicaid, including an estimated $1 trillion in reduced federal Medicaid spending from 2025 through 2034, the imposition of work requirements for certain adult enrollees, more frequent eligibility redeterminations, and increased cost-sharing for beneficiaries. These changes are expected to reduce overall Medicaid enrollment and access to care. Although the effect on our future product candidates or business is unknown, any decrease in the number of insured patients or reimbursement levels for our products could adversely affect our potential for revenue and our commercial prospects.

On December 19, 2025, CMS released two proposed rules that would incorporate MFN pricing principles into federal reimbursement for prescription drugs. The Global Benchmark for Efficient Drug Pricing Model, or GLOBE, for Medicare Part B, requires manufacturers of specified single source drugs and sole source biologics to pay incremental rebates based on international benchmark prices, with participation triggered for products meeting CMS's spending and eligibility criteria. On September 30, 2026, CMS finalized the GLOBE model, which becomes effective on November 30, 2026, with its performance period beginning on January 1, 2027. As finalized, GLOBE excludes certain cell and gene therapies; however, the scope of this exclusion, and whether it would apply to any of our product candidates, if approved, remains uncertain, and CMS could narrow or eliminate the exclusion in future rulemaking. On October 7, 2026, the Pharmaceutical Research and Manufacturers of America filed a lawsuit challenging the GLOBE model, and the outcome of this litigation, which could delay, modify or invalidate the model, is uncertain. The second proposal, the Guarding U.S. Medicare Against Rising Drug Costs, or GUARD, model for Medicare Part D, would similarly mandate manufacturer rebates for qualifying sole source drugs where the Medicare net price exceeds an MFN benchmark derived from international reference pricing methodologies. As proposed, GUARD would begin its performance period in 2027, and it has not been finalized. GUARD, if finalized, will likely also be subject to legal challenges that could delay its implementation or modify its impact on manufacturer pricing and

revenue. Additionally, in November 2025, CMS introduced the GENErating cost Reductions for U.S. Medicaid Model, or GENEROUS Model, a voluntary MFN framework for manufacturers participating in the Medicaid Drug Rebate Program. Although it is voluntary, the GENEROUS Model could also impact the drug pricing landscape for manufacturers.

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

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

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

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

These laws may impact, among other things, our clinical research program, as well as our proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services is subject to extensive laws and regulations designed to prevent fraud, kickbacks, self-dealing and other abusive practices, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, which may constrain the business or financial arrangements and relationships through which such companies sell, market and distribute pharmaceutical products. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive and other business arrangements. We may also be subject to federal, state and foreign laws governing the privacy and security of individual identifiable health information and other personally identifiable information. For more information, see the section titled “Business—Government regulation—Other Healthcare Laws and Compliance Requirements” included in our Annual Report on Form 10-K for the year ended December 31, 2025.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company’s attention from the business.

The failure to comply with any of these laws or regulatory requirements subjects entities to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Any action for violation of these laws, even if successfully defended, could cause a pharmaceutical manufacturer to incur significant legal expenses and divert management’s attention from the operation of the business. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities, or our arrangements with physicians, some of whom receive stock options as compensation, could be subject to challenge under one or more of such laws. If we or our employees, independent contractors, consultants, commercial partners and vendors violate these laws, we may be subject to investigations, enforcement actions and/or significant penalties. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct or business noncompliance, and the precautions we take to detect and prevent inappropriate conduct 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. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Risks Related to Data Privacy and Security

Data collection is governed by restrictive regulations governing the use, processing, and cross-border transfer of personal information.

We are subject to stringent privacy and data protection requirements and these requirements may become more complex as we grow our business and begin to operate in other jurisdictions. For example, the collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the European Economic Area, or the EEA, including personal health data, is subject to the EU General Data Protection Regulation, or the EU GDPR, and similarly, processing of personal data regarding individuals in the UK is subject to the UK General Data Protection Regulation and the UK Data Protection Act 2018, or the UK GDPR, and together with the EU GDPR, or the GDPR. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to having a legal basis or condition for processing personal data, stricter requirements relating to the processing of sensitive data (such as health data), where required by the GDPR obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, requiring data protection impact assessments for high risk processing and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EEA/UK, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million (£17.5 million under UK GDPR) or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR includes restrictions on cross-border data transfers of personal data to countries outside the EEA/UK that are not considered by the European Commission and UK government as providing "adequate" protection to personal data, or third countries, including the United States. The GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. Compliance with the GDPR is rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities.

To enable the transfer of personal data outside of the EEA or the UK, adequate safeguards (for example, the European Commission approved Standard Contractual Clauses, or SCCs and the UK International Data Transfer Agreement/Addendum, or UK IDTA) must be implemented in compliance with European and UK data protection laws. In addition, transfers made pursuant to the SCCs (and other similar appropriate transfer safeguards) need to be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular regarding applicable surveillance laws and relevant rights of individuals with respect to the transferred personal data, to ensure an "essentially equivalent" level of protection to that guaranteed in the EEA in the jurisdiction where the data importer is based, or the Transfer Impact Assessment. Further, the EU and United States have adopted its adequacy decision for the EU-U.S. Data Privacy Framework, or the Framework, which entered into force on July 11, 2023. This Framework provides that the protection of personal data transferred between the EU and the United States is comparable to that offered in the EU. This provides a further avenue to ensuring transfers to the United States are carried out in line with GDPR. There has been an extension to the Framework to cover UK transfers to the United States. The Framework could be challenged like its predecessor frameworks. We are required to implement these safeguards and carry out Transfer Impact Assessments when conducting restricted data transfers under the

GDPR and doing so will require significant effort and cost, and may result in us needing to make strategic considerations around where EEA or UK personal data is stored and transferred, and which service providers we can utilize for the processing of EEA/UK personal data. Although the UK is regarded as a third country under the EU GDPR, the European Commission has issued a decision recognizing the UK as providing adequate protection under the EU GDPR, or the Adequacy Decision, and, therefore, transfers of personal data originating in the EEA to the UK remain unrestricted. The UK government has confirmed that personal data transfers from the UK to the EEA remain free flowing.

Despite Brexit, the UK and EEA data protection regimes remain largely aligned. However, going forward, there is increasing risk for divergence in application, interpretation and enforcement of the data protection laws as between the UK and EEA, creating additional regulatory uncertainty. For example, the UK Data (Use and Access) Act 2025 (UK Act), now in force, further differentiates the UK's data protection regime. In December 2025, the European Commission adopted a decision determining that the UK continues to provide a level of data protection that is "essentially equivalent" to the EU standards and extended the validity of the UK adequacy decision for six years, through December 2031. While this renewal reduces immediate adequacy concerns, uncertainty remains regarding how UK data protection laws will evolve in the medium to longer term. The lack of clarity on future UK laws and regulations and their interaction with EU laws and regulations may affect our efforts to maintain a harmonized approach to processing European personal data and expose us to two parallel regimes where the UK GDPR and EU GDPR both apply with differing interpretation and enforcement approaches. This could increase our legal risk, uncertainty, complexity and compliance cost associated with the handling of European personal data, and may require us to adapt our privacy and data security compliance programs to account for legal and regulatory divergence between the UK and EEA.

In the EEA, the NIS 2 Directive (NIS 2) is replacing the cybersecurity legal framework under the current NIS framework, aiming to ensure a high level of cybersecurity in the region. NIS 2 brings new medium and large organisations providing services in the EEA within scope of the legal framework. It extends to additional sectors and expands the list of in-scope healthcare organisations, including to certain providers engaged in research and development of medicinal products. The new regime imposes direct obligations on management in respect of an in-scope organization's compliance with NIS 2, requires covered organisations to put in place certain cyber risk management measures, strengthens incident reporting requirements and provides supervisory authorities with a greater oversight. The majority of obligations will come into force when national legislation implementing NIS 2 becomes effective in the relevant EU Member State. EU Member States had until 17 October 2024 to transpose NIS 2 into national legislation, although many countries have still not completed the transposition. As such, the cybersecurity regulatory landscape in the EU is currently fragmented and uncertain. Although we are not currently subject to NIS 2, we have evaluated its requirements and have already implemented various cybersecurity measures that align with NIS 2 obligations. To the extent that we become subject to NIS 2 in the future, we will continue working closely with our Data Protection Officer to ensure that our compliance programs are fully aligned with NIS 2 and national implementing legislation where applicable. Under NIS 2 companies may be subject to administrative fines of up to the higher amount of €10 million or 2% of worldwide turnover.

In the United States, there has been a flurry of legislative activity related to privacy at the state level. In California, for example, the California Consumer Privacy Act, or CCPA, broadly defines personal information, creates comprehensive individual privacy rights and protections for California consumers (as defined in the law), places increased privacy and security obligations on entities handling personal data of consumers or households, and provides for civil penalties for violations and a private right of action for data breaches. The CCPA requires covered companies to provide certain disclosures to consumers about their data collection, use and sharing practices, and to provide affected California residents with ways to opt-out of certain sales or transfers of personal information. The California Privacy Rights Act, or CPRA, effective January 1, 2023, significantly modified the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. The CPRA also created a state agency vested with authority to implement and enforce the CCPA. While there is an exception for protected health information that is subject to HIPAA and clinical trial regulations, the effects of the CCPA, as amended by the CPRA are potentially significant and may require us to modify our data collection or processing practices and policies and to incur substantial costs and expenses in an effort to comply and decrease our potential exposure to regulatory enforcement and/or litigation.

Numerous other states have enacted similarly comprehensive privacy laws, adding additional complexity, variation in requirements, restrictions and potential legal risk, requiring additional investment of resources in compliance programs. These laws impact our strategies, the availability of previously useful data and could result in increased compliance costs and/or changes to our business practices and policies. The existence of comprehensive privacy laws in different states in the country make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance. There are also states that are specifically regulating health information. For example, Washington state passed a health privacy law that regulates the collection and sharing of health information, and the law also has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data. In addition, other states have proposed and/or passed legislation that regulates the privacy and/or security of certain specific types of information. For example, a small number of states have passed laws that regulate genetic data and biometric data specifically. These various privacy and security laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products. State laws are changing rapidly and there is discussion in the U.S. Congress of comprehensive federal data privacy laws to which we may become subject, if enacted.

At the federal level, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act (FTC Act). The FTC's current guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA security regulations, but this guidance may change in the future, resulting in increased complexity and the need to expend additional resources to ensure we are complying with the FTC Act. Moreover, regulators and legislators are increasingly scrutinizing and restricting certain personal data transfers and transactions involving foreign countries. For example, the Department of Justice's January 8, 2025, rule on "Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons," prohibits data brokerage transactions involving certain sensitive personal data categories, including health data, genetic data, and biospecimens, to countries of concern, including China. The regulations also restrict certain investment agreements, employment agreements and vendor agreements involving such data and countries of concern, absent specified cybersecurity controls. Similar state laws regulating health and genetic data and public procurement may also restrict transfers of data to, or partnerships with entities, outside the U.S. Actual or alleged violations of these regulations may be punishable by criminal and/or civil sanctions and may result in exclusion from participation in federal and state programs.

All of these evolving compliance and operational requirements impose significant costs, such as costs related to organizational changes, implementing additional protection technologies, training employees and engaging consultants and legal advisors, which are likely to increase over time. Further, various other jurisdictions around the world continue to propose new and/or amended laws that regulate the privacy and/or security of certain types of personal data. Complying with these laws, if enacted, would require significant resources and leave us vulnerable to possible fines and penalties if we are unable to comply. The regulatory framework governing the collection, processing, storage, use and sharing of certain information is rapidly evolving and is likely to continue to be subject to uncertainty and varying interpretations. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our existing data management practices or the features of our services and platform capabilities. Compliance with the above and any other applicable privacy and data security laws and regulations is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules, modify our data processing practices and policies, utilize management's time and/or divert resources from other initiatives and projects. Any failure or perceived failure by us, or any third parties with which we do business, to comply with our posted privacy policies, evolving laws, rules and regulations, industry standards, or contractual obligations to which we or such third parties are or may become subject, may result in actions or other claims against us by governmental entities or private actors, the expenditure of substantial costs, time and other resources or the incurrence of significant fines, penalties or other liabilities. In addition, any such action, particularly to the extent we were found to be guilty of violations or otherwise liable for damages, would damage our reputation and adversely affect our business, financial condition and results of operations.

If our security measures or those of our contractors, consultants or other service providers are breached or unauthorized access to confidential and/or proprietary information or other sensitive information, including individually identifiable health information or other personally identifiable information, is otherwise obtained, our reputation may be harmed, and we may incur significant liabilities.

We and the third parties upon which we rely face a variety of evolving threats, which could cause cybersecurity incidents or data breaches, which, could result in unauthorized access to systems and data, loss of data, and compromise, misuse, or corruption of such data and information. The systems of any CMOs that we may engage now or in the future, and present and future CROs, contractors, consultants and other service providers also could experience breaches or cybersecurity incidents leading to the exposure of confidential and sensitive information. Despite the implementation of security measures, our internal computer systems and information technology systems and infrastructure and those of our third party CROs, vendors, and other contractors and consultants upon which our business relies are vulnerable to breakdown or damage or interruption from, among other things, natural disasters, terrorism, war, telecommunication and electrical failures, and sophisticated cyber attacks, including the theft, fraud, and subsequent misuse of employee credentials, wrongful conduct by insider employees or vendors, denial-of-service attacks, ransomware attacks, business email compromises, computer malware, malicious codes, viruses, breakdown, wrongful intrusions, data breaches, and social engineering (including phishing attacks). Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources. Because the techniques used by computer programmers who may attempt to penetrate and sabotage our information technology systems and infrastructure, network security or our website change frequently and may not be recognized until launched against a target, we may be unable to anticipate these techniques or to adequately prevent or address them. Attempts to disrupt or gain unauthorized access to our and our third-party vendors' information systems from malicious third parties or insider threats may be enhanced or facilitated by evolving technologies, including artificial intelligence.

It is also possible that unauthorized access to our confidential and/or proprietary information or other sensitive information, including customer or employee information, may be obtained through inadequate use of security controls by customers, suppliers or other vendors. We rely on such third parties to implement effective security measures and identify and correct for any failures, deficiencies, compromises or breaches.

In the event of a cybersecurity incident or data breach, our company could be required to provide legal notifications and disclosures, and could suffer loss of business, severe reputational damage adversely affecting investor confidence, regulatory inquiries, investigations and orders, litigation, indemnity obligations, damages for contract breach, penalties and fines for violation of applicable laws or regulations, significant costs for remediation and other liabilities. For example, the loss of preclinical study or clinical trial data from completed or future preclinical studies or clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security compromise or breach were to result in a loss or misappropriation of, or damage to, our data, systems, or applications, or inappropriate disclosure of confidential or proprietary information or other sensitive information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

We have incurred and expect to incur significant expenses to prevent cybersecurity incidents and data breaches, including costs related to deploying additional personnel and protection technologies, training employees, and engaging third-party solution providers and consultants. Although we expend significant resources to create security protections that are designed to shield our confidential and/or proprietary information or other sensitive information, including customer data, against potential theft and security compromises or breaches, such measures cannot provide absolute security. Moreover, as we outsource more of our information systems to vendors and rely more on cloud-based information systems, the related security risks will increase, and we will need to expend additional resources to protect our technology and information systems.

Like other companies in our industry, we, and our third party vendors, have experienced and will continue to experience threats and cybersecurity incidents relating to our information technology systems and infrastructure. We remain at risk for future cybersecurity incidents and data breaches, including, without limitation, those that may occur as a result of third-party action, or wrongful conduct by insider employees or vendors or malfeasance and other causes. If, in the future, we experience a data breach or security incident, we could experience harm to our reputation, financial performance, and customer and vendor relationships. Further, we could experience possible legal notifications and disclosures, as well as litigation or regulatory investigations or actions by state and federal governmental authorities and non-U.S. authorities, including fines, penalties, and other legal and financial exposure and liabilities. Additionally, actual, potential or anticipated attacks or compromises may cause us to incur increasing costs, including costs to deploy additional personnel and protection technologies, train employees, conduct security incident investigation or remediation and engage third-party experts and consultants.

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 privacy and data security obligations. Further, although we maintain cyber liability insurance, this insurance may not provide adequate coverage against potential liabilities related to any experienced cybersecurity incident or breach.

Interruptions in the availability of server systems or communications with internet or cloud-based services, or failure to maintain the security, confidentiality, accessibility or integrity of data stored on such systems, could harm our business.

We rely upon a variety of internet service providers, third-party web hosting facilities and cloud computing platform providers to support our business. Failure to maintain the security, confidentiality, accessibility or integrity of data stored on or processed by such systems could result in interruptions in our operations, damage our reputation in the market, increase our service costs, cause us to incur substantial costs, subject us to liability for damages and/or fines, and divert our resources from other tasks, any one of which could materially adversely affect our business, financial condition, results of operations and prospects. If our security measures or those of our third-party data center hosting facilities, cloud computing platform providers, or third-party service partners, are breached, and unauthorized access is obtained to or there is misuse of our data or our information technology systems, we may incur significant legal and financial exposure and liabilities.

We also do not have control over the operations of the facilities of our cloud service providers and our third-party web hosting providers, and they also may be vulnerable to damage, security compromise or interruption from natural disasters, cybersecurity attacks, terrorist attacks, power outages and similar events or acts of misconduct. In addition, any changes in these providers' service levels may adversely affect our ability to meet our requirements and operate our business.

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

We may use and integrate artificial intelligence (AI) into our business processes both in our own development and implementation of AI and through the adoption of commercially available tools. Use of this technology could pose cybersecurity, data privacy, IT, intellectual property, regulatory, legal, operational, competitive, reputational and other risks and challenges that could affect our business. Specifically, risks related to accuracy, bias, AI hallucinations, discrimination, harmful content, misinformation, fraud, scams, targeted attacks (including model poisoning or data poisoning), surveillance, data leakage, inequality, environmental harms, and other harms may flow from our development, use, or deployment of AI technologies.

The rapid evolution of AI will require the application of significant resources to design, develop, test and maintain such systems to help ensure that AI is implemented in accordance with applicable law and regulation and in a socially responsible manner and to minimize any real or perceived unintended harmful impacts. If we enable or offer solutions that draw controversy due to perceived or actual negative societal impact, we may experience brand or reputational harm, competitive harm or legal liability. Additionally, the use of certain AI technology can give rise to intellectual property risks, including by disclosing or otherwise compromising our confidential or proprietary intellectual property and intellectual property infringement, or by undermining our ability to assert or defend ownership rights in intellectual property created with the assistance of AI tools.

Moreover, a growing number of legislators and regulators are adopting laws and regulations and have focused enforcement efforts on the adoption of AI and use of such technologies in compliance with ethical standards and societal expectations. These developments may increase our compliance burden and costs in connection with use of AI and lead to legal liability if we fail to meet evolving legal standards or if use of such technologies results in harms or other causes of action we did not predict. For example, the EU began implementing the Artificial Intelligence Act, or AI Act, on August 1, 2024. On July 27, 2026, Regulation (EU) 2026/1744, known as the Digital Omnibus on AI, entered into force and postponed the application of the AI Act's obligations for high-risk AI systems to December 2, 2027 for systems listed in Annex III and August 2, 2028 for systems covered by Annex I. The AI Act imposes significant obligations on providers and deployers of high-risk AI systems, and encourages providers and deployers of AI systems to account for EU ethical principles in their development and use of these systems. The scope of requirements depends on judicial interpretations and implementing guidance, and non-compliance can lead to significant fines.

In the U.S., the AI regulatory environment is complex and uncertain. Over the past year, states have advanced, and in some cases passed, dozens of laws focusing on AI governance and regulation, including on deployment of AI in healthcare settings. At the federal level, the FDA has advanced guidance and proposed frameworks for regulating AI in drug discovery, marketing submissions, and medical device development. At the same time, the Trump Administration has endorsed a federal moratorium on the enforcement of state AI laws, including through a December 11, 2025, executive order on "Ensuring a National Policy Framework for Artificial Intelligence." So far, these efforts have not been successful at curtailing state action on AI regulation, contributing to a complicated legislative patchwork, which may be litigated in state and federal courts. If we develop or use AI systems that are governed by the these laws or regulations, we will need to meet higher standards of data quality, transparency, and human oversight, and we would need to adhere to specific and potentially burdensome and costly ethical, accountability, and administrative requirements. We may also be subject to significant enforcement or litigation in the event of any perceived non-compliance.

The rapid evolution of AI will require the application of significant resources to design, develop, test and maintain our products and services to help ensure that AI is implemented in accordance with applicable law and regulation and in a socially responsible manner and to minimize any real or perceived unintended harmful impacts. Our vendors may in turn incorporate AI tools into their offerings, and the providers of these AI tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to privacy and data security. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business. Bad actors around the world also use increasingly sophisticated methods, including the use of AI, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. In addition, the use of generative AI models in our internal or third-party systems may create new attack surfaces or methods for adversaries, which could impact us and our vendors. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business.

AI-enabled cyber threats targeting financial systems, third-party infrastructure, and the use of AI tools could disrupt our treasury operations, financing activities, clinical programs, and regulatory compliance, resulting in material adverse effects on our business, financial condition, and ability to raise capital.

Cybersecurity threats continue to evolve in sophistication and scale, and recent advances in artificial intelligence have materially increased the effectiveness of certain cyberattack methods. Malicious actors are increasingly using AI-enabled tools to automate attacks, generate highly convincing phishing communications, and deploy "deepfake" technologies capable of impersonating company executives, financial institutions, vendors or other trusted parties. These techniques increase the risk of unauthorized access to our financial systems, fraudulent instructions or fund transfers, manipulation of payment activity, and other compromises that may be difficult to detect in real time.

As a clinical-stage biotechnology company, we depend on external financing to fund our operations and advance our development programs. A cybersecurity incident affecting our treasury systems, banking relationships, or payment processing infrastructure — whether through unauthorized access, system disruption, or fraud — could impair our ability to manage liquidity, complete financing transactions, or meet our financial obligations. Even a temporary loss of access to critical financial systems or counterparties could adversely affect our financial condition and operational continuity.

We also rely extensively on third-party vendors and service providers, including contract research organizations, contract manufacturing organizations, cloud service providers, and financial institutions. These third parties may be targeted by increasingly

sophisticated, AI-enabled cyberattacks, and a cybersecurity incident affecting a key third party could disrupt our clinical operations, delay development timelines, compromise sensitive data, or require significant remediation efforts, even if our own systems are not directly compromised. We may have limited visibility into, or control over, the cybersecurity measures implemented by our third-party partners, which may heighten these risks.

In addition, our internal evaluation and use of artificial intelligence-based tools across business functions may expose us to additional risks if such tools are deployed without appropriate governance, controls, and oversight. These risks include the inadvertent disclosure of confidential financial, clinical, or personal data; reliance on outputs that are incomplete, inaccurate, or biased; and challenges in maintaining appropriate records, audit trails, and internal controls. The legal and regulatory frameworks governing the development and use of artificial intelligence are rapidly evolving, and new or changed requirements could increase compliance costs, restrict our use of certain technologies, or expose us to regulatory or contractual liability.

Although we maintain cybersecurity risk management measures and incident response capabilities, these measures may not be effective in preventing or mitigating the impact of all cybersecurity incidents, particularly as threat actors continue to adapt their methods using emerging AI capabilities. A significant cybersecurity incident affecting our financial systems, key third-party relationships, or use of AI-based tools could have a material adverse effect on our business, results of operations, financial condition, ability to raise capital, or ability to comply with applicable reporting and regulatory obligations.

Risks Related to Ownership of Our Common Stock

Risks Related to Ownership Generally

Our principal stockholders and management own a large percentage of our stock and could be able to exert significant control over matters subject to stockholder approval.

As of December 31, 2025, our executive officers, directors, and 5% stockholders beneficially owned, in the aggregate, approximately 40% of our common stock. Accordingly, these stockholders could have the ability to influence us through this ownership position and may be able to determine the outcome of certain matters requiring stockholder approval. For example, these stockholders may be able to control the outcome of elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

If we fail to establish and maintain proper and effective internal control over financial reporting, our operating results and our ability to operate our business could be harmed.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. The Sarbanes-Oxley Act requires that we evaluate and determine the effectiveness of our internal control over financial reporting and, beginning with our second annual report following our initial public offering, provide a management report on internal control over financial reporting. However, while we remain a smaller reporting company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. In compliance with Section 404 of the Sarbanes-Oxley Act, we will continue to dedicate internal resources, continue to engage outside consultants, and maintain a detailed work plan to assess and document the adequacy of internal control over financial reporting. Additionally, we will enhance control processes as needed, validate their effectiveness through testing, and implement a continuous monitoring and improvement process.

Implementing any appropriate changes to our internal controls may distract our officers and employees, entail substantial costs to modify our existing processes, and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and harm our business. In addition, investors' perceptions that our internal controls are inadequate or that we are unable to produce accurate financial statements on a timely basis may harm our stock price and make it more difficult for us to effectively market and sell our service to new and existing customers.

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

The dual class structure of our common stock may limit your ability to influence corporate matters. Holders of our common stock are entitled to one vote per share, while holders of our non-voting common stock are not entitled to any votes. Nonetheless, each share

of our non-voting common stock may be converted at any time into one share of our common stock at the option of its holder by providing written notice to us, subject to the limitations provided for in our amended and restated certificate of incorporation. Additionally, stockholders who hold, in the aggregate, more than 10% of our common stock and non-voting common stock, but 10% or less of our common stock, and are not otherwise a company insider, may not be required to report changes in their ownership due to transactions in our non-voting common stock pursuant to Section 16(a) of the Exchange Act, and may not be subject to the short-swing profit provisions of Section 16(b) of the Exchange Act. No shares of non-voting common stock are currently outstanding.

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Certain holders of our common stock have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

Risks Related to our Charter and Bylaws

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws, as amended, or the amended and restated bylaws, contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer, or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of the holders of not less than 75% of the votes that all our stockholders would be entitled to cast in an annual election of directors;
- a requirement of approval of not less than 75% of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our amended and restated certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

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

Pursuant to our amended and restated bylaws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for state law claims for: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, or other employees to us or our stockholders; (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law or our amended and restated certificate of incorporation or amended and restated bylaws (including the interpretation, application or validity thereof); or (iv) any action asserting a claim governed by the internal affairs doctrine (the Delaware Forum Provision). The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act of 1933, as amended (the Securities Act) or the Securities Exchange Act of 1934. Our amended and restated bylaws further provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America are the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or the rules and regulations promulgated thereunder, or the Federal Forum Provision. In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the foregoing Delaware Forum Provision and Federal Forum Provision; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the U.S. federal securities laws and the rules and regulations thereunder.

The Delaware Forum Provision and the Federal Forum Provision may impose additional litigation costs on stockholders in pursuing any such claims. Additionally, these forum selection clauses may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage the filing of lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. In addition, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. While the Delaware Supreme Court and other states have upheld the validity of federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on us and/or our stockholders who assert that the provision is invalid or unenforceable. The Court of Chancery of the State of Delaware or the federal district courts of the United States of America may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

Risks Related to Tax

Changes in tax laws could adversely affect our business and 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 changes may have retroactive application) could adversely affect us or holders of our common stock. For example, the OBBBA was signed into law on July 4, 2025 and made significant changes to U.S. federal tax law. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. Prospective investors in our common stock should consult with their legal and tax advisors with respect to potential changes in tax laws and the tax consequences of investing in or holding our common stock.

As of December 31, 2025, we had U.S. federal, state and local net operating loss, or NOL, carryforwards of $319.9 million, $255.1 million and $257.6 million, respectively. $0.3 million of the federal amounts expire in 2037. The state NOLs begin to expire in 2037 and the local NOLs begin to expire in 2042. Approximately $319.6 million of the federal NOLs can be carried forward indefinitely. Certain NOL carryforwards could expire unused and be unavailable to offset future taxable income. In addition, in general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change NOL carryforwards or tax credits to offset future taxable income or taxes. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders who own at least 5% of a corporation's stock increases its ownership by more than 50 percentage points (by value) over its lowest ownership percentage within a specified testing period. Our existing NOLs or tax credits may be subject to limitations arising from previous ownership changes. In addition, future changes in our stock ownership, many of which are outside of our control, could result in an ownership change under Sections 382 and 383 of the Code and further limit our ability to utilize NOLs or tax credits. Our NOLs or tax credits may also be impaired under state law. Accordingly, we may not be able to utilize a material portion of our NOLs or tax credits. Furthermore, our ability to utilize our NOLs or tax credits is conditioned upon our attaining profitability and generating U.S. federal and state taxable income. As described above under "—Risks Related to Our Financial Condition and Capital Requirements", we have incurred significant net losses since our inception and anticipate that we will continue

to incur significant losses for the foreseeable future; and therefore, we do not know whether or when we will generate the U.S. federal or state taxable income necessary to utilize our NOLs or tax credits. Under current law, U.S. federal NOL carryforwards generated in taxable years beginning after December 31, 2017 will not be subject to expiration. However, any such NOL carryforwards may only offset 80% of our annual taxable income in taxable years beginning after December 31, 2020.

General Risk Factors

Adverse developments affecting the financial services industry could adversely affect our current and projected business operations and our financial condition and results of operations.

Adverse developments that affect financial institutions, such as events involving liquidity that are rumored or actual, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation as receiver. Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that us, the financial institutions with which we have credit agreements or arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. While it is not possible at this time to predict the extent of the impact that high market volatility and instability of the financial services industry could have on economic activity and our business in particular, the failure of other banks and financial institutions and the measures taken by governments, businesses and other organizations in response to these events could adversely impact our business, financial condition and results of operations.

Public health crises, such as a pandemic, epidemic or outbreak of other highly infectious or contagious diseases, could seriously harm our research, development and potential future commercialization efforts, increase our costs and expenses and have a material adverse effect on our business, financial condition and results of operations.

Public health crises, such as a pandemic, epidemic or outbreak of other highly infectious or contagious diseases, could adversely impact our business, the business operations of third parties on whom we rely and our ongoing or planned research and development activities. Additionally, timely enrollment in our ongoing and planned clinical trials is dependent upon clinical trial sites which may be adversely affected by global health concerns. Public health crises could result in increased adverse events and deaths in our clinical trials. Some factors from public health crises that could delay or otherwise adversely affect enrollment in the clinical trials of our product candidates, as well as our business generally, include:

- the potential diversion of healthcare resources away from the conduct of clinical trials to focus on public health crises, including the attention of physicians serving as our clinical trial investigators, hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our prospective clinical trials and the need for drugs, such as tocilizumab, and other supplies that clinical trial sites must have on hand to conduct our clinical trials to be used to address such public health crises;
- limitations on travel that could interrupt key trial and business activities, such as clinical trial site initiations and monitoring, domestic and international travel by employees, contractors or patients to clinical trial sites, including any government-imposed travel restrictions or quarantines that will impact the ability or willingness of patients, employees or contractors to travel to our clinical trial sites or secure visas or entry permissions, a loss of face-to-face meetings and other interactions with potential partners, any of which could delay or adversely impact the conduct or progress of our prospective clinical trials;
- interruption in global shipping affecting the transport of clinical trial materials, such as patient samples, investigational drug product and conditioning drugs and other supplies used in our prospective clinical trials;
- interruptions in operations at our third-party manufacturers, which could result in delays or disruptions in the supply of our current product candidates and any future product candidates; and
- business disruptions caused by potential workplace, laboratory and office closures and an increased reliance on employees working from home, disruptions to or delays in ongoing laboratory experiments and operations, product manufacturing and supply, staffing shortages, travel limitations or mass transit disruptions, any of which could adversely impact our business operations or delay necessary interactions with local regulators, ethics committees and other important agencies and contractors.

Any of these factors, and other factors related to any such disruptions that are unforeseen, could have a material adverse effect on our business and our results of operations and financial condition. Further, uncertainty around these and related issues could lead to

adverse effects on the economy of the United States and other economies, which could impact our ability to raise the necessary capital needed to develop and commercialize our product candidates.

The price of our stock may be volatile, and you could lose all or part of your investment.

The trading price of our common stock has been, and is likely to be in the future, highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this "Risk Factors" section, these factors include:

- the commencement, enrollment or results of our planned preclinical studies or clinical trials of our product candidates or any preclinical studies or future clinical trials we may conduct, or changes in the development status of our product candidates;
- our decision to initiate a preclinical study or clinical trial, not to initiate a preclinical study or clinical trial or to terminate an existing preclinical study or clinical trial;
- adverse results or delays in preclinical studies or clinical trials of our product candidates;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including, without limitation, the FDA's issuance of a "refusal to file" letter or a request for additional information;
- our failure to commercialize our product candidates;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- changes in laws or regulations applicable to our product candidates, including, but not limited to, clinical trial requirements for approvals;
- adverse developments concerning our manufacturers or suppliers;
- our inability to obtain adequate product supply for any licensed product or inability to do so at acceptable prices;
- our inability to establish collaborations, if needed;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- the size and growth of our initial target markets;
- our ability to successfully treat additional types of autoimmune diseases where B cells may play a role in initiating or maintaining disease;
- actual or anticipated variations in annual or quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- publication of news reports about us or our industry;
- inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;

•trading volume of our common stock;

•changes in accounting practices;

•ineffectiveness of our internal controls;

•disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;

•significant lawsuits, including patent or stockholder litigation;

•general political and economic conditions, including inflation and tariffs;

•global health concerns; and

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

In addition, the stock market in general, and The Nasdaq Global Select Market and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations in recent years that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. Securities class action litigation has often been instituted against companies, particularly in the biopharmaceutical and life sciences industries, following periods of volatility in the market price of a company's securities. We have been subject to such a securities class action lawsuit filed in February 2022 and voluntarily dismissed by the plaintiff in October 2022, against certain of our officers and certain of our current and former directors, and may become subject to additional securities class action lawsuits in the future. This type of litigation could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results or financial condition.

Our business is affected by macroeconomic conditions, including rising inflation, interest rates and supply chain constraints.

Various macroeconomic factors could adversely affect our business and the results of our operations and financial condition, including changes in inflation, interest rates, the risk of economic slowdown or recession in the United States, instability in the banking system, and overall economic conditions and uncertainties such as those resulting from the current and future conditions in the global financial markets. Recent supply chain constraints have led to higher inflation, which if sustained could have a negative impact on our product development and operations. If inflation or other factors were to significantly increase our business costs, our ability to develop our current pipeline and new therapeutic products may be negatively affected. Interest rates, the liquidity of the credit markets and the volatility of the capital markets could also affect the operation of our business and our ability to raise capital on favorable terms, or at all, in order to fund our operations. Similarly, these macroeconomic factors could affect the ability of our third-party suppliers and manufacturers to manufacture clinical trial materials for our product candidates.

We do not intend to pay dividends on our common stock, so any returns will be limited to the value of our stock.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock.

We are a "smaller reporting company," and we cannot be certain if the reduced reporting requirements applicable to smaller reporting companies will make our common stock less attractive to investors.

We are considered a "smaller reporting company" under Rule 12b-2 of the Exchange Act. We are therefore entitled to rely on certain reduced disclosure requirements, such as an exemption from providing selected financial data and executive compensation information. These exemptions and reduced disclosures in our SEC filings due to our status as a smaller reporting company also mean our auditors are not required to review our internal control over financial reporting and may make it harder for investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our common stock prices may be more volatile. We will remain a smaller reporting company for as long as (i) the market value of our common stock held by non-affiliates is less than $250.0 million or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our common stock held by non-affiliates is less than $700.0 million as of the prior June 30.

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

We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates or grant licenses on terms unfavorable to us.

We could be subject to significant legal proceedings which may adversely affect our results of operations or financial condition.

We are subject to the risk of litigation, derivative claims, securities class actions, regulatory and governmental investigations and other proceedings, including proceedings arising from investor dissatisfaction with us or our performance or claims brought by employees, government agencies or supplies. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. In addition, if any individuals acting on our behalf fails to satisfy his or her relevant legal or contractual duties, we could have liability to third parties, including the government or investors. If any claims were brought against us and resulted in a finding of substantial legal liability, the finding could materially adversely affect our business, financial condition or results of operations or cause significant reputational harm to us, which could seriously adversely impact our business. Allegations of improper conduct by private litigants or regulators, regardless of veracity, also may harm our reputation and adversely impact our ability to grow our business. Even if the allegations against us in future legal matters are unfounded or we ultimately are not held liable, the costs to defend ourselves may be significant and the litigation may subject us to substantial settlements, fines, penalties or judgments against us and may consume management's bandwidth and attention, some or all of which may negatively impact our financial condition and results of operations. Litigation also may generate negative publicity, regardless of whether the allegations are valid, or we ultimately are liable, which could damage our reputation, and adversely impact our sales and our relationship with our employees, customers, and partners. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

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

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. In the event that one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

****The U.S. Congress or the current administration may make substantial changes to fiscal, tax, and other federal policies that may adversely affect our business.***

Since the start of the current administration in 2025, there have been significant changes to U.S. trade, healthcare, immigration and government regulatory policy and additional changes are likely. For example, the U.S. government has imposed tariffs on most countries throughout the world, and the legal basis for these tariffs has continued to shift during 2026, including the U.S. Supreme Court's invalidation of tariffs imposed under IEEPA, the expiration of the global surcharge imposed under Section 122 of the Trade Act of 1974, and the imposition of tariffs under Section 301 of the Trade Act of 1974 that remain subject to ongoing litigation. The U.S. government has indicated that it may continue to impose tariffs broadly, including under alternative statutory authorities, which could lead to retaliatory actions by the countries with which the U.S. trades. Changes to U.S. policy implemented by the U.S. Congress, the current administration or any future administration have impacted and may in the future impact, among other things, the U.S. and global economy, international trade relations, unemployment, immigration, healthcare, taxation, the U.S. regulatory environment, inflation and other areas. In addition, the U.S. midterm elections held on November 3, 2026 have resulted in changes in the composition or control of one or both chambers of Congress, which could lead to changes in legislative, oversight and regulatory priorities, including with respect to drug pricing, healthcare, the FDA and trade policy. Public responses to the elections or their outcomes could also cause disruptions to our operations or those of the third parties on which we rely. Although we cannot predict the impact, if any, of these changes to our business, they could adversely affect our business. Until we know what policy changes are made, whether those policy changes are challenged and subsequently upheld by the court system and how those changes impact our business and the business of our competitors over the long term, we will not know if, overall, we will benefit from them or be negatively affected by them.

Item 2. Unregistered Sales of Equity Securities, Use of Proceeds and Issuer Purchases of Equity Securities.

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Rule 10b5-1 Trading Plans

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

Item 6. Exhibits.

The exhibits listed on the Exhibit Index immediately preceding such exhibits, which is incorporated herein by reference, are filed or furnished as part of this Quarterly Report on Form 10-Q.

Exhibit Number	Description
3.1	Third Amended and Restated Certificate of Incorporation of the Registrant, as currently in effect (incorporated by reference to Exhibit 3.1 to the Registrant's current report on Form 8-K (File No. 001-39103) filed with the SEC on October 30, 2019)
3.2	Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's current report on Form 8-K (File No. 001-39103) filed with the SEC on June 10, 2025)
3.3	Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's current report on Form 8-K (File No. 001-39103) filed with the SEC on June 11, 2026)
3.4	Amended and Restated Bylaws of the Registrant, as currently in effect (incorporated by reference to Exhibit 3.2 to the Registrant's current report on Form 8-K (File No. 001-39103) filed with the SEC on October 30, 2019)
3.5	Amendment No. 1 to the Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.3 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-39103) filed with the SEC on May 12, 2022)
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS*	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
104*	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibits 101*)

* Filed herewith.

** This certification will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent specifically incorporated by reference into such filing.

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.

Cabaletta Bio, Inc.

Date: November 5, 2026 By: /s/ Steven Nichtberger
Steven Nichtberger
Chief Executive Officer and President
(Principal Executive Officer)

Date: November 5, 2026 By: /s/ Anup Marda
Anup Marda
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

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

I, Steven Nichtberger, certify that:

1.I have reviewed this Quarterly Report on Form 10-Q of Cabaletta Bio, 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(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: November 5, 2026

By: /s/ Steven Nichtberger
Steven Nichtberger
Chief Executive Officer and President
(Principal Executive Officer)

Exhibit 31.2

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

I, Anup Marda, certify that:

1.I have reviewed this Quarterly Report on Form 10-Q of Cabaletta Bio, 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(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: November 5, 2026

By: /s/ Anup Marda
Anup Marda
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

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

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

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

Date: November 5, 2026

By: /s/ Steven Nichtberger
Steven Nichtberger
Chief Executive Officer and President
(Principal Executive Officer)

Exhibit 32.2

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

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

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

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

Date: November 5, 2026

By: /s/ Anup Marda
Anup Marda
Chief Financial Officer
(Principal Financial and Accounting Officer)