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 June 30, 2025

OR

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

For the transition period from_____ to _____

Commission File Number: 001-39103

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 August 1, 2025, the registrant had 91,465,233 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 clinical-stage 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 University of Pennsylvania, or Penn, Minaris Advanced Therapies, LLC, or Minaris (f/k/a WuXi Advanced Therapies, Inc) and/or Lonza Houston Inc., or Lonza, for our current manufacturing needs for our Phase 1/2 RESET™, or Restoring Self-Tolerance, clinical trials for resecabtagene autoleucel (rese-cel, formerly referred to as CABA-201) and our Phase 1 clinical trial of MuSK-CAART, or the MusCAARTes™ trial, 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, Penn, Minaris, Lonza 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 Penn and Nanjing IASO Biotherapeutics Co., Ltd., or IASO, and termination of one of these license agreements 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 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 which 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.
- We have identified conditions that raise substantial doubt about our ability to continue as a going concern. If we are unable to secure additional funding beyond our current cash position that enables our operations into the second half of 2026, we may be forced to delay, reduce or discontinue our product development programs efforts or other operations.

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 program, including our Phase 1/2 RESET™ clinical trials for rese-cel, our MusCAARTes™ trial, 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 or MusCAARTes™ trial;
- the timing of and our ability to obtain and maintain regulatory approval of our product candidates, including rese-cel, MuSK-CAART, and our 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 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 and other offerings, and the period over which such proceeds, together with existing cash, will be sufficient to extend our current cash runway beyond our current expectations into the second half of 2026 and meet our operating needs, including our ability to continue as a going concern;
- 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 Penn, the Children's Hospital of Philadelphia, or CHOP, Minaris and Lonza;
- 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, MuSK-CAART and any other product candidates;
- the potential receipt of revenue from future sales of rese-cel, MuSK-CAART and any other product candidates, if approved;
- the rate and degree of market acceptance and clinical utility of rese-cel, MuSK-CAART and any other product candidates;
- our estimates regarding the potential market opportunity for rese-cel, MuSK-CAART 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, MuSK-CAART 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, our MusCAARTes™ trial 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 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)

	June 30, 2025	December 31, 2024
Assets	(unaudited)	
Current assets:		
Cash and cash equivalents	$ 145,612	$ 163,962
Short-term investments	49,070	—
Prepaid expenses and other current assets	3,725	2,713
Total current assets	198,407	166,675
Property and equipment, net	2,374	2,743
Finance lease right-of-use assets	16,689	7,020
Operating lease right-of-use assets	4,528	6,315
Other assets	2,502	2,293
Total assets	$ 224,500	$ 185,046
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 7,193	$ 4,923
Accrued and other current liabilities	13,933	12,188
Finance lease liabilities, current portion	16,428	5,989
Operating lease liabilities, current portion	3,986	3,986
Total current liabilities	41,540	27,086
Finance lease liabilities, net of current portion	3,899	3,241
Operating lease liabilities, net of current portion	580	2,384
Total liabilities	46,019	32,711
Commitments and contingencies (see Notes 5 and 6)		
Stockholders' equity:		
Preferred stock, $0.00001 par value: 10,000,000 shares authorized as of June 30, 2025 and December 31, 2024; no shares issued or outstanding at June 30, 2025 and December 31, 2024	—	—
Voting and non-voting common stock, $0.00001 par value: 300,000,000 (293,590,481 voting and 6,409,519 non-voting) shares authorized as of June 30, 2025 and 150,000,000 (143,590,481 voting and 6,409,519 non-voting) shares authorized as of December 31, 2024; 91,451,899 voting shares issued and outstanding as of June 30, 2025 and 50,743,101 voting shares issued and outstanding as of December 31, 2024	1	1
Additional paid-in capital	608,651	501,435
Accumulated other comprehensive income	1	—
Accumulated deficit	(430,172)	(349,101)
Total stockholders' equity	178,481	152,335
Total liabilities and stockholders' equity	$ 224,500	$ 185,046

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 June 30,		Six months ended June 30,	
	2025	2024	2025	2024
Operating expenses:				
Research and development	$ 37,638	$ 23,427	$ 66,656	$ 45,381
General and administrative	8,268	6,852	16,386	12,929
Total operating expenses	45,906	30,279	83,042	58,310
Loss from operations	(45,906)	(30,279)	(83,042)	(58,310)
Other income (expense):				
Interest income	1,410	2,677	2,897	5,661
Interest expense	(571)	—	(865)	—
Other expense	(61)	—	(61)	—
Net loss	$ (45,128)	$ (27,602)	$ (81,071)	$ (52,649)
Other comprehensive income:				
Net unrealized gain (loss) on available-for-sale investments, net of tax	1	9	1	(68)
Net comprehensive loss	$ (45,127)	$ (27,593)	$ (81,070)	$ (52,717)
Net loss per share of voting and non-voting common stock, basic and diluted	$ (0.73)	$ (0.56)	$ (1.44)	$ (1.07)

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		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance—December 31, 2023	47,823,232	$ —	$ 469,396	$ 39	$ (233,237)	$ 236,198
Issuance of common stock, net of issuance costs	258,070	—	5,746	—	—	5,746
Stock-based compensation	—	—	3,791	—	—	3,791
Net unrealized losses on available-for-sale securities	—	—	—	(77)	—	(77)
Issuance of common stock in connection with exercise of stock options	167,813	—	1,109	—	—	1,109
Net loss	—	—	—	—	(25,047)	(25,047)
Balance—March 31, 2024	48,249,115	$ —	$ 480,042	$ (38)	$ (258,284)	$ 221,720
Stock-based compensation	—	—	5,013	—	—	5,013
Issuance of common stock in connection with exercise of stock options	27,407	—	250	—	—	250
Issuance of common stock under employee stock purchase plan	14,947	—	129	—	—	129
Net unrealized gains on available-for-sale securities	—	—	—	9	—	9
Net loss	—	—	—	—	(27,602)	(27,602)
Balance—June 30, 2024	48,291,469	$ —	$ 485,434	$ (29)	$ (285,886)	$ 199,519

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

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)

	Six months ended June 30,	
	2025	2024
Cash flows from operating activities:		
Net loss	$ (81,071)	$ (52,649)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	10,866	8,804
Depreciation	953	819
Non-cash finance lease expense	4,884	—
Non-cash operating lease expense	1,787	3,186
Accretion of operating lease liabilities	309	393
Amortization of discount on investments	(35)	(1,169)
Loss on foreign currency exchange rates	61	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,012)	210
Other assets	(209)	(543)
Accounts payable	2,186	317
Accrued and other current liabilities	2,067	(1,925)
Lease liabilities	(2,114)	(2,220)
Accrued interest payable under finance lease	100	—
Net cash used in operating activities	(61,228)	(44,777)
Cash flows from investing activities:		
Purchases of property and equipment	(946)	(1,582)
Purchases of investments	(49,035)	—
Proceeds from maturities of investments	—	24,500
Net cash (used in) provided by investing activities	(49,981)	22,918
Cash flows from financing activities:		
Proceeds from the issuance of common stock, warrants and pre-funded warrants, net of issuance costs	93,583	—
Issuance of common stock from ATM offering, net of sales agent commission and fees	2,595	5,746
Proceeds from issuance of common stock in connection with the exercise of stock options	—	1,359
Proceeds from issuance of common stock under employee stock purchase plan	197	129
Principal payments on finance leases	(3,554)	—
Net cash provided by financing activities	92,821	7,234
Effect of exchange rate changes on cash and cash equivalents	38	—
Net decrease in cash and cash equivalents	(18,350)	(14,625)
Cash and cash equivalents—beginning of period	163,962	193,238
Cash and cash equivalents—end of period	$ 145,612	$ 178,613
Supplemental disclosures		
Cash paid for interest	$ 765	$ —
Property and equipment purchases included in accounts payable and accrued expenses	$ 43	$ 375
Offering costs included in accounts payable and accrued expenses	$ 25	$ —
Right-of-use assets obtained in exchange for finance lease obligations	$ 14,934	$ —
Right-of-use assets obtained in exchange for operating lease obligations	$ —	$ 4,210

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 Bio and its wholly owned subsidiaries: Cabaletta Bio GmbH and Cabaletta Bio (Germany) GmbH. All intercompany balances and transactions have been eliminated in consolidation.

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

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 June 30, 2025, the Company has incurred an accumulated deficit of $430,172 and has cash, cash equivalents and investments of $194,682. The Company’s ultimate success depends on the outcome of its research and development activities. Management expects to incur additional losses in the future as it continues its research and development and will need to raise additional capital to fully implement its business plan and to fund its operations. The Company intends to raise such 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. The Company expects that its current cash, cash equivalents and investments may not be sufficient to fund operations for at least the next twelve months from the date of issuance of these unaudited condensed consolidated financial statements. The Company's cash forecast contains estimates and assumptions based on success of ongoing clinical trials, and management cannot predict the amount or timing of all expenditures with certainty. Accordingly, the Company has concluded that substantial doubt exists about the Company’s ability to continue as a going concern. The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business.

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 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 June 30, 2025 and the results of its operations and its cash flows for the interim periods ended June 30, 2025 and 2024. The results for the three and six months ended June 30, 2025 are not necessarily indicative of results to be expected for the year ending December 31, 2025, any other interim periods, or any future year or period. The balance sheet as of December 31, 2024 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 2024 Annual Report on Form 10-K, filed with the SEC on March 31, 2025 (2024 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 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 two 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 six months ended June 30, 2025, 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 2024 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 December 2023, the FASB issued ASU 2023-09, *Improvements to Income Tax Disclosures*. ASU 2023-09 enhances the transparency about income tax information through improvements to income tax disclosures primarily related to the rate reconciliation and income taxes paid information. The guidance is effective for public business entities for annual periods beginning after December 15, 2024. Early adoption is permitted. This update is effective beginning with the Company's 2025 fiscal year annual reporting period. 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.

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 June 30, 2025 and December 31, 2024, 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:

	June 30, 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	$ 84,930	$ 84,930	$ —	$ —
U.S. Treasury securities - original maturity less than three months	59,493	—	59,493	—
Short-term investments:				
U.S. Treasury securities	49,070	—	49,070	—
Total	$ 193,493	$ 84,930	$ 108,563	$ —

	December 31, 2024			
	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	$ 162,634	$ 162,634	$ —	$ —
Total	$ 162,634	$ 162,634	$ —	$ —

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 December 31, 2024.

	June 30, 2025		
	Amortized Cost	Gross Unrealized Gains	Fair value
Financial assets			
Cash	$ 1,189	$ —	$ 1,189
Money market funds	84,930	—	84,930
U.S. Treasury securities - original maturity less than three months	59,493	—	59,493
Included in cash and cash equivalents	145,612	—	145,612
U.S. Treasury securities - due in one year or less			—
Included in short-term investments	49,069	1	49,070
Total	$ 194,681	$ 1	$ 194,682

4. Accrued and Other Current Liabilities

Accrued and other current liabilities consist of the following:

	June 30, 2025	December 31, 2024
Manufacturing and other research and development services	$ 5,368	$ 2,255
Clinical trial research and development services	2,665	1,236
General and administrative services	386	342
Compensation expense	5,498	8,315
Other	16	40
	$ 13,933	$ 12,188

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 June 30, 2025.

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 $2,232 and $3,274 for the three and six months ended June 30, 2025 and $806 and $1,519 for the three and six months ended June 30, 2024, respectively. The Company is committed to pay up to a remaining $1,500 under the CARTA Services Agreement for cell processing manufacturing through December 31, 2025. The Company may incur additional expenses up to $322 through the remaining term of the CAROT Amended Addendum.

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 Association'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.

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. In December 2024 and through July 2025, the Company and Oxford entered into work orders with a cost of approximately $25,000 for certain process characterization and process performance qualification activities as part of commercial readiness activities. As of June 30, 2025, the Company has recognized project to date expense of $1,088 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.

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 January 2021, the Company entered into a Development and Manufacturing Services Agreement (Minaris Agreement) with Minaris Advanced Therapies, LLC, or Minaris (f/k/a WuXi Advanced Therapies, Inc.) to serve as an additional cell processing manufacturing partner for the MuSK-CAART Phase 1 clinical trial, or MusCAARTes™ trial. The Minaris Agreement is scheduled to expire upon completion of Minaris' services related to MuSK-CAART and rese-cel. In August 2023, and as extended in August 2024, the Company entered into an agreement with Minaris 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 commercial readiness activities for rese-cel. Under the August 2023 work orders, Minaris converted the Company's non-dedicated suite to a dedicated suite for GMP manufacturing for the Company's rese-cel and MuSK-CAART programs, or the Dedicated Suite, for an initial term of 18 months with two 18-month extensions at the Company's sole option on six months' notice prior to the end of the term. In August 2024, the Company sent a notice to Minaris to extend the initial term of the Minaris Agreement by 18 months through August 2026. In addition, the Company agreed to certain monthly minimum runs. In August 2024, the 2023 work order related to GMP manufacturing was amended to reduce the minimum monthly runs through the end of 2024. In lieu of the original $1,500 termination fee under the terms of the Minaris Agreement, the Company would incur up to a $1,080 termination fee if it terminates both the rese-cel and MuSK-CAART work orders for any reason. The Company may terminate for convenience the Minaris Agreement or any work order with six months' prior written notice. However, the Company may not terminate the Dedicated Suite without terminating both the MuSK-CAART and rese-cel GMP run work orders. Minaris may terminate for convenience the Minaris Agreement or any work order on 18 months' prior written notice, but such notice may not be effective prior to February 2028.

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 and initial work order.

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 June 30, 2025, 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 June 30,		Six months ended June 30,	
	2025	2024	2025	2024
	(in thousands)		(in thousands)	
Research and development expenses:				
Personnel	$ 12,001	$ 9,401	$ 23,366	$ 17,164
Clinical trials	9,070	5,313	17,581	9,735
Development services	4,197	4,112	7,765	8,459
Manufacturing of preclinical and clinical supplies	11,610	3,798	16,642	7,341
License of intellectual property	—	4	—	1,515
Other research and development costs [(1)]	760	799	1,302	1,167
General and administration expenses	8,268	6,852	16,386	12,929
Interest income	(1,410)	(2,677)	(2,897)	(5,661)
Interest expense	571	—	865	—
Other expense	61		61	
Net loss	$ 45,128	$ 27,602	$ 81,071	$ 52,649

[(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 two 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.

Finance lease commitments - Embedded leases

As described further in Note 6, in August 2023, the Company entered into new work orders under the Minaris Agreement for Minaris to serve as one of the Company's cell processing manufacturing partners for the global clinical development of rese-cel. Minaris converted the Company's non-dedicated suite to a Dedicated Suite for GMP manufacturing for the Company's rese-cel and MuSK-CAART programs, for an initial term of 18 months. The terms of the August 2023 work orders included both fixed costs and contingent variable costs. The lease commenced October 1, 2023. In 2024, the Company remeasured the lease following the resolution of the contingency related to variable costs and an amendment to the 2023 work order, which extended the term of the agreement by an additional 18 months through August 2026. The Company may terminate the Dedicated Suite lease for convenience with six months' prior written notice and up to a $1,080 termination fee if both the rese-cel and MuSK-CAART work orders are terminated.

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, resulting in the recognition of a right-of-use asset and lease liability of $14,934.

Summary of leases under ASC 842

The following table contains information pertaining to the Company's operating and finance leases for the six months ended June 30, 2025 and 2024.

	Six months ended June 30,	
	2025	2024
Cash paid in the measurement of lease liabilities		
Operating cash flows used for operating leases	$ 2,114	$ 2,220
Operating cash flows used for finance leases	765	—
Financing cash flows used for finance leases	3,554	—
Other information		
Weighted average remaining lease term - finance leases (in years)	1.2	—
Weighted average discount rate - finance leases	11.0%	—
Weighted average remaining lease term - operating leases (in years)	1.2	0.8
Weighted average discount rate - operating leases	11.0%	10.4%

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 June 30, 2025 are as follows:

	Finance Leases	Operating Leases
July 1, 2025 - December 31, 2025	$ 8,230	$ 2,114
2026	13,655	2,769
Total undiscounted lease payments	21,885	4,883
Less imputed interest	(1,558)	(317)
Total lease liability	$ 20,327	$ 4,566

9. Common Stock

Common Stock

Pursuant to the Company's Third Amended and Restated Certificate of Incorporation, as amended, the Company is authorized to issue 293,590,481 shares of voting common stock and 6,409,519 shares of non-voting common stock. In May 2024, the remaining 1,444,295 shares of non-voting common stock were converted to voting common stock and no shares of non-voting common stock are outstanding as of June 30, 2025.

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. 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 will expire fifteen months from the date of issuance. Aggregate net proceeds were $93,558 after deducting underwriting discounts and commissions and offering expenses. As of June 30, 2025, no pre-funded warrants or common stock warrants had been exercised.

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 S-3ASR to an S-3 (File No. 333-278126) by post-effective amendments. This 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.

2018 Stock Option and Grant Plan

In September 2018, the Company adopted the 2018 Stock Option and Grant Plan (the 2018 Plan), which provided for the Company to sell or issue common stock, or other stock-based awards, to employees, members of the board of directors and consultants of the Company. The Company generally granted stock-based awards with service conditions only (service-based awards), although there was one grant with performance conditions. As of December 31, 2020, there were no unvested options with performance conditions. Stock options granted under the 2018 Plan generally vest over three to four years. A total of 1,959,411 options were granted under the 2018 Plan prior to the Company's IPO in October 2019. No further grants may be made under the 2018 Plan subsequent to the IPO.

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, 2025, the total number of shares under the 2019 Plan was increased by 2,029,724; shares pursuant to the 2019 Plan Evergreen Provision. As of June 30, 2025, there were 400,304 shares remaining available for issuance under the 2019 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. To exercise the repriced options at the reduced exercise price, eligible participants must remain employed with the Company through a retention period of 12 months that begins on May 19, 2025.

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 is being amortized over the retention period, 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 [1]	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding as of January 1, 2025	11,231,148	$ 10.63	7.4	$ 989
Granted	3,093,050	1.71		
Forfeited/Cancelled	(84,325)	10.82		
Outstanding as of June 30, 2025	14,239,873	$ 8.69	7.3	$ 408
Options Exercisable at June 30, 2025	7,092,424	$ 9.30	6.0	$ 373

[1] The weighted average exercise prices and aggregate intrinsic values in this table will not reflect the impact of the May 2025 repricing until the retention period is complete in May 2026.

The aggregate intrinsic value of options is calculated as the difference between the exercise price of the options and the fair value of the Company's common stock. The weighted average grant-date fair value of stock options granted during the six months ended June 30, 2025 and 2024 was $1.46 and $17.41, respectively.

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

	Six months ended June 30,	
	2025	2024
Risk-free interest rate	3.94%—4.46%	3.78%—4.60%
Expected term	5.5 years—6.1 years	5.5 years—6.2 years
Expected volatility	112%—118%	104%—110%
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 and comparable publicly traded biotechnology companies for any period prior to the IPO needed to equal the expected term of the stock-based awards. The comparable companies were chosen based on their similar size, stage in the life cycle or area of specialty. The Company will continue to apply this process until historical information regarding the volatility of its own stock price becomes available to equal the expected term of stock-based awards.

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 June 30,		Six months ended June 30,	
	2025	2024	2025	2024
Research and development	$ 3,289	$ 2,596	$ 5,955	$ 4,556
General and administrative	2,416	2,417	4,911	4,248
Total	$ 5,705	$ 5,013	$ 10,866	$ 8,804

As of June 30, 2025, there was $47,434 of unrecognized compensation cost related to unvested option awards and vested option awards subject to the twelve month retention period, which is expected to be recognized over a weighted-average period of 2.4 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. There was no increase to the total number of shares available under the 2019 ESPP on January 1, 2024, 2023 or 2022, respectively. As of June 30, 2025, there were 190,326 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 six months ended June 30, 2025 and 2024 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 June 30, 2025 and December 31, 2024, 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 June 30, 2025 and December 31, 2024.

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. In May 2024, the remaining 1,444,295 shares of non-voting common stock were converted to voting common stock and no shares of non-voting common stock remain outstanding. Since the rights of the voting and non-voting common stock are identical, except with respect to voting, the undistributed losses of the Company have been allocated on a proportionate basis to the two classes. 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 June 30, 2025 and 2024 included outstanding pre-funded warrants to purchase, respectively, up to an aggregate of 10,800,000 and 1,168,054 shares of common stock.

Diluted net loss per share is calculated using the if-converted method as of June 30, 2024, which assumes conversion of all non-voting common stock to voting common stock.

	Three months ended June 30, 2025 Voting common stock	Six months ended June 30, 2025 Voting common stock
Basic and diluted net loss per share:		
Net loss	$ (45,128)	$ (81,071)
Weighted average number of shares outstanding	61,876,586	56,340,599
Net loss per share, basic and diluted	$ (0.73)	$ (1.44)

	Three months ended June 30, 2024		Six months ended June 30, 2024	
	Voting common stock	Non-voting common stock	Voting common stock	Non-voting common stock
Basic net loss per share:				
Numerator				
Allocation of undistributed losses	$ (27,318)	$ (284)	$ (51,608)	$ (1,041)
Denominator				
Weighted average number of shares used in basic per share computation	48,937,923	507,884	48,398,265	976,089
Net loss per share, basic	$ (0.56)	$ (0.56)	$ (1.07)	$ (1.07)
Diluted net loss per share:				
Numerator				
Allocation of undistributed losses for basic computation	$ (27,318)	$ (284)	$ (51,608)	$ (1,041)
Reallocation of undistributed losses as a result of conversion of non-voting to voting common shares	(284)	—	(1,041)	—
Allocation of undistributed losses	$ (27,602)	$ (284)	$ (52,649)	$ (1,041)
Denominator				
Weighted average number of shares used in basic per share computation	48,937,923	507,884	48,398,265	976,089
Add: conversion of non-voting to voting common shares outstanding	507,884	—	976,089	—
Weighted average number of shares used in diluted per share computation	49,445,807	507,884	49,374,354	976,089
Net loss per share, diluted	$ (0.56)	$ (0.56)	$ (1.07)	$ (1.07)

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

	As of June 30,	
	2025	2024
Stock options to purchase common stock	14,239,873	10,253,666
Warrants to purchase common stock	53,090,190	—
Total	67,330,063	10,253,666

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, 2024 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 clinical-stage biotechnology company focused on the discovery and development of innovative engineered T cell therapies that have the potential to provide deep and durable, perhaps curative, responses with one-time administration for patients with autoimmune diseases. Our proprietary CABA®, or Cabaletta Approach to B cell Ablation, platform encompasses two strategies. Our CARTA, or Chimeric Antigen Receptor T cells for Autoimmunity, approach is designed to potentially reset the immune system. Our legacy CAART, or Chimeric AutoAntibody Receptor T cells, approach is designed to engineer T cells to selectively engage and eliminate only disease-causing B cells. We believe our CABA® platform has the potential to safely enable complete and durable responses for a broad range of autoimmune diseases and that it has potential applicability across dozens of autoimmune diseases that we have identified, evaluated and prioritized.

Resecabtagene autoleucel (rese-cel, formerly referred to as CABA-201) is a 4-1BB co-stimulatory domain-containing fully human CD19-CAR T construct designed to treat patients with a broad range of autoimmune diseases and our lead product candidate within the CARTA strategy. Rese-cel is designed to achieve transient and deep depletion of all B cells following a single, weight-based infusion of T cells that are engineered to express an antibody fragment that recognizes a B cell receptor expressed on the surface of all B cells. The construct is designed to allow for the deep elimination of all B cells, including all B cells that contribute to disease, with subsequent repopulation by healthy naïve B cells. This approach has the potential to reset the immune system and result in meaningful clinical responses without chronic therapy requirements in patients.

The United States Food and Drug Administration, or the FDA, granted clearance of our rese-cel Investigational New Drug, or IND, application for treatment of systemic lupus erythematosus, or SLE, in patients with active lupus nephritis, or LN, or active SLE without renal involvement in March 2023. We announced the FDA subsequently granted clearance of our rese-cel IND applications for treatment of idiopathic inflammatory myopathies, or myositis in May 2023, systemic sclerosis, or SSc in October 2023, generalized myasthenia gravis, or gMG in November 2023, and multiple sclerosis, or MS in January 2025. In May 2024, we announced that we are working with active clinical sites to incorporate the RESET-PV™ trial as a sub-study within the Phase 1 DesCAARTes™ trial following the submission of a protocol amendment, to evaluate rese-cel in patients with mucosal pemphigus vulgaris, or mPV, and mucocutaneous pemphigus vulgaris, or mcPV.

RESET-Myositis™

The three adult myositis subtypes, dermatomyositis, or DM, anti-synthetase syndrome, or ASyS, and immune-mediated necrotizing myopathy, or IMNM, being evaluated in the RESET-Myositis™ Phase 1/2 clinical trial of rese-cel affect approximately 80,000 patients in the U.S. and approximately 85,000 patients in Europe. Myositis typically affects middle-aged individuals, particularly women, and disease is often refractory, despite existing therapies. In the United States, we believe approximately 20% to 25% of the prevalent population, or 16,000 to 20,000 people, would be potentially eligible patients for rese-cel.

The RESET-Myositis™ Phase 1/2 clinical trial, which is actively enrolling patients, is designed to treat six patients with DM, six patients with ASyS, six patients with IMNM, as well as six patients with juvenile idiopathic inflammatory myopathy, or JIIM, all in separate parallel cohorts, with a single weight-based dose of 1.0 x 10^6 cells/kg. We announced the FDA granted Fast Track Designation for rese-cel for the treatment of patients with dermatomyositis and Orphan Drug Designation for rese-cel for the treatment of myositis in January and February 2024, respectively. In March 2024, we announced the FDA granted Rare Pediatric Disease designation for rese-cel for juvenile dermatomyositis. In May 2025, we announced the FDA granted Regenerative Medicine Advanced Therapy, or RMAT, to rese-cel for the treatment of myositis.

Following a Type C meeting with the FDA and receipt of meeting minutes in April 2025, we are planning to implement the following design for two single-arm, sub-type disease-specific registrational cohorts in the ongoing RESET-Myositis™ trial, either of which, if successful, enable a future Biologics License Application, or BLA, submission for rese-cel in myositis. One cohort will evaluate approximately 15 patients with either DM or ASyS, and one cohort will evaluate approximately 15 patients with IMNM. Inclusion and exclusion criteria will remain highly similar to the Phase 1/2 cohorts. While a BLA for either cohort can be submitted

independently, we believe that together, these two cohorts have the potential to support a broad label to address many of the approximately 80,000 myositis patients in the U.S., including those with or without a history of IVIg use. The registrational cohorts will evaluate the same single, weight-based infusion of rese-cel at 1 x 10^6 cells/kg as used in the Phase 1/2 myositis cohorts. The primary endpoint for the registrational cohorts is based on the total improvement score, or TIS, to evaluate patient outcomes within 26 weeks of rese-cel infusion. The FDA supported the use of pooled rese-cel safety data from across the entire RESET™ clinical trial program to supplement myositis specific safety data for the BLA submission in myositis. In the recent Type C meeting, we aligned with the FDA on the size of the required safety database, which is expected to be approximately 100 autoimmune disease patients treated with the same single weight-based dose. We also aligned with the FDA on combining the Phase 1/2 DM & ASyS cohorts into a single cohort designed to treat six patients with either DM or ASyS. We plan to initiate registrational cohort enrollment in the second half of 2025 with expected BLA submission in 2027.

RESET-SLE™

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 U.S., and 150,000 patients in Europe, with LN as the most common end-organ manifestation, affecting approximately 30-40% of SLE patients.

The RESET-SLE™ Phase 1/2 clinical trial, which is actively enrolling patients, is designed to treat six SLE patients with active LN, and in a separate parallel cohort, six patients with active SLE without renal involvement, with a single weight-based dose of 1.0 x 10^6 cells/kg. In May 2023, we announced the FDA granted Fast Track Designation for rese-cel in patients with SLE and LN. In March 2024, Health Canada issued a No Objection Letter in response to a Clinical Trial Application, or CTA, for the RESET-SLE™ trial, and in October 2024, the European Medicines Agency allowed a CTA submitted by Cabaletta for the RESET-SLE™ trial to proceed, enabling us to begin the process of activating clinical trial sites and pursuing patient enrollment in these geographies. We anticipate aligning with the FDA on the registrational cohort design for studies in SLE/LN in 3Q25.

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, and scleroderma renal crisis. SSc affects approximately 90,000 patients in the U.S. and approximately 60,000 patients in Europe, typically middle-aged individuals, particularly women.

The actively enrolling RESET-SSc™ Phase 1/2 clinical trial of rese-cel is designed to treat six patients with severe skin manifestations and six patients with severe organ involvement associated with SSc, each in separate parallel cohorts, with a single weight-based dose of 1.0 x 10^6 cells/kg. We announced the FDA granted Fast Track Designation for rese-cel for SSc patients and Orphan Drug Designation for rese-cel for SSc in January and March 2024, respectively. We anticipate aligning with the FDA on the registrational cohort design for studies in SSc in 4Q25.

RESET-MG™

MG is a rare autoimmune disease characterized by autoantibodies that interfere with signaling at the neuromuscular junction, leading to potentially life-threatening muscle weakness. The majority of patients with MG have autoantibodies known to be pathogenic based on their interference with proteins in the NMJ, of which the majority target AChR. gMG affects approximately 55,000 patients in the U.S. and approximately 100,000 patients in Europe. 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.

The actively enrolling RESET-MG™ Phase 1/2 clinical trial of rese-cel is designed to treat six patients with AChR-positive gMG and six patients with AChR-negative gMG, each in separate parallel cohorts, with a single weight-based dose of 1.0 x 10^6 cells/kg. We anticipate aligning with the FDA on the registrational cohort design for studies in MG in 1H26.

RESET-PV™

Pemphigus vulgaris, or PV, is an autoimmune disease that occurs when the immune system produces antibodies that attack a protein called desmoglein, or 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 the painful blisters and erosions characteristic of PV. Approximately 15,000 patients in the U.S. and approximately 20,000 patients in Europe are affected by PV.

The ongoing RESET-PV™ trial is designed to evaluate rese-cel as a monotherapy without preconditioning in patients with mucosal pemphigus vulgaris, or mPV, and mucocutaneous pemphigus vulgaris, or mcPV. We anticipate sharing initial dose data from the RESET-PV™ trial in 2H25.

RESET-MS™

Multiple sclerosis is an autoimmune-mediated demyelinating disease of the central nervous system. The immune system attack on nerves in the brain and spinal cord impairs nerve electrical conduction, resulting in a range of symptoms including muscle weakness,

sensory loss, visual impairment, incoordination, memory loss, fatigue, and walking difficulty. MS is classified into relapsing or progressive forms based on the pattern of clinical symptoms over time. MS affects approximately 750,000 patients in the U.S. and approximately 550,000 patients in Europe.

The RESET-MS™ trial is a Phase 1/2 open-label, dose escalation study of rese-cel in subjects with relapsing and progressive forms of MS, evaluated in separate cohorts. In January 2025, we announced the FDA granted Fast Track Designation for rese-cel for relapsing and progressive forms of MS.

Manufacturing

Our manufacturing strategy is comprised of two stages. The initial stage is designed to leverage the extensive early-stage manufacturing expertise of our academic partners and contract development and manufacturing organizations, or CDMOs, for early development and clinical supply, and in parallel partner with commercially compliant CDMOs to support late-stage clinical studies and commercial production. Our aim is to achieve full manufacturing readiness through expanded CDMO relationships, establishment of our own manufacturing facilities, and/or through strategic partnership(s). For cell manufacturing, we have collaborated with the Clinical Cell and Vaccine Production Facility, or CVPF, at Penn. We have also collaborated with Minaris Advanced Therapies, LLC, or Minaris (f/k/a WuXi Advanced Therapies, Inc.), to serve as an additional and commercially compliant cell manufacturing partner for our RESET™ clinical trials. We also entered into a new technology transfer agreement and Development and Manufacturing Services Agreement in July 2024 and December 2024, respectively, with Lonza Houston Inc., or Lonza, to serve as one of our manufacturing partners for the global clinical development of rese-cel, including potential late-stage clinical trials and preparations for commercial readiness. Our manufacturing process at Lonza will be used for initiating registrational trial enrollment. For supply of lentiviral vector for the clinical and commercial manufacturing of rese-cel, we are currently working with Oxford Biomedica (UK) Limited, or Oxford, where we are advancing BLA readiness activities, and have previously manufactured lentiviral vector at the Children's Hospital of Philadelphia, or CHOP, and the University of Pennsylvania, or Penn.

As part of our innovative manufacturing strategy where we intend to increase scale, reduce cost of goods and improve patient experience, in November 2023, we partnered with Cellares Corp., or Cellares, to evaluate their automated manufacturing platform, the Cell Shuttle™, through the Cellares Technology Adoption Program, or TAP. In August 2024, we expanded our partnership with Cellares to facilitate the potential to incorporate the Cellares manufacturing platform to support the RESET™ clinical program. In March 2025, we and Cellares announced the successful conclusion of the TAP on Cellares' Cell Shuttle™, facilitating the potential integration of the Cell Shuttle™ into our clinical and commercial, if approved, manufacturing strategy for rese-cel.

Recent Developments

EULAR Clinical Data

In February 2025, we announced updated clinical and translational data from the first 10 patients in the RESET™ clinical trial program, with a data cut off of January 8, 2025. We are presenting new clinical and translational data from 18 evaluable patients who were dosed with rese-cel across the RESET-Myositis™, RESET-SLE™ and RESET-SSc™ trials at the EULAR 2025 Congress in three oral presentations, as of the data cut-off dates of May 6, 2025, for the RESET-Myositis™ and RESET-SSc™ trials and June 2, 2025, for the RESET-SLE™ trial.

In the RESET-Myositis™ trial, 7 out of 8 patients achieved a clinical response off all immunomodulators and off, or while actively tapering, steroids. Clinical responses were sustained throughout the follow-up period in all 7 responding patients. All 4 ASyS and DM patients achieved a clinically meaningful TIS response, with 3 of these patients having achieved a major TIS response as of the most recent follow-up. Clinically meaningful drug-free TIS responses were observed in 3 of 4 refractory patients with IMNM, which are consistent with published data. These findings continue to reflect the more modest TIS responses in IMNM compared to other myositis subtypes. Regarding safety findings, 4 of 8 patients experienced Grade 1 CRS (fever) and no ICANS was observed.

In the RESET-SLE™ trial, 7 out of 7 patients with sufficient follow-up to evaluate efficacy achieved substantial SLEDAI reductions off all immunomodulators and glucocorticoids. All 3 of the SLE patients without nephropathy achieved definition of remission in SLE, or DORIS, as of the latest follow-up, and the first LN patient achieved DORIS and a complete renal response. In the 8 patients with safety follow-up, 2 of 8 patients experienced Grade 1 CRS (fever), and 1 ICANS event was observed (Grade 4, previously reported).

In the RESET-SSc™ trial, both patients in the severe skin cohort had meaningful modified Rodnan Skin Score (mRSS) improvements after discontinuing immunomodulatory drugs and steroids, which was sustained out to 6 months in the first patient. The first patient also met the revised Composite Response Index in Systemic Sclerosis (CRISS) criteria starting at 3 months, highlighting the potential of rese-cel to provide a drug-free, clinical response in patients with SSc. 1 patient experienced transient Grade 2 CRS, and 1 ICANS event was observed (Grade 3, previously reported)

Overall, in the 18 evaluable patients who were dosed with rese-cel with at least 4 weeks of follow-up across the RESET-Myositis™, RESET-SLE™ and RESET-SSc™ trials, 94% had either no CRS or Grade 1 CRS (transient fever) and 89% had no ICANS

(2 patients with ICANS events previously reported). Peak rese-cel expansion was observed within approximately two weeks across myositis, lupus, and SSc™ patients. B cells were rapidly and transiently reduced in peripheral blood within the first month, and their repopulation was observed beginning approximately two months after infusion, generally expressing a transitional, naïve phenotype. Tissue-resident B cell depletion was confirmed via a lymph node biopsy in the first systemic sclerosis patient.

As of July 31, 2025, five 6-patient Phase 1/2 disease cohorts are fully enrolled across the RESET™ clinical development program.

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 June 30, 2025, we had $194.7 million in cash, cash equivalents and investments.

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.

Oxford Biomedica

In December 2021, we entered into a 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. In December 2024 and through July 2025, 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.

Minaris Manufacturing Agreement

In January 2021, we entered into a Development and Manufacturing Services Agreement, or the Minaris Agreement, with Minaris to serve as an additional cell processing manufacturing partner for the MuSK-CAART Phase 1 clinical trial, or MusCAARTes™ trial.

The Minaris Agreement is scheduled to expire upon completion of Minaris' services related to MuSK-CAART and rese-cel. In August 2023, as amended in August 2024, we entered into an agreement with Minaris 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 commercial readiness activities for rese-cel. Under the August 2023 work orders, Minaris converted our non-dedicated suite to a dedicated suite for GMP manufacturing for our rese-cel and MuSK-CAART programs, or the Dedicated Suite, for an initial term of 18 months with two 18 month extensions at our sole option on six months' notice prior to the end of the term. In August 2024, we notified Minaris that we would extend the initial term by 18 months through August 2026. In addition, we agreed to certain monthly minimum runs. In August 2024, the 2023 work order related to GMP manufacturing was amended to reduce the minimum monthly runs through the end of 2024. In lieu of the original $1.5 million termination fee under the terms of the Minaris Agreement, we would incur up to a $1.08 million termination fee if we terminate both the rese-cel and MuSK-CAART work orders for any reason. We may terminate for convenience the Minaris Agreement or any work order with six months' prior written notice, however, we may not terminate the Dedicated Suite without terminating both the MuSK-CAART and rese-cel GMP run work orders. Minaris may terminate the Minaris Agreement or any work order for convenience on 18 months' prior written notice, but such notice may not be effective prior to February 2028.

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 and initial work order.

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 or 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.

Master Translational Research Services Agreement

In October 2018, we entered into a Master Translational Research Services Agreement with Penn, or the Services Agreement, pursuant to which Penn agreed to perform certain services related to the research and development of the technology licensed to us under the License Agreement, as well as certain clinical, regulatory and manufacturing services. The Services Agreement will expire on the later of (i) October 19, 2021 or (ii) completion of the services for which we have engaged Penn under the Services Agreement. Either party may terminate this agreement with or without cause upon a certain number of days' prior written notice. The services encompassed by the Services Agreement are performed by different organizations at Penn pursuant to certain addenda to the Services Agreement, including the Center for Advanced Retinal and Ocular Therapeutics, or CAROT, Addendum, as amended in May 2020, and the CVPF Addendum.

In February 2023, we entered into a second Master Translational Research Services Agreement with Penn, or the CARTA Services Agreement, pursuant to which Penn agreed to perform certain research, development and manufacturing activities. The CARTA Services Agreement will expire on the later of (i) February 9, 2026 or (ii) completion of the services for which we have engaged Penn under the CARTA Services Agreement. Either party may terminate this agreement with or without cause upon a certain number of days' prior written notice. The services encompassed by the CARTA Services Agreement are performed by different organizations at Penn pursuant to certain addenda to the CARTA Services Agreement.

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.

Other Income

Other 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 Expense

Other expense consists primarily of expenses associated with foreign currency gains and losses.

Results of Operations for the three months ended June 30, 2025 and 2024

The following sets forth our results of operations for the three months ended June 30, 2025 and 2024:

	Three months ended June 30,		
	2025	2024	Change
	(in thousands)		
Statements of Operations Data:			
Operating expenses:			
Research and development	$ 37,638	$ 23,427	$ 14,211
General and administrative	8,268	6,852	1,416
Total operating expenses	45,906	30,279	15,627
Loss from operations	(45,906)	(30,279)	(15,627)
Other income (expense):			
Interest income	1,410	2,677	(1,267)
Interest expense	(571)	—	(571)
Other expense	(61)	—	(61)
Net loss	$ (45,128)	$ (27,602)	$ (17,526)

Research and Development

Research and development expenses were $37.6 million for the three months ended June 30, 2025 compared to $23.4 million for the three months ended June 30, 2024. The table below summarizes our research and development expenses:

	Three months ended June 30,		
	2025	2024	Change
	(in thousands)		
License of intellectual property	$ —	$ 4	$ (4)
Manufacturing of preclinical and clinical supplies	11,610	3,798	7,812
Clinical trials	9,070	5,313	3,757
Personnel	12,001	9,401	2,600
Development services	4,197	4,112	85
Other	760	799	(39)
	$ 37,638	$ 23,427	$ 14,211

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

- $7.8 million increase in manufacturing costs primarily due to expanded cell processing capabilities, increase in patient enrollment and related activities, including those for commercial readiness;
- $3.8 million increase in clinical trial costs primarily due to higher enrollment across multiple clinical studies for rese-cel;
- $2.6 million increase in personnel costs primarily driven by an increase in headcount to support overall growth related to our rese-cel program, including an increase of $0.7 million in stock-based compensation expense;

General and Administrative

General and administrative expenses were $8.3 million for the three months ended June 30, 2025 compared to $6.9 million for the three months ended June 30, 2024. The increase of $1.4 million in our general and administrative expenses include:

- $1.1 million of additional personnel costs, primarily driven by an increase in headcount, including for our international operations and $0.4 million of severance costs; and
- $0.3 million higher administrative costs, including legal, information technology and travel as well as other administrative costs.

Other Income

Interest income decreased by $1.3 million for the three months ended June 30, 2025 compared to the three months ended June 30, 2024, primarily due to lower cash, cash equivalents and investment balances earning interest, following the use of proceeds from the May 2023 financing and sales of common stock under the 2023 ATM Program in late 2023 and early 2024 and the timing of the June 2025 financing, which closed in mid-June 2025.

Interest Expense

Interest expense increased $0.6 million for the three months ended June 30, 2025 as compared to the three months ended June 30, 2024, primarily due to finance lease arrangements related to embedded leases within our manufacturing agreements with Minaris and Lonza.

Results of Operations for the six months ended June 30, 2025 and 2024

The following sets forth our results of operations for the six months ended June 30, 2025 and 2024:

	Six months ended June 30,		
	2025	2024	Change
	(in thousands)		
Statements of Operations Data:			
Operating expenses:			
Research and development	$ 66,656	$ 45,381	$ 21,275
General and administrative	16,386	12,929	3,457
Total operating expenses	83,042	58,310	24,732
Loss from operations	(83,042)	(58,310)	(24,732)
Other income (expense):			
Interest income	2,897	5,661	(2,764)
Interest expense	(865)	—	(865)
Other expense	(61)	—	(61)
Net loss	$ (81,071)	$ (52,649)	$ (28,422)

Research and Development

Research and development expenses were $66.7 million for the six months ended June 30, 2025 compared to $45.4 million for the six months ended June 30, 2024. The table below summarizes our research and development expenses:

	Six months ended June 30,		
	2025	2024	Change
	(in thousands)		
License of intellectual property	$ —	$ 1,515	$ (1,515)
Manufacturing of preclinical and clinical supplies	16,642	7,341	9,301
Clinical trials	17,581	9,735	7,846
Personnel	23,366	17,164	6,202
Development services	7,765	8,459	(694)
Other	1,302	1,167	135
	$ 66,656	$ 45,381	$ 21,275

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

- $9.3 million increase in manufacturing costs primarily due to expanded cell processing capabilities, increase in patient enrollment and related activities, including those for commercial readiness;
- $7.9 million increase in clinical trial costs primarily due to higher enrollment across multiple clinical studies for rese-cel;
- $6.2 million increase in personnel costs primarily driven by an increase in headcount to support overall growth related to our rese-cel program, including an increase of $1.4 million in stock-based compensation expense; partially offset by a
- $1.5 million decrease in license of intellectual property costs due to a $1.5 million milestone payment to IASO in the first quarter of 2024 for the first patient dosed in the rese-cel trial; and
- $0.7 million decrease in development services due to lower spend on lab consumables and external research activities.

General and Administrative

General and administrative expenses were $16.4 million for the six months ended June 30, 2025 compared to $12.9 million for the six months ended June 30, 2024. The increase of $3.5 million in our general and administrative expenses include:

- $3.1 million of additional personnel costs, primarily driven by an increase in headcount, including our international operations, an increase of $0.7 million in stock-based compensation expense and $0.4 million of severance costs; and
- $0.4 million higher administrative costs, including legal, information technology and travel as well as other administrative costs.

Other Income

Interest income decreased by $2.8 million for the six months ended June 30, 2025 compared to the six months ended June 30, 2024, primarily due to lower cash, cash equivalents and investment balances earning interest, following the use of proceeds from the May 2023 financing and sales of common stock under the 2023 ATM Program in late 2023 and early 2024 and the timing of the June 2025 financing, which closed in mid-June 2025.

Interest Expense

Interest expense increased $0.9 million for the six months ended June 30, 2025 as compared to the six months ended June 30, 2024, primarily due to finance lease arrangements related to embedded leases within our manufacturing agreements with Minaris and Lonza.

Liquidity, Capital Resources and Going Concern

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, we have generated cash from public offerings of our common stock and pre-funded warrants to purchase our common stock resulting in aggregate net proceeds of approximately $374.0 million. As of June 30, 2025, we had $194.7 million in cash, cash equivalents and investments which should enable us to fund our operations and capital expenditures into the second half of 2026. 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 June 30, 2025, we had an accumulated deficit of $430.2 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, costs relating to the build-out of our headquarters, 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.

We evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that the unaudited condensed consolidated financial statements are

issued. Based on our current operating plan, we believe there is substantial doubt about our ability to continue as a going concern for at least twelve months following the filing of this Quarterly Report on Form 10-Q, and we will need to obtain additional funding. Our cash forecast contains estimates and assumptions based on success of ongoing clinical trials, and we cannot predict the amount or timing of all expenditures with certainty. 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 certain planned activities to reduce costs.

At-The-Market Offering Sales Agreement

On March 31, 2025, we converted the S-3ASR to an S-3 (File No. 333-278126) by post-effective amendments. This 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.

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 will expire 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 June 30, 2025, no pre-funded warrants or common stock warrants had been exercised.

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:

	Six months ended June 30,	
	2025	2024
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (61,228)	$ (44,777)
Investing activities	(49,981)	22,918
Financing activities	92,821	7,234
Effect of exchange rate changes on cash and cash equivalents	38	—
Net decrease in cash and cash equivalents	$ (18,350)	$ (14,625)

Operating Activities

During the six months ended June 30, 2025, cash used in operating activities of $61.2 million was attributable to our net loss of $81.1 million, partially offset by non-cash charges of $18.8 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 $1.0 million in our net operating assets and liabilities.

During the six months ended June 30, 2024, cash used in operating activities of $44.8 million was attributable to a net loss of $52.7 million and a net change of $4.2 million in our net operating assets and liabilities, partially offset by non-cash charges of $12.0 million primarily from stock-based compensation, non-cash lease expense, accretion of lease liabilities and depreciation.

Investing Activities

During the six months ended June 30, 2025, cash used in investing activities of $50.0 million was attributable $49.0 million of purchases of investments and $1.0 million of purchases of property and equipment.

During the six months ended June 30, 2024, cash provided by investing activities of $22.9 million was attributable to $24.5 million from the maturity of short-term investments, partially offset by purchases of $1.6 million of property and equipment.

Financing Activities

During the six months ended June 30, 2025, cash provided by financing activities of $92.8 million was attributable to $93.6 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 Employee Stock Purchase Plan, or 2019 ESPP, offset by $3.6 million in principal payments on finance leases.

During the six months ended June 30, 2024, cash provided by financing activities of $7.2 million was from $5.7 million in sales of common stock, net of issuance costs paid, and $1.5 million from the exercise of employee stock options and purchases of shares under our 2019 ESPP.

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, 2024, as filed with the SEC on March 31, 2025.

There have been no material changes to the Company's contractual obligations and other commitments since December 31, 2024, except as otherwise described herein with respect to the Lonza Agreement.

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, 2024, as filed with the SEC on March 31, 2025, 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, cash equivalents and investments of $194.7 million as of June 30, 2025. 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 June 30, 2025 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 June 30, 2025, 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, 2024.*

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.

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, multiple sclerosis, or MS, 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, 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 will be 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. 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 products 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 other similarly designed cellular immunotherapies to treat cancer, there have been life threatening events related to ICANS and CRS requiring intense medical intervention, such as intubation or medications to support blood pressure, and in several cases, 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 and CAAR 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 the MuSK CAAR and rese-cel and did not observe any confirmed off target activity for MuSK-CAART or 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 are 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. 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, 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, DSG3-CAART and MuSK-CAART are the first three product candidates 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 clinical trials of DSG3-CAART, MuSK-CAART or rese-cel RESET™ trials 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 DSG3-CAART, MuSK-CAART or rese-cel, or if they are viewed as less safe, potent or pure than other therapies, our ability to develop other CAAR T or 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 the clinical endpoints selected, which may require us to complete additional clinical trials or impose stricter approval conditions than we currently expect.

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.

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 commits, 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 relevant competent authorities and the granting of a marketing authorization by those authorities 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 DesCAARTes™ trial, MusCAARTes™ trial, and RESET™ trials in SLE, myositis, SSc, gMG, MS 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 institutional review board, or 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;
- limitations on our recourse in our CRO relationship with Penn as compared to a CRO that is not an academic institution;
- 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™, DSG3-CAART, MuSK-CAART 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, DSG3-CAART, MuSK-CAART 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 DesCAARTes™ trial, our MusCAARTes™ trial, our RESET™ trials in SLE, myositis, SSc, gMG, PV and MS 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 MusCAARTes™ trial, our RESET™ trials in SLE, myositis, SSc, gMG, PV and MS 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 our RESET-PV™ trial, RESET-MS™ and our MusCAARTes™ 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 DesCAARTes™ trial, our MusCAARTes™ trial and 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 DSG3-CAART, MuSK-CAART, or 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 DesCAARTes™ trial, our MusCAARTes™ trial, and RESET™ trials, respectively.

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. Although we are the first and only company developing CAAR T drug candidates, we are one of several 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.

Specifically, while rituximab is the first drug to have received regulatory approval in the United States in over 60 years for the treatment of PV, the target indication for DSG3-CAART, and the indication we are evaluating in the RESET-PV™ study, we are aware that multiple biopharmaceutical companies have therapies in clinical development. We are also aware of other biopharmaceutical companies developing therapies for MuSK MG, SLE, myositis, SSc, gMG and MS. While we do not expect these product candidates to be directly competitive to our product candidates, even if we obtain regulatory approval of our product candidates, the availability and price of these other products 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, DSG3-CAART and MuSK-CAART. 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, and our Chief Financial 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 of June 30, 2025, we had 167 full-time employees and three part-time employees. 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, the University of Pennsylvania, or Penn's, operations, Minaris Advanced Therapies, LLC, or Minaris', operations, Lonza Houston Inc., or Lonza's, operations 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, the Israel-Hamas war, and the conflict in the Middle East may disrupt our global clinical trials and increase the likelihood of supply interruptions. Additionally, the effect of global financial and economic conditions and geopolitical events, including the consequences of the presidential transition 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. 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 current geopolitical tensions with China. For example, the BIOSECURE Act, legislation that Congress considered in 2024 but did not pass, would have, among other things, prohibited U.S. federal funding in connection with biotechnology equipment

or services produced or provided by certain named Chinese "biotechnology companies of concern." Although Congress has not reintroduced legislation similar to the BIOSECURE Act, if Congress does seek to pass a similar law, it would be expected to have a significant impact on the pharmaceutical industry in the United States. In March 2025, Altaris, LLC, a healthcare investment firm headquartered in New York, completed its acquisition of the US and UK based operations of Minaris. On February 28, 2024, former President Biden signed Executive Order 14117 ("Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern") which implements a new framework to protect the privacy of personal data shared between the U.S. and Europe, which may, in effect, impact privacy laws with "countries of concern" such as China or Russia.

In addition, due to our adoption of a more flexible work model following the COVID-19 pandemic, our 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 six months ended June 30, 2025 and 2024, we recorded net losses of $81.1 million and $52.6 million, respectively. As of June 30, 2025, we had an accumulated deficit of $430.2 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 are reliant on several manufacturing and support services from Penn through two Master Translational Research Service Agreements, or the CAART Services Agreement and CARTA Services Agreement, respectively, and collectively, the Services Agreements. We also rely on Penn for current manufacturing of rese-cel. Our ability to rely on services from Penn is limited to a specified period of time, to specific capabilities, and is subject to Penn's right to terminate these services with or without cause. We are reliant on Minaris manufacturing services for MuSK-CAART and 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 is 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. We have also identified conditions that raise substantial doubt about our ability to continue as a going concern. 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 MusCAARTes™ trial and 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. As of June 30, 2025, we had $194.7 million of cash, cash equivalents and investments. Since our initial public offering, we have generated cash from public offerings of our common stock and pre-funded warrants to purchase our common stock resulting in aggregate net proceeds of approximately $374.0 million. While we currently expect our existing cash, cash equivalents and investments to be sufficient to fund our operations into the second half of 2026, which includes complete Phase 1/2 clinical data in the RESET-SLE™, RESET-Myositis™ and RESET-SSc™ trials and clinical data from the RESET-PV™ dose escalation trial, 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 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.

Based on our current operating plan, we believe there is substantial doubt about our ability to continue as a going concern for at least twelve months following the filing of this Quarterly Report on Form 10-Q, and we will need to obtain additional funding. We may be forced to delay or reduce the scope of our product development programs, reduce our research and development costs and/or limit or cease our operations if we are unable to obtain additional funding to support our current operating plan. Our cash forecast contains estimates and assumptions based on the success of our ongoing clinical trials, and management cannot predict the amount or timing of all expenditures with certainty. Nevertheless, our financial statements do not include any adjustments that might result from the outcome of this uncertainty. We will need to raise additional capital to fund our future operations and remain as a going concern. However, we cannot guarantee that we will be able to obtain any or sufficient additional funding or that such funding, if available, will be obtainable on terms satisfactory to us.

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.

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, 2025 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. Our compensation committee determined the size of the increase to the reserved pool under the Plan Amendment based on projected equity awards to anticipated new hires, projected annual equity awards to existing employees and an assessment of the magnitude of increase that our institutional investors and the firms that advise them would likely find acceptable. We anticipate that the increased share reserve under our 2019 Plan, as amended by the Plan Amendment, will be sufficient to provide equity incentives to attract, retain, and motivate employees for a period of two years following the effective date of the Plan Amendment.

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.

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 candidates 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 candidates is heavily dependent on in-licenses to patent rights and other intellectual property granted to us by third parties. For example, we depend heavily on our License Agreement with Penn and CHOP, which was entered into in 2018, amended and restated in July 2019, and further amended in May 2020 and October 2021, pursuant to which we obtained (a) a non-exclusive, non-sublicensable, worldwide research license to intellectual property controlled by Penn and CHOP 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 such 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, which know-how satisfies certain criteria and is listed on a mutually agreed to schedule, to make, have made, use, sell, offer for sale, import and have imported products in the same two subfields of use. We also 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 agreements with Penn, CHOP and IASO impose, 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 Penn, CHOP and IASO may have the right to terminate these license agreements, in which event we might not be able to market our product candidates. 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 candidates, 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 candidates, 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 candidates 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. Pursuant to our License Agreement with Penn and CHOP, Penn controls such activities for the patent rights licensed to us under such agreement. Therefore, although we provide input to IASO, Penn and CHOP 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 candidates 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 License Agreement or IASO Agreement and other interpretation-related issues;
- whether we have breached the License Agreement or 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 candidates, 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 candidates, 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 candidates.

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 License Agreement and IASO Agreement grant 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, including rights licensed to us by Penn relating to our DSG3-CAART and DSG3/1-CAART product candidates, was 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 and DSG3/1-CAART product candidates 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, such as Penn, 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 patent or pending patent application that we license now or that we may license or 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 licensed intellectual property rights;
- it is possible that our current or future 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 DesCAARTes™ trial, MusCAARTes™ trial and 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, including Penn, Minaris and Lonza, 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 Sates 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 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, availability and cost of alternative sources of supply and demand in affected markets. Supply chain disruptions and delays as a result of any new tariff policies or trade restrictions could negatively impact our cost of materials 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, testing and our clinical trials and any future product candidates may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business.

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, including Penn, Minaris, and Lonza, 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 August 2018, we entered into a License Agreement with Penn and CHOP which was amended and restated in July 2019, and further amended in May 2020 and October 2021, or the License Agreement, pursuant to which we were granted licenses to certain patent rights for the research and development of products, as well as an exclusive license under those same patent rights to make, use, sell and import such products, in the autoimmune disease and alloimmune response subfields, in each case, for the treatment of humans. In January 2021 and as amended in August 2022, we entered into an agreement with Minaris to serve as an additional cell processing manufacturing partner for our MusCAARTes™ trial, and have since completed enabling engineering and patient production runs. In August 2023, as amended in August 2024, we entered into an agreement with Minaris 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 commercial readiness activities for rese-cel. In December 2024, we entered into an agreement with Lonza to serve as an additional cell processing manufacturing partner for the global clinical development of rese-cel in multiple indications, including potential late-stage clinical trials and commercial readiness activities for rese-cel. 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 Penn, Minaris and Lonza for our current manufacturing activities and Penn and/or Minaris and/or Lonza's failure to perform or 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 Penn, Minaris and Lonza for our current manufacturing activities for our preclinical and clinical research. If Penn and its affiliated entities were to fail to perform their obligations in accordance with the terms of the Services Agreements or terminate the Services Agreements, or if Minaris were to fail to perform their obligations in accordance with the terms of the Minaris Agreement or terminate the Minaris Agreement, or 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.

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."

In addition, the CAART Services Agreement is scheduled to expire on the later of October 19, 2021 or completion of all research and development projects, and unless the CAART Services Agreement is amended, Penn will not be obligated to provide any further services under the CAART Services Agreement after that time. We currently anticipate that research and development projects under the CAART Services Agreement will continue through at least 2025. In addition, Penn has the right to terminate the CAART Services Agreement in whole at any time with 90 days' notice and to terminate any research and development project being performed under the CAART Services Agreement if the Penn service provider appointed to lead such project is unavailable and Penn is unavailable to find a replacement within 60 days for such service provider. Penn also has the right to terminate certain manufacturing services being performed under the CAART Services Agreement with 180 days' written notice. From time to time, we may enter into further addenda to the CAART 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 CARTA Services Agreement is scheduled to expire on the later of February 9, 2026 or 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 Minaris Agreement is scheduled to expire upon completion of Minaris' services related to MuSK-CAART and rese-cel. In August 2023, as amended in August 2024, we entered into new work orders under the Minaris Agreement for Minaris to serve as one of our cell processing manufacturing partners for the planned global clinical development of rese-cel in multiple indications, including potential late-stage clinical trials and commercial readiness activities for rese-cel. Under the August 2023 work orders, Minaris will convert our non-dedicated suite to a dedicated suite for GMP manufacturing for our rese-cel and MuSK-CAART programs, or the Dedicated Suite, for an initial term of 18 months with two 18 month extensions at our sole option on six months notice prior to the end of the term. In August 2024, we notified Minaris that we would extend the initial term by 18 months through August 2026. We may terminate for convenience with six months prior written notice, however, we may not terminate the Dedicated Suite without terminating both the MuSK-CAART and rese-cel GMP run work orders. In lieu of the existing 18 month termination right for convenience under the Minaris Agreement, Minaris may not terminate prior to February 2028. If Minaris were to fail to perform their obligations in accordance with the terms of the Minaris Agreement or terminate the Minaris 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.

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 or CAAR 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.

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 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 Minaris and 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 MuSK-CAART and 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 or CAAR 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 or CAAR 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 or CAAR 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 Penn, Minaris, Lonza, or other third-party CMOs, or at any manufacturing facility that we may establish, will not occur in the future.

Penn, Minaris, 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.

Penn, Minaris, 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 if the previously proposed federal legislation known as the BIOSECURE Act or a similar law were to be enacted. 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 or CAAR 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, gMG or MS. 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 incoming U.S. administration may propose policy changes that create additional uncertainty for our business and may result in increased regulatory uncertainty, judicial interpretations overturing 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 of 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 institutional review board, or 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 the quality, safety and efficacy of ATMPs, 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.

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 disease 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 treating the same indication or disease or the same biologic for a different indication or disease 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 idiopathic inflammatory myopathies (IIM, or 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 as a drug for a rare pediatric disease does not guarantee that an NDA or BLA for such drug 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 FDA's rare pediatric disease priority voucher program began to sunset on December 20, 2024, on failure to pass a continuing resolution package that included its reauthorization. Under the amended statutory sunset provisions, after December 20, 2024, the FDA may award a priority review voucher for an approved rare pediatric disease product application only if the sponsor has rare pediatric disease designation for the drug and if that designation was granted by December 20, 2024. After September 30, 2026, the FDA may not award any rare pediatric disease priority review vouchers. Congress may vote to reauthorize this program, but its future remains unknown at this time. Absent any such reauthorization, if a BLA for rese-cel is not approved prior to September 30, 2026 for any reason, regardless of whether it meets the criteria for a rare pediatric disease priority review voucher, it will not be eligible for a priority review voucher.

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, for the treatment of patients with systemic sclerosis to improve associated organ dysfunction and for the treatment of relapsing and progressive forms of MS. 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. 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 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.***

Currently, federal agencies in the U.S. are operating under a continuing resolution that is set to expire on September 30, 2025. 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 changes in the 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, 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, 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. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue to fund our operations.

With the change in the U.S. presidential administration in 2025, there is substantial uncertainty as to whether and how the Trump administration will seek to modify or revise the requirements and policies of the FDA and other regulatory agencies with jurisdiction over our product candidates and any products for which we obtain approval. This uncertainty could present new challenges and/or opportunities as we navigate development and approval of our product candidates. Additionally, the new administration could issue or promulgate executive orders, regulations, policies or guidance that adversely affect us or create a more challenging or costly environment to pursue the development of new therapeutic candidates.

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, in 2025, the U.S. imposed blanket tariffs on virtually all imports to the U.S. and significantly higher so-called reciprocal tariffs applicable to imports from many countries. 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 the FDA placing the product on a list of discontinued products, which would revoke the product's ability to be marketed.

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. Breach of certain environmental, health and safety laws and regulations could also in certain circumstances constitute a breach of our License Agreement with Penn. 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, 2024.

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, 2024.

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 signal 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 Health and Human Services (HHS) to identify and communicate most-favored-nation 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 most-favored-nation 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 (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 (PBMs) in drug pricing and market access.

Further, the Medicare Drug Price Negotiation Program, administered by CMS as part of the Inflation Reduction Act of 2022, commonly referred to as 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.

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, 2024.

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) 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. On June 4, 2021, the EC issued new forms of standard contractual clauses for data transfers from controllers or processors in the EU/EEA (or otherwise subject to the GDPR) to controllers or processors established outside the EU/EEA. The UK is not subject to the EC's new standard contractual clauses but has published its own transfer mechanism, the International Data Transfer Agreement and International Data Transfer Addendum, or the IDTA, which enable transfers from the UK, and has also implemented a similar Transfer Impact Assessment requirement. 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 will be 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. The UK Government had introduced a Data Protection and Digital Information Bill which failed in the UK legislative process. The UK Government introduced the Data Protection and Digital Information Bill which failed in the UK legislative process. A new Data (Use and Access) Bill ("UK Bill") has now been introduced into parliament. The aim of the UK Bill is to reform the UK's data protection regime. If passed, the final version of the UK Bill may have the effect of further altering the similarities between the UK and EEA data protection regime. This may lead to additional compliance costs and could increase our overall risk. The respective provisions and enforcement of the EU GDPR and UK GDPR may further diverge in the future and create additional regulatory challenges and uncertainties.

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, the California Consumer Privacy Act, or CCPA, went into effect on January 1, 2020, and became subject to enforcement by the California Attorney General's office on July 1, 2020. The CCPA broadly defines personal information, and 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.

Additionally, the California Privacy Rights Act, or CPRA, was passed in November 2020 and as of January 1, 2023 has imposed additional obligations on companies covered by the legislation. The CPRA significantly modified the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. The CPRA also created a new state agency that is 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.

Similar laws have been passed in numerous other states and proposed in others. Such proposed legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and/or changes in business practices and policies. The existence of comprehensive privacy laws in different states in the country would 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 recently passed a health privacy law that will regulate 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 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 a new comprehensive federal data privacy law to which we may likely become subject, if enacted.

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.

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.

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, 2024, our executive officers, directors, and 5% stockholders beneficially owned, in the aggregate, approximately 28% 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 have begun and will continue to dedicate internal resources, potentially engage outside consultants, and adopt 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. In May 2024, 1,444,295 shares of non-voting common stock were converted to voting common stock and no shares of non-voting common stock remain 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.

On March 31, 2025, we converted the S-3ASR to an S-3 by post-effective amendments. This S-3 was declared effective on March 31, 2025. We have 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, or the 2024 ATM Program, pursuant to its S-3, and subject to the limitations thereof. The S-3 and 2024 Sales Agreement replaced our former registration statement and sales agreement, pursuant to which we had a $100.0 million at-the-market offering program, all of which we sold. 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 $7.7 million, consisting of $5.1 million in 2024 and $2.6 million in 2025. In June 2025, our stockholders approved an amendment to our Third Amended and Restated Certificate of Incorporation to increase the number of authorized shares of common stock from 150,000,000 to 300,000,000 (293,590,481 voting and 6,409,519 non-voting).

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. 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 will expire fifteen months from the date of issuance. Aggregate net proceeds were $93.6 million after deducting underwriting discounts and commissions and offering expenses. In connection with this offering, our executive officers and directors entered into lock-up agreements, whereby they agreed to, among other things, subject to certain exceptions, not to offer, sell, assign, transfer, pledge, contract to sell, lend or otherwise dispose of or announce the intention to otherwise dispose of, any shares of common stock or securities convertible into or exercisable or exchangeable for common stock for a period of 90 days, which will expire on September 9, 2025. 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 amounts of our common stock under the Shelf Registration Statement or otherwise, the market price of our common stock could decline significantly.

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.

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.

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. 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.

In 2017, the U.S. Congress and the Trump administration made substantial changes to U.S. policies, which included comprehensive corporate and individual tax reform. In addition, the Trump administration called for significant changes to U.S. trade, healthcare, immigration and government regulatory policy. With the transition to the Biden administration in early 2021, changes to U.S. policy occurred and since the start of the Trump Administration in 2025, U.S. policy changes have been implemented at a rapid pace and additional changes are likely. Changes to U.S. policy implemented by the U.S. Congress, the Trump administration or any new 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. 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.

Our ability to utilize our net operating losses and certain other tax attributes to offset future taxable income may be subject to certain limitations.

As of December 31, 2024, we had U.S. federal, state and local net operating loss carryforwards of $157.4 million, $181.4 million and $88.7 million, respectively. $0.3 million of the federal amounts expire in 2037. The state net operating losses begin to expire in 2037 and the local net operating losses began to expire in 2024. Approximately $157.2 million of the federal net operating losses can be carried forward indefinitely. Certain net operating loss 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 net operating loss carryforwards or tax credits, or NOLs or 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 or groups of stockholders who owns at least 5% of a corporation’s stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a specified testing period. Our existing NOLs or credits may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change, our ability to utilize NOLs or credits could be further limited by Sections 382 and 383 of the Code. 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. Our NOLs or credits may also be impaired under state law. Accordingly, we may not be able to utilize a material portion of our NOLs or credits. Furthermore, our ability to utilize our NOLs or 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 credits. Under current law, U.S. federal net operating loss carryforwards generated in taxable years beginning after December 31, 2017 will not be subject to expiration. However, any such net operating loss carryforwards may only offset 80% of our annual taxable income in taxable years beginning after December 31, 2020.

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, or the IRS, and the U.S. Treasury Department. For example, the OBBBA was signed into law on July 4, 2025 and made significant changes to U.S. federal tax law. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many changes to tax laws 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. We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock.

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, including the presidential transition in the United States. 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.

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 June 30, 2025, 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	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)
3.4	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)
10.1† *	Development and Manufacturing Services Agreement, dated as of December 19, 2024, between the Registrant and Lonza Houston Inc.
4.1	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Registrant's current report on Form 8-K (File No. 001-39103) filed with the SEC on June 12, 2025)
4.2	Form of Common Stock Warrant (incorporated by reference to Exhibit 4.2 to the Registrant's current report on Form 8-K (File No. 001-39103) filed with the SEC on June 12, 2025)
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.

† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to Item 601(b)(10) of Regulation S-K.

** 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: August 7, 2025

By: /s/ Steven Nichtberger

Steven Nichtberger
Chief Executive Officer and President
(Principal Executive Officer)

Date: August 7, 2025

By: /s/ Anup Marda

Anup Marda
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 10.1

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

Development and Manufacturing Services Agreement

(the "Agreement")

by and between

Lonza Houston Inc.

14905 Kirby Drive
Houston, Texas 77047

("**Lonza**")

and

Cabaletta Bio, Inc.

2929 Arch Street
Suite 600
Philadelphia, PA 19104

("**Customer**")

Effective as of December 19, 2024 (the "Effective Date")

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Recitals

WHEREAS, Customer is engaged in the development and research of certain products and requires assistance in the development and manufacture of such products;

WHEREAS, Lonza and its Affiliates have expertise in the evaluation, development and manufacture of products;

WHEREAS, Customer wishes to engage Lonza for Services relating to the development and manufacture of Product(s) as described in this Agreement; and

WHEREAS, Lonza, and/or its Affiliates, are prepared to perform such Services for Customer on the terms and subject to the conditions set out herein.

WHERAS, the Parties agree that any Services performed under this Agreement or a SOW will broadly relate to preclinical and clinical development and manufacturing services only and do not extend to commercial Services or manufacture.
WHEREAS, where the Customer wishes to instruct Lonza to perform services related to manufacture of Product for commercial use, the Parties agree that a new agreement or amendment will need to be entered into.
NOW, THEREFORE, in consideration of the mutual promises contained herein, and for other good and valuable consideration, the Parties intending to be legally bound, agree as follows:

1 Definitions and Interpretation

"Ad-hoc Batch" means the number of cGMP Batches that may be purchased by the Customer in addition to the Monthly Minimum Batch Commitment and as further defined in the applicable SOW.

"Affiliate" means, with respect to either Party, any corporation, company, partnership or other business entity which directly or indirectly, through one or more intermediaries, Controls, is Controlled by or is under common Control with such Party. For purposes of this definition, the term "Control" and, with the correlative meanings, the terms "Controlled by" and "under common Control" means direct or indirect ownership of fifty percent (50%) or more of the securities or other ownership interests representing the equity voting stock or general partnership or membership interest of such entity or the power to direct or cause the direction of the management and policies of such entity, whether through the ownership of voting securities, by contract, or otherwise.

"Agreement" means this agreement, incorporating all Appendices and SOWs and the Quality Agreement, as amended from time to time by written agreement of the Parties.

"Applicable Laws" means all relevant federal, state, and local laws, statutes, rules, and regulations of the [***], any jurisdiction in which the Facility(ies) are located, and upon mutual written agreement between the Parties, any other countries, which are applicable to the performance of the Services (as defined below) and/or the Parties' respective obligations hereunder, including all relevant laws, statutes, rules, and regulations in all countries in which Customer

develops or commercializes the Products, whether in effect as of the Effective Date or adopted thereafter, including (i) the applicable regulations and guidelines of any Regulatory Authority and all applicable cGMP together with amendments thereto; and (ii) data protection, patient privacy, and electronic transmission or transaction laws and regulations in all countries in which information or data that is protected by any applicable privacy laws is received, transmitted, collected, or otherwise processed. The cost of any additional regulatory assessment (in relation to (i) above) shall be borne by Customer and documented in a SOW or Change Order.

"Approval" means the marketing approval by the FDA or EMA or other Regulatory Authority (as defined below) of Product from the Facility for commercial supply.

"Assist" means the supply of Customer Materials to Lonza free of charge or at a reduced cost.

"Background Intellectual Property" means any Intellectual Property either (i) owned or controlled by a Party or any of its Affiliates prior to the Effective Date or (ii) developed or acquired by a Party or any of its Affiliates independently from the performance of the Services hereunder during the Term of this Agreement and without aid or reference to the other Party's Confidential Information. Intellectual Property rights encompassed in Lonza's Confidential Information shall form part of, and be included in, Lonza's Background Intellectual Property. Intellectual Property rights encompassed in Customer Confidential Information shall form part of, and be included in, Customer's Background Intellectual Property. For clarity, Background Intellectual Property of a Party shall exclude any Intellectual Property licensed (whether under this or any other agreement) to it by the other Party or any Affiliate of the other Party.

"Batch" means the Product produced from a single run or, to the extent applicable and specified in advance by Customer, combined consecutive runs of the Manufacturing Process. For clarity, a Batch can be a Pilot Batch, Engineering Batch, Process Validation Batch, or cGMP Batch. Other batch types may be mutually agreed by the Parties in a SOW, but any new type will be a subtype of the aforementioned Batch type categories.

"Batch Record" means the executed version of a given Master Batch Record containing the production record, or, as applicable, relevant portions thereof, pertaining to a given Batch but excluding any Lonza Operating Documents included therein

"Cancellation Fee" has the meaning given in Clause 6.5.

"Capital Equipment" means those certain pieces of new equipment described in a SOW that are to be acquired and paid for on terms to

be agreed in accordance with the applicable SOW and this Agreement.

"Certificate of Analysis" or "CoA" means a document prepared by or for Lonza listing tests performed by Lonza or authorized (or identified in any SOW) External Laboratories, the Specifications and test results.

"Certificate of Compliance" or "CoC" means a document prepared by or for Lonza: (i) listing the manufacturing date, unique Batch number, and concentration of Product in such Batch; and (ii) certifying that such Batch was manufactured in accordance with the Specifications, the Master Batch Record and cGMP, if applicable.

"cGMP" means any laws, regulations, and regulatory guidelines, applicable in the [***], any jurisdiction in which the Facility(ies) are located, and any other countries the Parties may mutually agree upon in writing as set forth in the Quality Agreement, as amended from time to time, relating to the manufacture of medicinal products for human use (together with amendments thereto), including (without limitation) current Good Manufacturing Practices as specified in the ICH guidelines and, in particular (without limitation), ICH Q10 "Guidance for Industry Q10 Pharmaceutical Quality System", the US Federal Food Drug and Cosmetic Act at 21CFR (Chapters 210, 211, 600 and 610, 820), the Rules Governing Medicinal Products in the European Union (Eudralex), Volume 4 in particular - without limitation- Part I (for Drug Products) as promulgated under the European Union Directives 2001/83/EC and 2001/20/EC and European Commission Directives 2003/94/EC and 91/356/EC; European Medicines Agency Note for Guidance CPMP/ICH/4106/00; the US FDA 21 CFR 210/211/600, and 21 CFR part 11 and 610; and other agency regulations and regulatory guidelines as applicable to drug substance and drug product manufacture. Lonza's operational quality standards that reference applicable GMP regulations are defined in internal cGMP documents.

"cGMP Batch" means any Batch that is required under this Agreement or applicable SOW to be manufactured in accordance with cGMP and meet Specifications.

"Change Order" has the meaning set forth in Clause 3.3.

"Commencement Date" means the date of initiation of (i) the production of the Batch(es), which in the case of a Batch using cells shall mean the date of removal of the vial of cells from frozen storage for the production of a Batch; or (ii) all other Services, as applicable.

"Competitor" means [***].

“Confidential Information” means any and all information that is non-public and that is disclosed or otherwise made available by one Party or any of its Affiliates (whether in oral, written, electronic or visual form) to the other Party under or in connection with this Agreement, including the process designs, process models, drawings, plans, data, databases, formulae, methods, know-how, trade secrets, and other Intellectual Property of a Party. The Confidential Information of each Party shall exclude any Confidential Information of the other Party or any Affiliate of a Party provided under this Agreement. The Confidential Information of Customer includes, without limitation, all technical and other non-public information relating to Product(s), Customer Background Intellectual Property, and Customer Materials and the same will be subject to Clause 12 (except to the extent necessary for Lonza to exercise its rights or perform its obligations under this Agreement, including in connection with the licenses granted by Customer to Lonza in Section 9). Confidential Information of Lonza includes, without limitation, all technical and other non-public information relating to Lonza Background Intellectual Property and the same will be subject to the terms of Clause 12 (except to the extent necessary for Customer to exercise its rights or perform its obligations under this Agreement, including in connection with the licenses granted by Lonza to Customer in Section 9).

“Corruption Laws” means all applicable anti-bribery and anti-corruption laws and regulations, including but not limited to the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act 2010, and the Organization for Economic Co-operation and Development (OECD) Convention on Combating Bribery of Foreign Public Officials in International Business Transactions.

“Customer Materials” means any Raw Materials, components of Product, or other materials of any nature provided by Customer, as specified in a SOW.

“Customer-Provided Items” means, Customer Confidential Information, Customer Background Intellectual Property, Customer Materials, the Manufacturing Process, and any and all other information, materials, and Intellectual Property that in each case is provided by or on behalf of the Customer to Lonza or any of Lonza’s Affiliates, but excluding any Lonza Background Intellectual Property and Lonza Confidential Information.

“Delivery” has the meaning provided in Clause 7.1.

“Development Services” means all activities other than the manufacture of a Batch and activities performed in support of such Batch.

“Drug Product” means the formulation of the Drug Substance in its final dosage form.

“Drug Product Batch” means a Batch of Drug Product in its final dosage form.

"Drug Substance" means an active pharmaceutical or biopharmaceutical ingredient that is intended for further downstream processing into its drug product dosage form to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the human body. Drug substance can be formulated as a bulk or small volume unit that is further processed into drug product finished dosage form.

"Drug Substance Batch" means a Batch of Drug Substance in its final dosage form.

"EMA" means the European Medicines Agency, or any successor agency thereto.

"Engineering Batches" means a Batch of Product that is intended to demonstrate the transfer of the Manufacturing Process to the Facility or changes in the Manufacturing Process.

"External Laboratories" means any Third Party instructed by Lonza, with Customer's prior consent, to conduct certain activities not customarily performed by Lonza which are required to complete the Services.

"Facility" means Lonza's manufacturing facilities in [***].

"Failed Batch" shall have the meaning set out in Clause 7.4.3.

"FDA" means the United States Food and Drug Administration, or any successor agency thereto.

"GDPR" means any applicable data protection or privacy laws, rules and regulations, including but not limited to, the European Union e-Privacy Directive 2002/58/EC, the European Union General Data Protection Regulation 2016/679, the UK Data Protection Act 2018, the Swiss Federal Act on Data Protection, and any other laws equivalent thereto.

"Handling Fee" means the: (i) handling fee of [***]; and (ii) for the management and handling of activities performed by the External Laboratories, a fee of [***].

"Intellectual Property" means (i) rights in inventions (whether or not patentable), patents, discoveries, improvements, data, information, reports, assays, trade secrets, copyrights, trademarks, trade names, service marks, logos, domain names, rights in designs, rights in computer software, database rights, intellectual property rights in confidential information (including know-how, and any other intellectual property rights), in each case whether registered or unregistered, and any and all related documentation; (ii) all applications (or rights to apply) for, and renewals or extensions of, any of the rights described in the foregoing clause (i); and (iii) all rights and applications that are similar or equivalent to the rights and application described in the foregoing

clauses (i) and (ii), which exist now, or which come to exist in the future, in any part of the world.

"International Trade Restrictions" means any export control requirements and trade, financial and economic sanctions which apply to this Agreement and the Services under the laws, regulations and rules of the [***] and any other relevant jurisdiction; and all necessary export and re-export written consents, permits, and authorizations required by International Trade Restrictions.

"Lonza Operating Documents" means, [***].

"Lonza Manufacturing Process Documents" means, in either electronic or paper form, documents used in the Manufacturing Process wherein Lonza's custom and platform manufacturing process and/or Lonza-developed analytical methods are used to produce the Product including, but not limited to, manufacturing procedures, Raw Material specifications, and Lonza-developed methods.

"Lonza-Procured Materials" means Raw Materials that Lonza purchases pursuant to the terms of the Agreement and any applicable SOW. For avoidance of doubt, Lonza-Procured Materials excludes Customer Materials.

"Lonza Responsibility" means a failure primarily due to Lonza's (or its Affiliates', Subcontractors', or External Laboratories') negligence, willful misconduct, or material breach of its obligations hereunder. Lonza Responsibility shall not include any failure due to a biological reason not caused or exacerbated (where the biological reason could have been remedied but for such exacerbation) by Lonza's (or its Affiliates', Subcontractors', or External Laboratories') negligence, willful misconduct or material breach of its obligations hereunder.

"Manufacturing Process" means the specific production process provided by Customer (the "CABA" platform manufacturing process), excluding processes performed pursuant to the Lonza Operating Documents for the manufacture of Product as such process may be improved by Customer or Lonza or anyone acting on Lonza's behalf or engaged by Lonza, (excluding any Lonza Background Intellectual Property, New General Application Intellectual Property, and/or Lonza Confidential Information).

"Master Batch Record" means a formal set of unexecuted documents, production and control records, and instructions, including in electronic form, for the manufacture of a Batch of the Product that detail steps and elements of the Manufacturing Process, along with test and analytical methods and other procedures, directions, and controls associated with the manufacture and testing of the Product but excluding in Lonza Operating Documents included therein.

"Monthly Minimum Batch Commitment" means the minimum number of cGMP Batches required to be purchased by the Customer per month (if any) as further defined in the applicable SOW.

"New Customer Intellectual Property" has the meaning given in Clause 9.3.1.

"New General Application Intellectual Property" has the meaning given in Clause 9.3.2.

"Party" or "Parties" means each of Lonza and Customer and, together, the "Parties".

"Persistent Supply Failure" means, due in all cases to a Lonza Responsibility, the Delivery by Lonza of less than [***] of the cGMP Batches included in the applicable Monthly Minimum Batch Commitment, in compliance with cGMP and meeting Specifications, over a [***] period.

"Pilot Batches" means a Batch of Product designated as a Pilot Batch in the applicable SOW that is not required to comply with cGMP and is not required to meet Specifications.

"Price" means the price for the Services and Products as set out in an applicable SOW. Unless otherwise stated, the Price excludes [***].

"Process Validation Batch" means a Batch that is produced with the intent to show reproducibility of the Manufacturing Process and is required to complete process validation studies.

"Product" means the Drug Product as described in Appendix B or otherwise in a SOW to be manufactured by Lonza for Customer as specified in such SOW.

"Quality Agreement" means the written quality agreement, to be entered into by the Parties in accordance with Section 4.1 of the Agreement, that, subject to cGMP requirements, defines, establishes, and documents manufacturing and testing activities and responsibilities of the Parties in relation to quality. Upon signature by both Parties, the Quality Agreement and any amendments thereto are incorporated into and shall be an integral part of this Agreement.

"Raw Materials" means all ingredients, solvents, primary packaging materials, filter, single-use liquid-paths, and other components of the Product required to perform the Manufacturing Process or Services set forth in the bill of materials (excluding any general consumables or wearables).

"Regulatory Authority" means the FDA, EMA, Health Canda, MHRA, and any other similar regulatory authority as may be agreed upon in writing or covered under the definition of Applicable Laws.

"Release" has the meaning given in Clause 7.1.

"Safety Stock" means the stock of Raw Materials and consumables in addition to the net needs for a particular Batch to mitigate the potential risk of Raw Materials and consumables shortages necessary for the performance of Services. Required Safety Stock amounts are shown in Appendix C unless otherwise set forth in an SOW.

"Services" means all or any part of the services (including manufacturing of Batches) to be performed by Lonza under this Agreement, particulars of which are set out in a SOW.

"Services Data" means any and all data obtained by Lonza or any Affiliate, Subcontractor, or External Laboratory of Lonza in the course of Lonza's or such other entities' performing Services hereunder, provided such data (i) does not contain any identifiable Customer Confidential Information; (ii) is anonymized and aggregated as required under Applicable Law (which for purposes hereof includes all data privacy and protection laws in any jurisdiction); and (iii) in any event used in a way that cannot provide for the identification of the Customer or Product.

"SOP" means a standard operating procedure.

"Specifications" means the specifications for Product, as agreed between the Parties, which may be amended from time to time in accordance with this Agreement.

"Stage of Work" means an individual stage of the Services as set out in the SOW.

"Statement of Work" or "SOW" means a document specifying the Services to be performed, which may include, the development/transfer of the Manufacturing Process, Development Services, and/or manufacture a Product that will be established and signed by the Parties during the Term of this Agreement. Attached as Appendix A is the first Statement of Work agreed to between the Parties. Any Statement of Work will be hereby incorporated and made a part of this Agreement. It is contemplated that each separate project shall have its own Statement of Work. As each subsequent Statement of Work is agreed to by the Parties, each shall state that it is to be incorporated and made a part of this Agreement and shall be consecutively numbered as A-2, A-3, etc.

"Subcontractor" means any Third Party to whom Lonza seeks to subcontract any Services or other activities hereunder other than non-essential, routine tasks or tasks not specific to the Services (e.g., janitorial services, electrical upgrades, etc.).

"Tax" or "Taxes" means any and all federal, state, county, local, foreign and other taxes of any kind whatsoever (including, without limitation, income, profits, premium, estimated, excise,

sales, use, occupancy, gross receipts, franchise, ad valorem, severance, capital levy, production, transfer, license, stamp, environmental, withholding, employment, unemployment compensation, payroll related and property taxes, import duties, levies and other governmental charges or assessments), whether or not measured in whole or in part by net income, and including deficiencies, interest, additions to tax or interest, and penalties with respect thereto, that are imposed on Lonza with respect to the Services hereunder, but excluding [***].

"Term" has the meaning given in Clause 13.1.

"Third Party" means any party other than Customer, Lonza, and their respective Affiliates.

In this Agreement, (a) references to the Parties are to the Parties to this Agreement; (b) headings are used for convenience only and do not affect the interpretation of the Agreement;(c) references to a statutory provision include references to the statutory provision as modified or re-enacted or both from time to time and to any subordinate legislation made under the statutory provision; (d) references to the singular include the plural and vice versa; and (e) references to the word "including" are to be construed without limitation.

In this Agreement, for any Autologous Cell Therapy specific terms and conditions refer to Appendix B hereof. Where specified, the provisions contained in Appendix B shall replace in their entirety the corresponding provisions contained in this Agreement as they relate to any Autologous Cell Therapy programs with Lonza and Customer. Other than those terms contained in Appendix B, the terms of this Agreement shall govern with respect to any Autologous Cell Therapy programs with Lonza and Customer.

2 Performance of Services

2.1 Performance of Services. Customer hereby retains Lonza to perform the Services set out in each SOW. Lonza shall itself and through its Affiliates, diligently perform the Services as provided in the SOW(s), in accordance with the terms and conditions of this Agreement and Applicable Law, and shall use commercially reasonable efforts to perform the Services without any material defect and according to the estimated timelines as set out in the SOW(s).

2.2 Owing to the unpredictable nature of the biological processes involved in the Services, but subject to Section 2.1, 6.2, and 10.1.4 the timelines set down for the performance of the Services are estimates only, so long as Lonza uses commercially reasonable efforts to continuously meet all deadlines and [***] notifies Customer as soon as Lonza has reason to believe that any timeline might not be achieved. Lonza shall retain appropriately qualified and trained personnel with the requisite knowledge and experience to perform the Services in accordance with this Agreement.

2.3 Any refusal or failure by Lonza or its Affiliates, External Laboratories, Subcontractors, or agents and their personnel involved in the performance of the Services to perform its obligations hereunder on account of a good faith effort to comply with Applicable Laws (as advised by counsel) shall not constitute a breach of any obligation under this Agreement.

2.4 Subcontractors and External Laboratories. Lonza may utilize a Subcontractor or an External Laboratory to perform the Services solely if expressly authorized (i.e. by executing an SOW identifying such Third Party) or otherwise with Customer's prior written consent not

to be unreasonably withheld or delayed; provided that Lonza shall remain liable for the performance of any of its obligations hereunder that it outsources to a Subcontractor or External Laboratory and for any act or omission of any such Subcontractor or External Laboratory in connection with this Agreement if such Subcontractor or External Laboratory is not one Customer requires Lonza to use notwithstanding Lonza's expressed concerns or objections. For the avoidance of doubt, Lonza shall not be responsible for any Services performed by External Laboratories or any Subcontractor which Customer requires Lonza to use if Lonza has expressed concerns or objection about the use of such party (including, but not limited to, reasons such as such party is not qualified or Lonza has experienced an unsatisfactory performance from such party).

2.5 Affiliates. Lonza, in its sole discretion, may instruct one or more of its Affiliates to perform any of Lonza's obligations contained in this Agreement and any particular SOW as set forth in a SOW, provided, however, that Lonza shall remain fully responsible to Customer in respect of those obligations. Any of Lonza's Affiliates shall be subject to all of the applicable terms and conditions applicable to Lonza under this Agreement. An Affiliate of Lonza may execute a SOW with the Customer pursuant to this Agreement and submit invoices to the Customer under the SOW. In such circumstances all references in this Agreement to Lonza shall be deemed to be to the applicable Affiliate of Lonza with respect to that particular SOW. The Affiliate shall be entitled to enforce this Agreement with respect to such SOW in its own name or as an intended Third Party beneficiary, and all references to Lonza herein shall be construed as reference to such Affiliate, therefore Customer shall be entitled to enforce this Agreement with respect to such SOW directly against such Affiliate (or at Customer's election against Lonza). The Affiliate and Lonza shall be jointly and severally liable to the Customer for any obligations and liabilities undertaken pursuant to such SOW and subject to the terms of this Agreement.

2.6 Technology Transfer.

2.6.1 Pursuant to the separate Process Development and non-cGMP Production Agreement entered into between the Parties (or their Affiliates), dated July 26, 2024 (the "Technology Transfer Agreement"), Customer has agreed to transfer the Manufacturing Process for the Product that is the subject of such Technology Transfer Agreement.

2.6.2 For any Product that is not the subject of the Technology Transfer Agreement, the Parties expressly agree that Customer shall transfer to Lonza the Manufacturing Process, Customer Confidential Information, Customer Background Intellectual Property, Customer Materials, and any other information or materials, as reasonably required by Lonza to perform the Services, as set forth in a Statement of Work. The Parties expressly agree that they shall work together in good faith to complete such transfer.

2.6.3 The customs value of the finished Product provided by Lonza to the Customer comprises the contractual Price of the Product, in addition to the value of the Customer-provided Assist. In order for Lonza to comply with its customs obligations, the value of an Assist must be declared to the customs authority at the time of import and export, and therefore Customer shall declare to Lonza the appropriate value of the Assist in accordance with Applicable Laws, which shall be incorporated into the customs declaration.

2.6.4 Upon request, Customer shall provide the export control classification or any government classification or commodity jurisdiction determinations, any preferential trade agreements under which the Product originates, Certifications of Origin or certifications/declarations of preferential origin eligibility, and Country of Origin. Unless otherwise noted, because the shipping terms in this

Agreement are FCA (Incoterms 2020), Lonza is solely responsible for export compliance provided under this Agreement included, but not limited to, export clearance of direct shipments.

2.7 Master Batch Record. In accordance with an applicable SOW or as otherwise set forth in the Technology Transfer Agreement, Lonza shall prepare (with Customer's assistance) the Master Batch Record for the Manufacturing Process. Customer shall inform Lonza of any specific requirements Customer may have relating to the Master Batch Record, including any information or procedures Customer requires to have incorporated therein. If Lonza is unable to include any such information or procedures it shall notify Customer accordingly, specifying its rationale, and the Parties shall work together in good faith on a mutually agreeable resolution.

2.8 Pilot Batches. For any Pilot Batch(es) required to be manufactured pursuant to a SOW, Lonza shall manufacture such Pilot Batch(es) in accordance with the terms of this Agreement and applicable SOW, but, shall have no obligation to meet Specifications or comply with cGMP in relation to the Pilot Batch(es) (and Lonza makes no warranty in this regard). Customer shall have the right to make whatever use of the Pilot Batch(es) as it shall determine, provided that such use is not for human use and does not violate any Applicable Laws. Unless Lonza and Customer agree otherwise, all Pilot Batch(es) shall be shipped to Customer. Customer shall pay to Lonza the Price for such Pilot Batch(es) plus, as applicable, the Raw Materials, testing and Handling Fee associated with such Pilot Batch(es) as set forth in the SOW.

2.9 Engineering Batches. For any Engineering Batch(es) required to be manufactured pursuant to a SOW, Lonza shall manufacture such Engineering Batch(es) in accordance with the terms of this Agreement and applicable SOW, but shall have no obligation to meet Specifications or comply with cGMP in relation to the Engineering Batch (and Lonza makes no warranty in this regard). Notwithstanding the foregoing, Lonza shall be obligated to execute each Engineering Batch in accordance with the engineering Batch Record and to use commercially reasonable efforts to meet the acceptance criteria mutually agreed in advance by the Parties, at set forth in the SOW, for the particular Engineering Batch. Further, Lonza will provide a Certificate of Testing for all Engineering Batch(es) containing all agreed upon testing for the Customer to provide in submissions to Regulatory Authorities. If Lonza determines that an Engineering Batch does meet cGMP and the Specifications, it may, subject to Customer's agreement in its sole discretion, release such Engineering Batch as a cGMP Batch. The Price of the Engineering Batch as set forth in the applicable SOW shall apply regardless of whether released as a cGMP Batch. Customer shall pay to Lonza the Price for such Engineering Batch(es) plus the Raw Materials, testing and Handling Fee(s) associated with such Engineering Batch(es) as set forth in the SOW, unless Lonza or its Affiliates or Subcontractors were grossly negligent, or committed willful misconduct, causing an Engineering Batch to fail to meet the applicable mutually agreed acceptance criteria set forth in advance by the Parties. If it is determined by the Parties or a mutually agreed upon independent laboratory determines Lonza or its Affiliates or Subcontractors were grossly negligent, or committed willful misconduct in the manufacture of any Engineering Batches, causing such Engineering Batch to fail to meet mutually agreed acceptance criteria set forth in advance in writing by the Parties, such Batch shall be treated as a Failed Batch under Section 7.4.3. Customer shall have the right to make whatever use of released cGMP and non-cGMP Engineering Batch(es) at its discretion so long as such use does not violate any Applicable Laws. However, Engineering Batches not released as cGMP are not for human use.

2.10 cGMP Batches.

2.10.1 Unless otherwise agreed between the Parties in writing, cGMP manufacture shall not commence until at least [***] has been manufactured in compliance with cGMP and within Specifications for cGMP Batches. Additionally, prior to

commencement of manufacturing of cGMP Batches Lonza shall review the process assumptions in the SOW and make amendments to the Manufacturing Process upon written agreement of the Parties. If such amendment to the Manufacturing Process is material, [***] that has been manufactured in compliance with cGMP and within Specifications for cGMP Batches may be required. In the event that there is a material difference between the process assumptions in the SOW and the process results demonstrated during the manufacture of Engineering Batches, or Pilot Batches as applicable, the Parties shall meet to discuss in good faith and may agree on a revision to the Batch Price to reflect such difference.

2.10.2 Lonza will, in accordance with the terms of this Agreement, the applicable SOW, and the Quality Agreement, manufacture at the Facility and Release to Customer, subject to and in accordance with the requirements of Clause 7.1, cGMP Batches in accordance with the Manufacturing Process, cGMP and this Agreement, and which meet the Specifications at Release. Customer shall not be responsible for the payment of any cGMP Batches failing to meet Specifications or cGMP due to a Lonza Responsibility.

2.10.3 Notwithstanding Clause 2.10.2, to the extent that an Engineering Batch is not performed to cGMP and manufactured within Specifications or a material amendment to the Manufacturing Process is implemented after the manufacturing of an Engineering Batch immediately prior to the Batches set forth in Clause 2.10.3.1 or Clause 2.10.3.2 and the Parties agree to proceed, Lonza shall not be responsible, except in the case of Lonza's (or its Affiliates' or Subcontractors') gross negligence, willful misconduct or material breach of its obligations hereunder, for failure to meet the Specifications and Customer shall pay for:

2.10.3.1 the [***] manufactured; and/or

2.10.3.2 the [***] manufactured following any material change in the Manufacturing Process agreed to or requested by Customer.

2.11 Process Validation Batches.

2.11.1 As applicable, Lonza shall manufacture and deliver Process Validation Batches as mutually agreed by the Parties pursuant to a SOW sufficient to support the robustness of the Manufacturing Process and permit the Parties to complete and submit the necessary documents to the Regulatory Authorities.

2.11.2 Prior to commencement of Process Validation Batches, Lonza and Customer shall agree on a process validation plan identifying the validation requirements of the Manufacturing Process and identify necessary regulatory support.

2.11.3 The Price of any regulatory support activities and process validation activities that are in addition to the Price of Process Validation Batches, shall be set forth in the applicable SOW, and shall be paid for by the Customer at the Price set out in the applicable SOW.

2.12 Raw Materials.

2.12.1 Lonza-Procured Materials. Lonza shall purchase the necessary Lonza-Procured Materials as well as consumables, including the purchase of Lonza-Procured Materials and consumables necessary for the manufacturing of the Product as well as any Safety Stock. Customer shall, in accordance with the terms and conditions of this Agreement, be responsible for the costs for all such

Lonza-Procured Materials and consumables ordered or irrevocably committed to be procured by Lonza hereunder for the manufacture of Batches pursuant to Binding Purchase Orders and to meet the Safety Stock requirements in accordance with the Agreement and (if applicable) Raw Material disposition costs under Clause 2.12.4, as well as any applicable Handling Fee. In the event that Customer requires Lonza to source Lonza-Procured Materials from a supplier outside of Lonza's supply chain, and as a result Lonza is unable using diligent efforts to obtain the necessary quantity of Lonza-Procured Materials to initiate the manufacture of a Batch in accordance with the estimated timeline, to the extent the delay extends at least [***], it shall be a Customer delay subject to Clause 6.4. Lonza shall invoice Customer for all Raw Material disposition costs for which Customer is responsible for under Clause 2.12.4. Lonza shall be fully responsible for the replacement cost of any Lonza-Procured Materials and consumables if the need for the same is due to loss or damage of such Lonza-Procured Materials caused by Lonza's or its Affiliates' or Subcontractors' negligence, willful misconduct, or any material breach of obligations under this Agreement. For clarity, Lonza's responsibility for the loss, damage or destruction of Raw Materials, including Lonza-Procured Materials, relating to a Failed Batch and those lost, damaged or destroyed during manufacturing are set forth in Sections 7.4.3 and 7.5, respectively.

2.12.2 Customer Materials. Subject to the terms hereof (including Clause 7.2, 7.4.3 and 7.5) Customer shall, at its cost, provide or arrange for the provision of all required Customer Materials, including the Customer Materials required for any Safety Stock, that Customer is obligated, pursuant to this Agreement or a SOW, to supply for manufacture of Product. Unless otherwise agreed in a SOW, Customer shall provide such Customer Materials in a timely manner so they can be tested and released by Lonza at least [***] prior to the scheduled start date of the Service for which such Materials are to be used.

2.12.3 Safety Stock. Lonza shall manage the Safety Stock in accordance with Lonza's Safety Stock standard practices unless otherwise agreed as between the Parties in a SOW. Any request from Customer to maintain the Safety Stock below the required minimums according to Appendix C shall be agreed upon in writing between the Parties. Notwithstanding the foregoing, if, as a result of Customer requesting minimums below the required Safety Stock levels set forth in Appendix C, Lonza does not have the necessary quantity of Raw Materials or, consumables to initiate the manufacture of a Batch in accordance with the estimated timeline, and such delay extends at least [***] the Batch shall be deemed a Customer delay subject to Clause 6.4.

2.12.4 Disposition of Raw Materials.

2.12.4.1 Batch Cancellation. Upon cancellation of a Batch by Customer or expiration or termination of this Agreement, Customer shall, within [***] from written notice of the cancellation, expiration, or termination, request in writing from Lonza one of the following options, at Customer's cost (except as otherwise noted in this subsection), for disposition of unused Raw Materials or consumables purchased for Customer or in the case of a Batch cancelation that were purchased solely for manufacturing such cancelled Batch: (i) store without charge Raw Materials and/or consumables for a subsequent Batch of Product to be manufactured under this Agreement; provided there are Binding Orders for subsequent Batches committed; (ii) store such Raw Materials and/or consumables for a reasonable period of time that is mutually agreeable (with at least [***] provided without charge

starting on the date on which Customer provides notice of the cancellation, expiration, or termination); (iii) ship Raw Materials and/or consumables to a Customer designated location; or (iv) dispose of the Raw Materials and/or consumables. If Customer does not provide a written request regarding the Raw Materials and consumables within [***], then Lonza shall provide additional notice to Customer and, if Customer does not respond within [***], then decide on the disposition of the Raw Materials and consumables at Customer's cost. If Customer requests Lonza to dispose of such Raw Materials, such disposal shall be at no additional cost to Customer and Lonza shall be responsible for the handling, transport, and disposal of hazardous materials and waste generated by or on behalf of Lonza in connection with any SOW unless otherwise specified in a SOW.

2.12.4.2 Expiration of Raw Materials. Customer shall pay any associated disposal cost of Raw Materials in the event that they pass their expiry date; provided, however, that Lonza will be obligated to pay for any Raw Material costs necessary to replace inventory of Raw Materials in the Safety Stock that has expired prior to the Commencement of the next Batch to the extent that such expiration is due to a delay in the Commencement by Lonza and within its control.

2.12.4.3 Process and Material Changes. Where a process or material change request is required by a change in Applicable Law or requested by Customer or Lonza and will lead to costs for the purchase and/or disposition of Raw Materials, an estimate of the costs will be provided to Customer in writing. Upon Customer's confirmation in writing of the purchase of Raw Materials for a process or material change, Customer shall be fully liable for the disposition costs of the Raw Materials to the extent such process or material change is required by Applicable Laws or requested or approved by Customer.

2.12.4.4 Vendor Raw Material Changes. Where the vendor or supplier of a certain Raw Material makes a change to the Raw Material such that the change will result in the inability of Lonza to use the current inventories of that certain Raw Material and therefore requiring disposition of the Raw Material, Lonza and Customer will work jointly to minimize such disposition costs.

2.12.4.5 The disposition costs of Raw Materials for purposes not enumerated herein shall be negotiated in good faith between the Parties. However unless otherwise set forth in an SOW, Lonza shall be responsible, at Lonza's sole cost and expense (without reimbursement), for the generation, collection, storage, handling, transport, and release of hazardous materials and waste generated by or on behalf of Lonza in connection with any SOW unless otherwise specified in a SOW.

2.12.4.6 Mitigating Disposition Costs. Lonza agrees to use reasonable efforts to mitigate Customer's cost related to the disposition of Raw Materials and consumables costs in connection with a cancelled Batch. For clarity, Customer is never responsible for Raw Materials and consumables costs in connection with a Batch that is cancelled due to Lonza's material breach of this Agreement.

2.12.5 Specifications. Specifications will be agreed to by the Parties prior to the initiation of Services. The Parties acknowledge that during the course of the

performance of the Services the Specifications may change based upon scientific or technical considerations as mutually consented to by the Parties (such consent not to be unreasonably withheld, conditioned or delayed) and Lonza will make all commercially reasonable efforts to accommodate Customer's reasonable request(s) for changes to the Specifications.

3 Project Management and Governance

3.1 SOWs. As of the date of this Agreement, the initial SOW is set out in Appendix A. Each subsequent, SOW is and shall be incorporated and made part of this Agreement. The Parties contemplate that there shall be separate SOWs covering different projects as agreed by the Parties. Prior to commencing Services hereunder, each SOW shall be agreed by the Parties in writing and shall include a description of the Services to be provided, the Product to be manufactured, Specifications, a schedule for completion of the SOW, pricing details, and such other information as is necessary for the relevant Services. Any expenses to be reimbursed by Customer shall be specifically identified in the applicable SOW. In case of conflict between this Agreement and a SOW, this Agreement shall prevail to the extent such SOW does not expressly provide that it shall govern with respect to such conflict and specifically identifies the Clause(s) of this Agreement that such SOW intends to modify.

3.2 Modification of Statement of Work. Should either Party desire to change a Statement of Work or to include additional Services to be provided by Lonza, such Party may propose to the other Party an amendment to the Statement of Work with the desired changes or additional Services (each, a "Change Order"). Each Change Order shall detail the requested changes to the applicable task, responsibility, milestone, deliverable, fees, budget, estimated timelines or other matter (as applicable). A Change Order will become effective as an amendment to the appliable SOW upon the execution of such Change Order by both Parties' authorized representatives. For clarity, no change in the Services or Quality Agreement shall be implemented by Lonza without the prior written consent of Customer or agreement of the Steering Committee (as defined in Section 3.4) or joint project team meeting as documented in the minutes of each in each instance. If Lonza makes any Lonza-requested change without Customer's consent in accordance with a fully executed Change Order and such change results in a Failed Batch, then, without limiting Customer's other remedies under this Agreement, Lonza shall [***] reimburse Customer for its reasonable costs and expenses incurred in connection with such Failed Batch (including the cost of Customer Materials and reasonable costs paid to Third Parties for further processing of such Batch).

3.3 Project Management. With respect to each SOW, each Party will appoint a designee who will be responsible for overseeing the performance of the SOW (each, a "Project Manager"). All day-to-day communication(s) between Parties related to the performance of the Services shall be between such appointed Project Managers, unless otherwise agreed in writing between the Parties.

3.4 Steering Committee. Each Party shall name a mutually agreed upon equal number of representatives for a "Steering Committee" composed of appropriate representatives from various functional areas as determined by each Party (for example, representatives could include Manufacturing, Quality, Process and Analytical Development, Supply Chain and Business Development). The Steering Committee shall meet a minimum of [***] to be adjusted based on project needs, as determined by the Project Managers or Steering Committee. Such meetings may be held either in-person or virtually. A quorum of one representative from each Party will be required for every meeting. All decisions by the Steering Committee will be made by consensus, with one vote cast by each Party. Lonza shall be responsible for coordinating meetings, compiling meeting minutes, and circulating minutes to Steering Committee members. In the event that a Steering Committee deadlock or dispute cannot be resolved after [***], such dispute shall be escalated to a senior executive of each of Customer and Lonza. In

case such escalated dispute cannot be resolved after another [***], either Party may initiate the dispute resolution provision in Clause 16.8.

The primary function of the Steering Committee is to ensure the ongoing communication between the Parties and discuss and resolve any issues arising under this Agreement. In addition to the primary function described above, the Steering Committee shall also take on the following responsibilities:

3.4.1 discuss and seek resolution of issues around management of the Services;

3.4.2 agree and monitor deadlines and milestones for the Services; and

3.4.3 discuss and recommend any changes to the Services. However, such changes will not take effect until they have been incorporated into a written amendment to the SOW, or a new SOW, in each case which has been signed by the Parties.

3.5 Person in Plant. Subject to prior approval by Lonza in writing (not to be unreasonably withheld, conditioned or delayed), Customer shall be permitted, [***], to have [***] or, if pre-approved by Lonza, in its sole discretion, [***] at the Facility at which Services are performed as reasonably requested by Customer, at any time during the actual performance by Lonza of activities in respect of Manufacturing Process for the purpose of observing, reporting on, and consulting as to the performance of the Services. Such employees or contractors shall be subject to and agree to abide by confidentiality obligations consistent with those set forth in Clause 12 and Lonza's customary practices (to the extent consistent with industry standards), operating procedures and security procedures regarding persons in plant, as communicated in advance or on site to Customer, and any reasonable instructions of Lonza's employees at the Facility. Customer's employees or contractors at the Facility shall be and remain personnel of Customer, and Customer shall be solely responsible for the payment of compensation for such Customer employees or contractors (including, as applicable, all withholding, income and other payroll taxes, workers' compensation insurance, health insurance, and other similar statutory and fringe benefits). Customer covenants and agrees to maintain workers' compensation benefits and employers' liability insurance as required by Applicable Laws with respect to any Customer employee at the Facility.

3.6 Inspections of Inventories. On reasonable notice from Customer, Lonza shall provide a digital inventory of process specific Raw Materials, Customer Materials and Product in Lonza's control. Subject to prior approval by Lonza in writing (not to be unreasonably withheld, conditioned or delayed), Customer shall be permitted annually to have [***] or, if pre-approved by Lonza in its sole discretion, [***] at the Facility to visually inspect Customer Material and Product inventories.

3.7 Training. At mutually agreed dates and times, and as may be set forth in greater detail in a SOW and/or Quality Agreement, Customer's employees and agents (including independent contractors) (i) may conduct training of Lonza personnel, which training may occur at the Facility or at Customer's facility and (ii) will receive from Lonza initial and maintenance training regarding site-specific Facility SOPs, as may be necessary to comply with any applicable Lonza facility and/or safety policies while onsite.

4 Quality

4.1 Responsibility for quality assurance and quality control of Product shall be allocated between Customer and Lonza as set forth in the Quality Agreement. If there is a conflict between the terms and conditions of this Agreement and the Quality Agreement, the terms and conditions of this Agreement shall prevail with the exception that the Quality Agreement shall control for matters relating to quality assurance-related terms and conditions. In the event of a conflict between any of the provisions of this Agreement and the Quality Agreement with

respect to any commercial matters, including allocation of risk, liability, and financial responsibility, the provisions of this Agreement shall govern. If the Quality Agreement is not in place at the Effective Date, Lonza and Customer commit to enter into the Quality Agreement in a timely manner, but in no event later than the Commencement Date of cGMP Services.

4.2 Additional provisions regarding inspections by Regulatory Authorities and audits shall be set out in the Quality Agreement (but in no case shall the Quality Agreement reduce the scope of any inspection or audit rights otherwise provided herein or impose any fee on Customer). At Lonza's expense, Lonza will maintain all material licenses, permits and regulatory approvals for Facility and use of the Facility use to manufacture Product. Lonza will [***] notify Customer if Lonza receives notice that any such license, permit, or approval is or may be revoked or suspended.

4.3 Records. Lonza will maintain complete and accurate records for the manufacture of the Product, in accordance with, and for the time periods required by, Applicable Laws and in accordance with the Quality Agreement.

4.4 Regulatory Support.

4.4.1 On Customer's reasonable request to Lonza specifying such request is in support of a Regulatory Authority request, Lonza shall provide Customer (or such Regulatory Authorities directly) with such files and other documents in Lonza's possession regarding Lonza's manufacturing processes and procedures for Product and with such assistance and reasonable cooperation, as is reasonably necessary for Customer to comply with its obligations under Applicable Law as sponsor of clinical trials of Product, or to file or maintain Regulatory Authority approvals for Products (including providing the Batch documentation associated with any manufacturing runs and additional input as reasonably requested by Customer that may be used to support an IND filing or other regulatory submissions). If requested by Customer, Lonza shall provide regulatory writing services in support of Customer's regulatory submissions as mutually agreed in an SOW, at Lonza's then-customary rates for such activities.

4.4.2 On Customer's reasonable request to Lonza specifying such request is in support of a Regulatory Authority request, Lonza shall provide Customer with assistance and reasonable cooperation to support Customer in connection with a filing for Approval of the Product to a Regulatory Authority, and securing and maintaining such Approval. On request in writing from Customer, Lonza shall provide to Customer or directly to the Regulatory Authority, as determined by Lonza, documents and any other material and information that are reasonably requested by Customer for submission, or for use in the preparation of applications to be submitted to any Regulatory Authority for the purpose of seeking, obtaining or maintaining such Approval for Product in any country, in accordance with timelines mutually agreed by the Parties, which may require a Change Order. Further, upon Customer's reasonable request to Lonza specifying such request is in support of a Regulatory Authority request, Lonza will provide Customer with the documents reasonably requested by Customer or necessary for Customer to address an inquiry from a Regulatory Authority, which may require a Change Order. If the Manufacturing Process is performed using a Lonza proprietary process or Lonza proprietary analytical assay(s), Lonza will provide the necessary Lonza Manufacturing Process Documents and other relevant documents to the Regulatory Authority directly or the regulatory affairs department of Customer solely for the purpose of including in a filing for Approval of the Product to a Regulatory Authority or otherwise in connection with regulatory interactions or matters. If Lonza Confidential Information is reasonably necessary for Customer to include in a filing for Approval of the

Product to a Regulatory Authority, or necessary for Customer to address an inquiry from a Regulatory Authority, Lonza shall, at its sole discretion and as permitted by the Regulatory Authority, either provide the Lonza Confidential Information directly to the Regulatory Authority, provide a letter of authorization to a Lonza master file kept by the Regulatory Authority, or provide the Lonza Confidential Information under strict confidentiality to the regulatory affairs department of Customer solely for the purpose of including in a filing for Approval of the Product to a Regulatory Authority or to address an inquiry from a Regulatory Authority.

4.4.3 At a reasonable time prior to Customer's submission of any information to a Regulatory Authority related to Lonza or the Services provided under this Agreement, to the extent time reasonably permits (only if Customer has not caused any delay), Customer shall provide to Lonza, for Lonza's review, copies of the information prior to submission. In addition, Customer shall provide final versions of submitted information to Lonza within a reasonable time frame after submission to the Regulatory Authority.

5 Insurance

5.1 Each Party shall for itself and all of its applicable Affiliates obtain and maintain at its own cost and expense from a qualified insurance company,

5.1.1 comprehensive general liability insurance coverage in the amount of at least [***] (or equivalent in other tradable currency) per claim or [***] (or equivalent in other tradable currency) in the annual aggregate, during the Term and for [***] after Release of the last Product manufactured or Services provided under this Agreement;

5.1.2 products liability coverage in the amount of at least [***] (or equivalent in other tradable currency) per claim and in the annual aggregate, during the Term and for [***] after Release of the last Product manufactured or Services provided under this Agreement; and

5.1.3 employer's liability or workers compensation in the amount of at least [***] or formal equivalent per claim or the minimum amount as required by Applicable Law.

5.2 Customer shall, during the Term obtain and maintain at its own cost and expense from a qualified insurance company adequate property insurance covering the risk of loss of Customer Materials.

5.3 Each Party shall provide the respective other Party with a certificate of such insurance upon reasonable request.

5.4 Insurance limits herein may be achieved by a combination of primary and umbrella/excess liability policies.

5.5 Nothing contained within this Clause shall limit a Party's liability under this Agreement.

6 Forecasting, Ordering and Cancellation

6.1 Forecasting. Unless otherwise specified in an Appendix hereto, no later than [***], Customer shall use commercially reasonable efforts to supply Lonza with a written forecast showing Customer's good faith estimated quarterly requirements for cGMP Batches for the following [***] period (the "Forecast"). No later than [***] following Lonza's receipt of a Forecast, Lonza shall provide written notice to Customer of whether it has (as of the date of issue of such response to the Forecast) capacity available to manufacture the number of cGMP

Batches forecasted therein and shall provide Customer with an estimated production schedule showing the estimated Commencement Date and delivery date of each cGMP Batch. The Forecast and notice of available capacity given in this Clause 6.1 shall not be binding on Customer or Lonza and Lonza shall not be required to reserve any capacity for Customer based on such Forecast. See Appendix B for Autologous Cell Therapy that shall replace this section for any Autologous Cell Therapy programs with Lonza and Customer.

6.2 Binding Purchase Orders. Unless otherwise specified in an Appendix hereto or in an SOW, Customer shall place purchase orders binding on Customer for the number of cGMP Batches it wishes to order, at least [***] (or earlier as may be agreed by Customer in its sole discretion after being reasonably requested by Lonza) prior to the Commencement Date for such cGMP Batches in accordance with Lonza's most recent response to the Forecast but subject always to available capacity at the applicable time. Lonza shall use commercially reasonable efforts to accept such purchase order (subject to available capacity), and at the point of such acceptance by Lonza, it shall be regarded as a "Binding Purchase Order". Each Binding Purchase Order shall be signed by an authorized representative of Customer and shall authorize Lonza to manufacture such cGMP Batches of the Product as are set forth therein. Any delivery date set forth in Lonza's written confirmation of a Binding Purchase Order shall be an estimate delivery date only. Any additional or inconsistent terms or conditions of any Lonza response or any Customer purchase order, acknowledgement or similar standardized form given or received pursuant to this Agreement shall have no effect and such terms and conditions are hereby rejected. See Appendix B for Autologous Cell Therapy that shall replace this section for any Autologous Cell Therapy programs with Lonza and Customer.

6.3 Minimums. If specified in an SOW, Customer undertakes to purchase from Lonza Monthly Minimum Batch Commitment as further defined and subject to the conditions set forth in the SOW. Unless otherwise specified in a SOW, if Customer fails to purchase the requisite number of Batches in such Monthly Minimum Batch Commitment in such month, Customer shall have the following options:

*** If the Customer cannot utilize a planned cGMP batch, this slot can be converted to an Engineering Batch with [***] written notice at the price indicated in the appliable SOW for such Engineering Batch; or**

*** Choose to not convert the cGMP batch to an Engineering Batch and pay for the missed slot.**

If a Monthly Minimum Batch Commitment is set forth in any SOW, Customer may not cancel a batch pursuant to Section 6.5.4 to avoid purchasing the requisite number of Batches in such Monthly Minimum Batch Commitment in such month. If Customer does cancel a Batch such that the Monthly Minimum Batch Commitment in such month is not achieved, a Cancellation Fee of [***] of the Price of each such cGMP Batch cancelled is payable.

For the avoidance of doubt Customer may also separately propose that Lonza perform additional Engineering Batches (beyond those to be performed during actual manufacturing gaps per the above), in which case Lonza shall use commercially reasonable efforts to schedule such Engineering Batch. See Appendix B for Autologous Cell Therapy that shall replace this section for any Autologous Cell Therapy programs with Lonza and Customer.

6.4 Customer Delay.

6.4.1 Subject to the terms of this Agreement (including Clause 14 (Force Majeure)) and the Technology Transfer Agreement, Customer shall be responsible for any delays in the Services and for all additional costs and expenses (including any disposition of Raw Materials under Clause 2.12.4 and the expiry of Raw Materials resulting from the delay) arising out of any delay. If

Customer requests a delay and if Lonza using commercially reasonable efforts is unable to accommodate rescheduling of the Service or Batch, such will constitute a cancellation of such Batch and, in such case, Customer shall pay Cancellation Fees to Lonza, calculated as if Customer had cancelled such Service or Batch as at the date by which such Service or Batch was set to be performed or Customer should have provided the Manufacturing Process, Customer Confidential Information, Cell Line (if applicable) and/or Customer Background Intellectual Property to Lonza, as a result of Customer's failure to provide the Manufacturing Process, Customer Confidential Information, Customer Background Intellectual Property and any other information or materials that may be reasonably required by Lonza to perform the Services.

6.4.2 If the Customer requests to change the Commencement Date, Lonza shall use commercially reasonable efforts to accommodate the request, but Lonza shall not have any obligation to accept such request. Any such change requested by Customer may result in a mutually agreed reasonable change charge to be documented in a Change Order. Any delay by Customer of more than [***] may be considered a cancellation pursuant to Clause 6.5 and subject to a Cancellation Fee.

See Appendix B for Autologous Cell Therapy that shall replace this section for any Autologous Cell Therapy programs with Lonza and Customer.

6.5 Cancellation of Services. Customer may cancel Services, including production of a Batch to be manufactured under a SOW, upon written irrevocable (unless agreed to in writing by Lonza) notice to Lonza, subject to Customer's obligation to pay for all Services rendered up to the date of notice of cancellation, plus the payment of a cancellation fee as set forth in the applicable SOW, or as calculated below unless otherwise set forth in the SOW (the "Cancellation Fee"). In any case, no Cancellation Fee will be owed in the event that Customer cancels any Services due to Lonza's material breach of this Agreement. Any amounts prepaid by Customer for any Services shall be deducted from any Cancellation Fee payable for such Services. See Appendix B for Autologous Cell Therapy for a discussion regarding a Ramp Down Fee which may be applied separately to any Cancelation Fee.

6.5.1 Development Services. If Customer provides written notice of cancellation of any Development Services, Customer shall pay for any of the cancelled Development Services Lonza performed prior to the date of notification of cancellation and for any of such cancelled Development Services which would (were it not for the cancellation) have been performed during the period of [***] post-cancellation notification.

6.5.2 Pilot Batch(es). If Customer provides written notice of cancellation of any Pilot Drug Product Batch less than or equal to [***] prior to the Commencement Date of such Pilot Drug Product Batch or at any time thereafter, then a Cancellation Fee of [***] of the Price of each such Pilot Drug Product Batch(es) cancelled is payable. If Customer provides written notice of cancellation of any Pilot Batch at least [***] prior to the Commencement Date, then no Cancellation Fee is owed.

6.5.3 Engineering Batch: If Customer provides written notice of cancellation to Lonza of an Engineering Batch,

6.5.3.1less than or equal to [***] prior to the Commencement Date of such Engineering Batch or at any time thereafter, then a Cancellation Fee of [***] of the applicable Price of each such Batch cancelled is payable;

6.5.3.2more than [***] prior to the Commencement Date of such Engineering Batch, then no Cancellation Fee is payable.

6.5.4 cGMP Batches. If Customer provides written notice of cancellation of a cGMP Batch to Lonza:

6.5.4.1 less than or equal to [***] prior to the Commencement Date of one or more such cGMP Batch or at any time after, then a Cancellation Fee of [***] of the Price of each such cGMP Batch cancelled is payable;

6.5.4.2 more than [***] prior to the Commencement Date of one or more cGMP Batches, then [***] is payable.

6.6 Payment of Cancellation Fee. Any Cancellation Fee payable under Clause 6.5 and amounts payable pursuant to Clause 6.7 shall be payable within [***] following Customer's receipt of an invoice or as otherwise mutually agreed in writing by the Parties following the written notice of cancellation associated with the cancelled Service or Batch.

6.7 Additional Costs. In addition to any Cancellation Fee, Customer shall pay for any otherwise unpaid costs associated with the cancelled Service and/or Batch that Lonza has, through the date of cancellation, incurred, or is irrevocably committed to pay to a Third Party in accordance with the terms of this Agreement and applicable SOW, including, without limitation, [***]. For clarity, Customer is never responsible for the foregoing costs in connection with a Services or Batches that are cancelled due to Lonza's material breach of this Agreement.

6.8 Replacement Project. Notwithstanding the foregoing, following the cancellation of a Batch, Lonza shall use commercially reasonable efforts to secure an equivalent replacement project (which shall exclude any batch associated with a binding purchase order, project then under contract with Lonza, or additional batches which are ordered within the framework of such existing contracted project) for the manufacturing space, and for the same dates and duration that would have been occupied by Customer. In the event that Lonza is able to (or would be able to if using commercially reasonable efforts) secure an equivalent replacement project, then the Cancellation Fee to be paid by the Customer for the cancelled Batch shall be reduced by an amount equal to the amount paid for such replacement project.

7 Customs, Delivery, and Acceptance

7.1 Packaging and Shipping. Lonza will package and label the Product for shipment in accordance with the Master Batch Record, the Quality Agreement and, to the extent applicable and as agreed in advance by Customer, Lonza's SOPs in effect at the time of performance by Lonza. Lonza shall release the Product for delivery by supplying to Customer the Certificate of Analysis, the Certificate of Compliance and such other documentation defined in the Quality Agreement as is reasonably required to meet all applicable regulatory requirements of the Regulatory Authorities (except in the case of Pilot and Engineering Batches, in which case Lonza may release the Product by issuing a written notice of release to Customer and including a Certificate of Testing for Engineering Batch(es) and test results for Pilot Batch(es)) (the "Release") not later than the date of the Delivery (as defined below) of Product. Customer shall provide a ship-to address within [***] of release notification. Unless otherwise agreed in a SOW, Lonza shall deliver the Product Free Carrier (FCA) (Incoterms® 2020) at the applicable Facility cleared for export and loaded onto any collecting vehicle by Lonza ("Delivery"). Lonza shall [***] inform Customer if Lonza reasonably believes that it shall be unable to meet a delivery date.

7.2 Transfer of Title and Risk of Loss.

7.2.1 Product. Title in the Product shall pass to Customer upon Release in accordance with Clause 7.1. When there are no additional Lonza Services for such Product, risk of loss shall remain with Lonza until the earlier of (a) Delivery to Customer and (b) [***] after Release.

7.2.2 Customer Materials. With respect to any Customer Materials, title and risk of loss shall remain with the Customer throughout Services and shall not transfer to Lonza. Notwithstanding the foregoing and subject to the Materials Cap, Lonza shall be responsible for loss, damage or destruction to Customer Materials when in Lonza's (or its Affiliates' or Subcontractors') possession or control prior to the use in manufacturing to the extent such loss or damage is attributable to negligence or willful misconduct. For clarity, Lonza's responsibility for Customer Materials during the manufacture of Product is set forth in Section 7.5 hereof and Lonza's responsibility for Customer Materials in connection with a Failed Batch are set forth in Section 7.4.3 hereof.

7.3 Storage. Lonza will arrange for shipment or storage on Customer's behalf. Customer shall take Delivery of such Product from the Facility, at Customer's expense, within [***] after Release or pay applicable storage costs. Lonza shall provide storage for such Product (and [***] for any unused Customer Materials that are not going to be used in subsequent Services at no charge for up to [***] after Release. Any additional storage beyond [***] and up to a maximum of [***] after Release will be subject to availability and subject to storage fees at Lonza's then-current storage rate. Notwithstanding anything to the contrary contained in this Agreement, in no event shall Lonza be required to store any Product (or other Customer Materials) for more than [***] after Release. Lonza will at all times label (or otherwise designate) the Product and Customer Materials as the property of Customer. Lonza shall keep the Product and Customer Materials free and clear of all claims, encumbrances, and liens. Lonza will store all Product and Customer Materials in a safe and environmentally controlled manner in accordance with the Quality Agreement, Customer's reasonable instructions, and Applicable Laws and will notify Customer as soon as reasonably practical following any destruction, damage or loss of such materials.

7.4 Acceptance/Rejection of Product.

7.4.1 Promptly following Release of a Batch, Customer or its designee will have the right to inspect and test such Batch to determine compliance with cGMP, and the Specifications, to the extent that such Batch is required pursuant to this Agreement or the applicable SOW to meet cGMP and/or achieve the Specifications (and whether or not the Batch was actually shipped to Customer or was stored at Lonza or shipped to another Lonza Facility). Customer shall notify Lonza in writing of any rejection of a Batch that was required to meet cGMP and/or achieve Specification, based on any claim that it fails to meet cGMP and/or achieve Specifications, as applicable, within [***] of Release, after which time all unrejected Batches shall be deemed accepted. The foregoing does not prohibit Customer from rejecting an already-accepted Batch due to a latent defect so long as Customer notifies Lonza of the rejection within the earlier of (i) [***] at the latest following Customer's discovery of the latent defect and (ii) [***] of Release. For clarity, payment for Product by Customer shall not constitute acceptance thereof.

7.4.2 In the event that Lonza believes that a Batch has been incorrectly rejected, Lonza may require that Customer provide to Lonza, at Lonza's cost, Batch samples for testing so long as Lonza notifies Customer of the same within [***] after receipt of notice of rejection, after which time Lonza shall have waived its right to challenge the rejection. Lonza may retain and test the samples of such Batch. In

the event of a discrepancy between Customer's and Lonza's test results such that Lonza's test results fall within relevant Specifications, or there exists a dispute between the Parties over the extent to which such failure is attributable to a given Party, the Parties shall cause an independent laboratory [***] to review records, test data and perform comparative tests and/or analyses on samples of the Product that allegedly fails to conform to Specifications. Such independent laboratory shall be mutually agreed upon by the Parties. The independent laboratory's results shall be in writing and shall be final and binding save for manifest error. Expenses of such laboratory testing and review shall be borne by the Party whose position is determined to have been in error or, if the laboratory cannot place the fault noticed and complained about, then the Parties shall share equally the expenses of the laboratory.

7.4.3 Lonza shall, at its expense and at Customer's sole discretion, either replace or credit Customer for any Batch that was required by this Agreement to have met cGMP and/or achieved the Specifications but that failed to conform with the Specifications and/or meet cGMP (a "Failed Batch"), provided that it is determined (by the Parties or the independent laboratory) that such failure was due to a Lonza Responsibility. Such replacement, if elected by Customer, shall be made [***], subject always to available manufacturing capacity, and in any case as soon as reasonably possible after confirmation of Lonza Responsibility. In the event Customer requests replacement of the Failed Batch, any amount Customer paid towards the Failed Batch, inclusive of the cost of Raw Materials (up to the Materials Cap), shall be credited to the cost of such replacement Batch. Lonza shall replace, or, at Customer's sole discretion, credit, Customer for Raw Materials, including, without limitation, Customer Materials, used in a Failed Batch up to [***] ("Materials Cap"). The Material's Cap may be modified in an SOW if explicitly set forth therein. Customer shall provide Lonza reasonable documentation regarding the cost of any Customer Materials that are sought for reimbursement or credit.

7.4.4 Where possible (subject to available manufacturing capacity), such replacement Batch shall be manufactured with the next scheduled cGMP Batch. Any Failed Batch shall have no negative impact on Customer's satisfaction of the Monthly Minimum Batch Commitment, meaning that each Batch ordered by Customer, regardless of any subsequent Batch failure, shall be counted towards the Monthly Minimum Batch Commitment (but, for clarity, any replacement Batch shall not be counted towards the Monthly Minimum Batch Commitment). Other than (i) if due to gross negligence or intentional breach; or (ii) in the case of Persistent Supply Failure for which Customer shall have the right to terminate pursuant to Clause 13.2.3, Customer acknowledges and agrees that its sole remedy with respect to a Failed Batch that is a Lonza Responsibility is as set forth in Clause 7.4.3, and in furtherance thereof, Customer hereby waives all other remedies at law or, if relevant, in equity regarding the foregoing claims. Clause 7.4.3 shall always be subject to the provisions of Clauses 11.4 and 11.5. The Parties further agree that in the event that any Batch is a Failed Batch and such failure is primarily caused by any defect in any Customer Confidential Information, Customer Material, Customer Background Intellectual Property, and/or any other information, material or Intellectual Property supplied by or on behalf of the Customer, then Lonza shall not have any liability with regard to such Failed Batch.

7.4.5 Except with respect to Engineering Batches as set forth in Section 2.9 hereof, any Batch that is not required by this Agreement or a SOW to meet Specification or cGMP may not be rejected by Customer and Lonza shall not have any replacement obligations in respect thereto, unless such Batch fails to satisfy its mutually agreed acceptance criteria as set forth in the applicable SOW and it is

agreed by the Parties or determined by a mutually agreed upon independent laboratory to the extent caused by the gross negligence or willful misconduct of Lonza or its Affiliates or Subcontractors.

7.5 Damage, Loss or Destruction of Material.

7.5.1 If during the manufacture of Product, Materials are lost, destroyed or damaged by Lonza personnel (or personnel of its Affiliates, Subcontractors or External Laboratories), and such loss, damage or destruction was caused by a Lonza Responsibility, then, except as provided in Sections 7.5.2 or 7.5.3 below, Lonza shall be responsible for any loss, damage or destruction to the materials used or necessary for the Services or for the manufacturing of the Product, including but not limited to Raw Materials, work-in-progress, and Customer Materials (collectively, "Materials"), that occurs while such Materials are under Lonza's custody or control or the custody or control of an Affiliate, Subcontractor or External Laboratory.

7.5.2 Unless otherwise set forth in an SOW, Customer acknowledges and agrees Lonza's limit of liability for destruction, loss or damage caused by a Lonza Responsibility to the Materials of the Customer, including Customer Materials, in relation to a Batch of Product will not exceed the Materials Cap on a per Batch basis. Customer acknowledges and agrees that its sole remedy with respect to damaged, lost or destroyed Materials as set forth above in this Section 7.5, and in furtherance thereof, Customer hereby waives all other remedies at law or, if relevant, in equity regarding the foregoing claims.

7.5.3 Notwithstanding anything to the contrary set forth in the preceding Section 7.5.1, if during the manufacture of Product pursuant to an SOW, Materials are destroyed, lost or damaged by Lonza personnel (or personnel of its Affiliates, Subcontractors or External Laboratories) as a result of such personnel acting at and in accordance with the specific, documented direction of Customer, then Lonza will have no liability to Customer as the result of such destruction, loss or damage.

8 Price and Payment

8.1 Pricing. Customer shall pay for all of the Services hereunder in accordance with the terms and conditions hereof. Pricing for the Services provided by Lonza are set out in the applicable SOW. Unless otherwise set forth in a SOW and unless there are material Manufacturing Process changes or scope changes, Prices are firm and cannot change unless agreed in writing. In the event of changes to the Services based on Customer's request, any change to cost must be documented and mutually agreed in writing through a Change Order.

8.2 Raw Materials and Handling Fees. In addition to Clause 8.1, as set forth in the applicable SOW, Customer shall also pay for all Raw Materials, single use bags, and consumables ordered or irrevocably committed to be procured by Lonza, and the applicable Handling Fees for the Services, manufacture of Batches and to meet the Safety Stock requirements in accordance with the Agreement.

8.3 Taxes. Unless otherwise indicated in writing by Lonza, all Prices and charges are exclusive of value added tax (VAT) and of any other applicable Taxes and fees of whatever nature imposed by or under the authority of any government or public authority and all such charges applicable to the Services shall be paid by Customer.

8.4 Invoicing.

8.4.1 Unless otherwise stated in the applicable SOW, Lonza shall issue invoices to Customer for (i) [***] of the Price for Services upon commencement of the applicable Stage of Work and (ii) [***] upon completion of applicable Stage of Work.

8.4.2 Unless otherwise stated in the applicable SOW, Lonza shall issue [***] invoices for Batches. In the event the Batches are ordered under a suite fee / production fee model per the SOW the suite fee and production fee will be invoiced [***] for the production. Unless otherwise stated in the applicable SOW, charges for Lonza-Procured Materials (and any applicable Handling Fee) for each Batch shall be invoiced upon the receipt of materials or ordering, unless otherwise agreed in the applicable SOW. Unless otherwise agreed in the applicable SOW, all invoices are strictly net and payment must be made within [***] of date of receipt. Until such time that Lonza receives payment in full for each Batch and any other deliverable, Lonza shall maintain a security interest or pledge in such Batch and other deliverable for which the payment has not been received in full. Payment shall be made without deduction, deferment, set-off, lien or counterclaim, except that Customer may withhold disputed amounts in the event of a good faith dispute. In the event of a payment dispute, Customer shall nevertheless pay the undisputed portion of the applicable invoice and the Parties will work reasonably and in good faith to resolve the dispute as quickly as possible. When sending payment to Lonza, the Customer shall quote the relevant invoice number in its remittance advice. See Appendix B for Autologous Cell Therapy that shall replace this section for any Autologous Cell Therapy programs with Lonza and Customer.

8.5 Interest. If Customer is in default of payment of any undisputed invoice on the due date, interest shall accrue on any amount overdue at the lesser of (i) a rate of [***] per month, payable on demand; or (ii) the maximum interest rate allowable by the governing law of this Agreement. Interest shall accrue on undisputed amounts from the date when the same was due and payable until full payment. In the event payment for any for any undisputed amount or any amount not disputed in good faith remains outstanding more than [***] beyond receipt of the invoice, Lonza shall, at its sole discretion, and without prejudice to any other of its accrued rights to the extent such a right is available under applicable state contract law, be entitled to suspend the provision of the Services and or delivery of Product until all overdue or disputed amounts have been paid in full including interest for late payments and Customer shall be liable for any and all costs incurred by Lonza from any such delay to the Services unless otherwise agreed in the SOW.

8.6 Price adjustments.

8.6.1 Annual Price Increase. Not more than [***] following the first anniversary of the Effective Date, and upon [***] prior notice, Lonza may adjust the Price in accordance with the lesser of (i) [***] or (ii) the increase in the US CPI-U published by the United States Bureau of Labor Statistics in effect for the last month available before Lonza's notice of adjustment compared to the index value for the month immediately preceding the Effective Date or the index value applicable for the last price adjustment. The new Price reflecting such Batch Price adjustment shall be effective for any Batch for which the Commencement Date is on or after the effective date of Lonza's notice to Customer of the Price adjustment.

8.6.2 Exceptional Price Increase. In addition to the above, the Price may be changed by Lonza, upon reasonable prior written notice to Customer (providing reasonable detail in support thereof), to reflect (i) an increase in out-of-pocket costs (such as energy or to procure Raw Materials by more than [***] based on

the cost to procure such item as of the date of the latest amended Price); and (ii) any material change in an environmental, safety or regulatory standard that substantially impacts Lonza's cost and ability to perform the Services subject to Lonza using commercially reasonable efforts to minimize the impact to Customer.

8.6.3 Capital Equipment. Unless otherwise agreed in a SOW, any Capital Equipment required to be acquired for the performance of the Services shall be owned, and managed by, Lonza and the Parties shall mutually agree on any related expenses in an SOW, including for example any applicable decommissioning fees or expenses. Other terms on procurement of equipment may be agreed by the Parties prior to commencement of the relevant Services. The Parties shall notify each other in writing as early as possible and sufficiently in advance in the event that a Party foresees such purchase requirement.

9 Intellectual Property

9.1 Background Intellectual Property; No Implied License. Except as expressly otherwise provided herein, neither Party nor its Affiliates will, as a result of this Agreement, acquire any license, right, title, interest in or to, any Background Intellectual Property of the other Party. Neither Party shall acquire any right, title or interest in any of the trademarks, service marks or logos belonging to the other Party. No right or license, whether express or implied, is granted to one Party by the other Party, except to the extent expressly authorized by this Agreement.

9.2 Ownership of Customer-Provided Information. All Customer-Provided Items provided to Lonza by or on behalf of Customer in connection with this Agreement, in any form whatsoever, shall remain the sole and exclusive property of Customer. Lonza will not acquire any right, title or interest in such Customer-Provided Items as a result of its performance of the Services and shall use such Customer-Provided Items solely as necessary to perform the Services. Lonza agrees it will not use or evaluate the Customer-Provided Items, or any portions thereof, for any purpose except as directed or permitted in writing by Customer. Without Customer's prior written consent or as otherwise explicitly set forth in a SOW, Lonza agrees that it will not analyze or reverse engineer the Customer-Provided Items, or transfer or make Customer-Provided Items available to Third Parties (other than External Laboratories or Subcontractors as agreed to in any SOW).

9.3 New Intellectual Property Ownership

9.3.1 Customer Ownership. Subject to Section 9.3.2, Customer shall own all right, title, and interest in and to any and all Intellectual Property that Lonza and its Affiliates, Subcontractors, External Laboratories or other contractors, or agents develops, conceives, invents, first reduces to practice, or makes, solely or jointly with Customer or others, that to the extent the same is a direct derivative of or improvement to a Product, Customer Background Intellectual Property, Customer Material, or Manufacturing Process, and to the extent that it does not include or disclose any Lonza Confidential Information or Lonza Background Intellectual Property (collectively, and in all cases including all Intellectual Property that would constitute a new COMPANY Intellectual Property (as such term is defined in the Technology Transfer Agreement), the "New Customer Intellectual Property"). Customer is not permitted to include or disclose Lonza Confidential Information, including Lonza Background Intellectual Property, when seeking protection for, or exploiting New Customer Intellectual Property, without prior written consent from Lonza, not to be unreasonably conditioned, delayed or withheld. For avoidance of doubt, New Customer Intellectual Property shall include any material, processes, or other items to the extent the

same directly embody, or are claimed or covered by, any of the foregoing Intellectual Property, but excluding any New General Application Intellectual Property as defined below. For clarity, New Customer Intellectual Property shall exclude Lonza Intellectual Property and no right, title or ownership of any Lonza Intellectual Property is granted to Customer for it to use the New Customer Intellectual Property or otherwise, except to the extent explicitly stated in this Agreement.

9.3.2 Lonza Ownership. Notwithstanding Clause 9.3.1, and subject to the licenses granted herein by Lonza, Lonza shall own all right, title, and interest in Intellectual Property that Lonza and/or its Affiliates, Subcontractors, External Laboratories or other contractors, or agents, solely or jointly with Customer, develops, conceives, invents, or first reduces to practice or makes in the course of performance of the Services that (i) is generally applicable to the development or manufacture of chemical or biological products or product components and is not specific to a Product, and the use or practice of which would not require the use or disclosure of any Customer-Provided Items; or (ii) is an improvement of, or direct derivative of, any Lonza Background Intellectual Property (collectively, "New General Application Intellectual Property"). For avoidance of doubt, New General Application Intellectual Property shall include any material, processes, or other items to the extent the same embody, or that are claimed or covered by, any of the foregoing Intellectual Property.

9.3.3 Lonza shall not incorporate any Lonza Background Intellectual Property (or any other Intellectual Property of Lonza or its Affiliates, including any Lonza New General Application Intellectual Property) into a Product or Manufacturing Process without Customer's prior consent and mutual agreement on any fee that would be owed in connection with a corresponding technology transfer. To the extent any such Lonza Background Intellectual Property or other Intellectual Property of Lonza or its Affiliates is incorporated into a Product or Manufacturing Process without Customer's prior consent, then Lonza hereby grants to Customer a royalty-free and fully paid-up license solely to the extent necessary for Customer to use, sell, offer to sell, make, have made, and import the Product using such Lonza Background Intellectual Property, other Intellectual Property of Lonza or its Affiliates including any Lonza New General Application Intellectual Property or Lonza Confidential Information.

9.3.4 If Customer provides consent to allow Lonza to incorporate Lonza Background Intellectual Property, Lonza New General Application Intellectual Property or Lonza Confidential Information into the Manufacturing Process (thereafter known as an "Improved Product Manufacturing Process"), then Customer and Lonza shall in good faith agree in writing to an Intellectual Property fee at the time of such incorporation of Lonza Background Intellectual Property, Lonza New General Application Intellectual Property or Lonza Confidential Information into the Manufacturing Process.

9.3.5 Lonza is not permitted to, and shall not, in seeking protection for, or exploiting, New General Application Intellectual Property, disclose Customer Confidential Information, without prior written consent from Customer, not to be unreasonably conditioned, delayed or withheld. For clarity, New General Application Intellectual Property shall exclude Customer Intellectual Property and no right, title or ownership of any Customer Intellectual Property is granted to Lonza for it to use the New General Application Intellectual Property or otherwise, except to the extent explicitly stated in this Agreement.

9.4 Assignment of New Intellectual Property.

9.4.1 Assignment to Customer. Lonza shall, and shall cause its Affiliates, Subcontractors, External Laboratories or other contractors or agents and their personnel involved in the performance of the Services to, [***] disclose to Customer in writing all New Customer Intellectual Property. Lonza hereby assigns to Customer all of its right, title and interest in any New Customer Intellectual Property. Lonza shall execute, and shall require its personnel as well as its Affiliates, Subcontractors, External Laboratories or other contractors or agents and their personnel involved in the performance of the Services to execute, any documents reasonably required to confirm Customer's ownership of the New Customer Intellectual Property, and any documents required to apply for, maintain and enforce any patent or other right in the New Customer Intellectual Property.

9.4.2 Assignment to Lonza. To the extent that Customer has or obtains any rights, title or interest in New General Application Intellectual Property, Customer hereby assigns to Lonza all of its right, title and interest in any New General Application Intellectual Property. Customer shall execute, and shall require its personnel as well as its Affiliates, or contractors or agents and their personnel involved in the performance of the Services, to execute, any documents reasonably required to confirm Lonza's ownership of the New General Application Intellectual Property, and any documents required to apply for, maintain and enforce any patent or other right in the New General Application Intellectual Property.

9.5 Prosecution of Patents.

9.5.1 Subject to the following subsection, Customer shall have the sole right and discretion whether or not to file, prosecute and maintain patent applications and patents claiming the New Customer Intellectual Property, at Customer's expense. Lonza shall reasonably cooperate with Customer, at Customer's expense, to the extent that Lonza's cooperation is necessary or reasonably useful for Customer to file, prosecute, maintain, defend, and enforce patent applications and patents claiming any New Customer Intellectual Property.

9.5.2 Unless the Parties agree otherwise, at least [***] prior to filing any application disclosing or claiming any New Customer Intellectual Property, Customer shall provide a draft thereof to Lonza, for Lonza's prior review. Within [***] of receipt of such an application ("Review Period"), Lonza shall notify Customer of any Lonza Confidential Information, Lonza Background Intellectual Property or New Lonza Intellectual Property and Customer shall delete the information that Lonza has identified as Lonza Intellectual Property or Confidential Information contained therein and Lonza shall approve of such revised draft (such approval not to be unreasonably delayed, conditioned or withheld). Subject to the following subsection, Lonza shall have the sole right and discretion whether or not to file, prosecute and maintain patent applications and patents claiming the New General Application Intellectual Property, at Lonza's expense. Customer shall reasonably cooperate with Lonza, at Lonza's expense, to file, prosecute, maintain, defend, and enforce patent applications and patents claiming any New General Application Intellectual Property, to the extent that Customer's cooperation is necessary or reasonably useful for Lonza to file, prosecute, maintain, defend, and enforce patent applications and patents claiming any New General Application Intellectual Property.

9.5.3 Unless the Parties agree otherwise, at least [***] prior to filing any application disclosing or claiming any New General Application Intellectual Property, Lonza shall provide a draft thereof to Customer, for Customer's prior review and

approval, not to be unreasonably conditioned, delayed or withheld. Within [***] of receipt of such an application, Customer shall notify Lonza of any Customer Confidential Information or New Customer Intellectual Property and Lonza shall delete identified Customer Confidential Information and New Customer Intellectual Property.

9.6 License Grants.

9.6.1 In addition to the license grants described above, and so long as Customer is not in breach of this Agreement in a manner that would permit Lonza to terminate the Agreement (so, for example, subject to any applicable cure periods), Lonza hereby grants to Customer, solely to the extent necessary for Customer to use, sell, offer to sell, import, and otherwise commercialize or exploit Products or other products manufactured under this Agreement and other products that are derivatives or modifications of the Products using the Manufacturing Process ("Other Customer Products") and subject to the terms and conditions set forth herein, a non-exclusive, world-wide, royalty-free, fully paid-up, perpetual, irrevocable license, including the right to grant sublicenses through multiple tiers, under the Lonza Background Intellectual Property and New General Application Intellectual Property. Customer will [***] provide notice to Lonza of the identity of any such sublicensee under any tier and the territory in which any such sublicense is granted. Customer shall ensure that any and all sublicensees comply with the terms and conditions of this Agreement.

9.6.2 Subject to this Agreement, Customer hereby grants Lonza the non-exclusive, non-transferrable and non-sublicensable license to use (or permit its Affiliates, permitted Subcontractors, and External Laboratories use on Lonza's behalf to the extent the same would not require a sublicense under any Intellectual Property rights of Lonza) the Customer-Provided Items, Customer Background Intellectual Property used or disclosed by Customer in connection with this Agreement, and New Customer Intellectual Property, in each case during the Term solely for the purpose of fulfilling Lonza's obligations under this Agreement.

9.7 Technology Transfer to Customer or Third Party. Customer will have an irrevocable right to transfer the Manufacturing Process, and Lonza shall transfer the Manufacturing Process [***] upon Customer's request, to Customer and/or any Third Party designated by Customer in writing for the manufacture of Products (and any Other Customer Products) (the "Technology Transfer"). Lonza shall provide reasonably necessary documents to complete such Technology Transfer and Customer shall reimburse Lonza for reasonable costs (based on a full-time employee rate for such support) and expenses incurred in connection therewith.

10 Representations and Warranties

10.1 Lonza represents and warrants that:

10.1.1 it has the necessary corporate authorizations, and the full power and right, to enter into and perform this Agreement, and there are no outstanding agreements, assignments, licenses, encumbrances or rights of any kind that would prevent its performance under this Agreement;

10.1.2 to the best of Lonza's knowledge, the conduct and the provision of the Services, excluding the use of Customer-Provided Items, will not infringe, misappropriate or violate (as the case may be) any Intellectual Property rights of any Third Party;

10.1.3 it shall [***] notify Customer in writing if it receives or is notified of a formal written claim from a Third Party alleging that (i) the Services under this Agreement or any activity directly impacting the Product; or (ii) any Lonza Confidential Information, Lonza Background Intellectual Property, or New General Application Intellectual Property, as it relates to the Services under this Agreement, infringes, misappropriates, or violates (as the case may be) any intellectual property rights of any Third Party;

10.1.4 the Services shall be performed in a professional and workmanlike manner and in accordance with Applicable Laws and the terms of this Agreement, and shall not be performed in violation of any agreement, judgment, order or decree to which Lonza is a party;

10.1.5 it has not granted, and will not grant during the Term, any option, lien, license to any Third Party that conflict with the Intellectual Property rights granted to Customer hereunder;

10.1.6 if paid for in full by Customer, all deliverables to Customer (including, for clarity, any Product) will be transferred to Customer free and clear of any liens or encumbrances;

10.1.7 except with respect to any Development Services, Pilot Batches, and Engineering Batches (which, unless otherwise agreed in an SOW, are not required by this Agreement to be performed in accordance with cGMP and achieve the Specifications), the manufacture of Product shall be performed in accordance with cGMP and will meet the Specifications at the date of delivery;

10.1.8 it or its Affiliates hold all necessary permits, approvals, consents and licenses (excluding any licenses related to the Product) required to operate the Facility and perform the Services, except to the extent that failure to maintain such permits, approvals, consents and licenses do not have a material adverse impact on the ability to manufacture the Product in the Facility or perform the Services;

10.1.9 it has never been, and to its knowledge, will not employ, contract with or retain any person to perform Services under this Agreement if such person is, debarred under the Generic Drug Enforcement Act of 1992, 21 U.S.C. Sec. 335a (a) or (b) (the "Act"). If during the Term Lonza becomes debarred, suspended, excluded, sanctioned, or otherwise declared ineligible under the Act, Lonza will immediately notify Customer. If Lonza becomes debarred, suspended, excluded, sanctioned, or otherwise declared ineligible under the Act, it shall [***] cease all activities relating to this Agreement. If Lonza becomes aware of or receives notice that any person employed or retained by Lonza who is involved in the provision of the Services (i) comes under investigation for a debarment action, (ii) is debarred, or (iii) engages in any conduct or activity that could lead to a debarment action, Lonza shall [***] notify Customer;

10.1.10 as of the Effective Date it is not a party to any litigation, arbitration, or mediation, and is not in receipt of any warning letter from a Regulatory Authority, involving the research, development, or commercialization of pharmaceutical products that is reasonably expected to have an adverse impact on Lonza's performance of this Agreement, and Lonza will [***] notify Customer in the event Lonza becomes a party to any such litigation, warning letter, arbitration or mediation;

10.1.11 its employees, consultants, contractors, and other personnel assigned

to perform Services hereunder have agreed in writing to confidentiality obligations no less stringent than the ones set forth in this Agreement and are obligated to assign all Intellectual Property rights arising within the scope of their employment or engagement by Lonza to Lonza (and, for clarity, any such rights in New Customer Intellectual Property shall be assigned to Customer through Lonza hereunder); and

10.2 Customer represents and warrants that:

10.2.1 it has the necessary corporate authorizations, and the full power and right, to enter into and perform this Agreement, and there are no outstanding agreements, assignments, licenses, encumbrances or rights of any kind, that would prevent its performance under this Agreement;

10.2.2 to the extent so specified in the applicable SOW, all Customer Materials supplied by Customer shall be provided with a Certificate of Analysis or other relevant documentation as may be defined in the Quality Agreement demonstrating that, to the best of Customer's knowledge at the time of shipment, such Customer Materials meet the following Lonza acceptance criteria: (i) they are not contaminated; (ii) excluding any Customer Materials that are apheresis materials, test negative for mycoplasma and bioburden (if applicable); (iii) have been manufactured in accordance with cGMP (if applicable); (iv) are free from all liens, charges, or encumbrances (for clarity an outstanding non-overdue invoice owed to a vendor in the ordinary course of Customer Materials does not constitute a lien, charge, or encumbrance); and (v) meet other testing requirements and/or specifications as may be agreed in writing by the Parties;

10.2.3 all Customer Materials supplied by Customer shall be provided with any environmental, health and safety information related to the Customer Materials that were provided by the applicable vendor to Customer and are reasonably necessary to perform the Services (including employee health and safety, of the handling, manufacture, distribution, use and disposal of the Customer Materials), and will update, clarify, correct, supplement and amend such information as necessary;

10.2.4 it has not entered into any agreement with a Third Party (including, without limitation, governmental entities, universities, funding authorities or consortia) and will not enter into any agreement without Lonza's prior written consent that would convey to a Third Party any rights that would conflict with Lonza's exclusive ownership and control of Lonza Intellectual Property, including New General Application Intellectual Property, or Lonza's use thereof, as set forth in this Agreement;

10.2.5 as of the time that the Quality Agreement is signed, it will have an appropriate Quality function to ensure Customer's ongoing compliance with cGMP;

10.2.6 it shall [***] notify Lonza in writing if it receives or is notified of a formal written claim from a Third Party alleging that any Customer-Provided Items and/or the use thereof by Lonza or its Representatives for the provision of the Services infringes, misappropriates or violates (as the case may be) any Intellectual Property rights of any Third Party; and

10.2.7 its Affiliates, officers, directors, employees and agents and the officers, directors, employees and agents of its Affiliates, have not paid and will not pay,

offer or promise to pay, directly or indirectly, any monies or anything of value to any governmental official or employee or any political party or candidate for political office for the purpose of influencing any act or decision of such official, employee or candidate to obtain or retain business, or to direct business to any person.

10.3 DISCLAIMER: THE WARRANTIES EXPRESSLY SET FORTH IN THIS AGREEMENT AND THE TECHNOLOGY TRANSFER AGREEMENT ARE IN LIEU OF ALL OTHER WARRANTIES, AND ALL OTHER WARRANTIES, BOTH EXPRESS AND IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, WITH RESPECT TO THE PRODUCTS, RAW MATERIALS (INCLUDING CUSTOMER MATERIALS) AND SERVICES PROVIDED UNDER THIS AGREEMENT ARE EXPRESSLY DISCLAIMED, INCLUDING WITHOUT LIMITATION ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE WITH RESPECT TO THE SAME.

11 Indemnification and Liability

11.1 Indemnification by Lonza. Subject to Clauses 11.4 and 11.5, Lonza shall indemnify the Customer, its Affiliates, and the respective officers, employees and agents of Customer and/or its Affiliates ("Customer Indemnitees") from and against any loss, damage, costs, liability, and/or expenses (including reasonable attorney fees) payable to Third Parties that Customer Indemnitees may suffer as a result of any Third Party claim arising directly out of (i) any material breach of the Agreement by Lonza; (ii) any allegation that the performance of the Services (excluding use by Lonza or any Lonza Indemnitees or any External Laboratory or Subcontractor of any Customer-Provided Items in accordance with Customer's instructions) infringes any intellectual property rights of a Third Party; or (iii) the gross negligence, willful misconduct, or violation of Applicable Law by Lonza, its Affiliates, and its and their the respective officers, employees, agents, and contractors (including any Subcontractor), except, in each case (of (i) through (iii)), to the extent (a) that such claims resulted from the gross negligence, or the intentional or willful misconduct or breach of this Agreement by any Customer Indemnitees or (b) in the case of (iii), Customer directed such Subcontractor, consistent with last sentence of Clause 2.4. Further, Lonza shall indemnify the Customer Indemnitees from and against any loss, damage, costs, liability, and/or expenses (including reasonable attorney fees) payable to Third Parties that Customer Indemnitees may suffer as a result of any Third Party claim arising directly out of the use, collection, receipt, aggregation, hosting, mining or otherwise storing or maintenance of any Service Data.

11.2 Indemnification by Customer. Subject to Clause 11.4, Customer shall indemnify Lonza, Lonza's Affiliates, and the respective officers, employees and agents of Lonza and/or its Affiliates ("Lonza Indemnitees") from and against any loss, damage, costs, liability, and/or expenses (including reasonable attorney fees) payable to Third Parties that Lonza Indemnitees may suffer as a result of any Third Party claim arising directly out of (i) any material breach of the Agreement by Customer in Clause 10.2 above; (ii) any claims alleging that the supply or use of the Customer-Provided Items in accordance with Customer's instructions in the course of performance of Services infringes any intellectual property rights of Third Parties; (iii) manufacture, Customer's or a Third Party's (for clarity excluding Lonza's or its Affiliates' or Subcontractors') use, labelling, marketing, promotion, sale, or distribution of any Product or any product containing the Product, including any claims of product liability; (iv) any and all penalties, fees, expenses and costs whatsoever in connection with the failure by Customer to pay Taxes as required hereunder; or (v) any injuries suffered by Customer's employee or representative while at the Facility or elsewhere; except, in each case (of (i) through (v)), to the extent that such claims resulted from the gross negligence, or the intentional or willful misconduct or breach of this Agreement by any Lonza Indemnitees or contractors (including External Laboratory or Subcontractor).

11.3 Indemnification Procedure. In order for a Party to be indemnified under this Clause 11, it shall [***] notify the indemnifying Party in writing of such claim. The indemnitor shall have the right to control the defense and/or settlement thereof; provided, however, that any indemnitee shall have the right to retain its own counsel at its own expense. The indemnitee shall use all reasonable steps to mitigate any loss or liability in respect of any such claim or proceedings and to cooperate with the indemnifying Party in the investigation of any liability covered by this Clause 11. The indemnitee shall permit, and shall cause its Affiliates and their respective directors, officers, employees and agents to permit, the indemnitor, at its discretion, to settle any such claim, lawsuit or other action and agrees to the complete control of such defense or settlement by the indemnitor; provided, however, that in order for the indemnitor to exercise such rights, such settlement shall not adversely affect the indemnitee's rights under this Agreement or impose any obligations on the indemnitee in addition to those set forth herein. No such claim, lawsuit or other action shall be settled without the prior written consent of the indemnitor, which shall not be unreasonably withheld or delayed, and the indemnitor shall not be responsible for any legal fees or other costs incurred other than as provided herein. If a settlement contains an absolute waiver of liability for the indemnified party and no admission of fault on the indemnified party, and each party has acted in compliance with the requirements of this Clause 11.3, then the indemnified party's consent shall be deemed given. The indemnitee, its Affiliates and their respective directors, officers, employees and agents, shall reasonably cooperate with the indemnitor in the investigation of any liability covered by this Clause 11. The failure to deliver prompt written notice to the indemnitor of any claim, to the extent prejudicial to its ability to defend such claim, shall relieve the indemnitor of any obligation to the indemnitee under this Clause 11.

11.4 DISCLAIMER OF CERTAIN DAMAGES. SUBJECT TO CLAUSE 11.6, IN NO EVENT SHALL EITHER PARTY AND/OR ANY OF ITS AFFILIATES BE LIABLE (IN EACH CASE WHETHER IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY, UNDER INDEMNITY OR OTHERWISE HOWSOEVER ARISING) FOR ANY INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE OR CONSEQUENTIAL LOSSES OR DAMAGES; ARISING FROM OR RELATED TO THIS AGREEMENT, SUFFERED OR INCURRED BY SUCH OTHER PARTY OR ITS AFFILIATES IN CONNECTION WITH THIS AGREEMENT, INCLUDING LOSS OF PROFITS, LOSS OF REVENUE, LOSS OF GOODWILL OR REPUTATIONAL HARM, EVEN IF ADVISED OF THE POSSIBILITY OF SUCH DAMAGES; PROVIDED THAT THIS CLAUSE 11.4 SHALL NOT PRECLUDE ANY CLAIM BY LONZA OR ANY OF ITS AFFILIATES FOR ANY UNPAID INVOICES (INCLUDING THE PROFIT ELEMENT OF ITS CHARGES) AND/OR THE CANCELLATION FEES AND/OR TERMINATION FEES AND PROVIDED THAT THIS CLAUSE 11.4 SHALL NOT PRECLUDE ANY CLAIM BY LONZA FOR THE PROFIT ELEMENT OF ITS CHARGES.

11.5 LIMITATION OF LIABILITY. SUBJECT TO CLAUSE 11.6, THE AGGREGATE LIABILITY OF CUSTOMER, LONZA OR ANY OF THEIR AFFILIATES, THEIR RESPECTIVE OFFICERS, DIRECTORS, EMPLOYEES, AND AGENTS, AND ANYONE ACTING ON THEIR RESPECTIVE BEHALF FOR ANY AND ALL INJURIES, COSTS, LIABILITY, CLAIMS, LOSS, EXPENSES, OR DAMAGES WHATSOEVER ARISING OUT OF OR IN RELATION TO THIS AGREEMENT AND THE SOWS (IN EACH CASE WHETHER IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY, UNDER INDEMNITY OR OTHERWISE HOWSOEVER ARISING) SHALL NOT EXCEED, IN THE AGGREGATE, AN AMOUNT EQUAL TO [***] OF THE TOTAL AGGREGATE AMOUNTS PAID UNDER THIS AGREEMENT BY CUSTOMER (OR ANY OF ITS AFFILIATES) TO LONZA (OR ANY OF ITS AFFILIATES) IN THE [***] PRECEDING THE DATE ON WHICH THE APPLICABLE CLAIM FOR DAMAGES AROSE, PROVIDED THAT THE LIABILITY OF LONZA AND ITS AFFILIATES IN RELATION TO A SPECIFIC PRODUCT OR SERVICE SHALL NOT EXCEED, IN THE AGGREGATE, AN AMOUNT EQUAL TO [***] OF THE TOTAL AGGREGATE AMOUNTS PAID BY CUSTOMER UNDER ANY SOW(S) THAT COVER THAT PRODUCT OR SERVICE IN THE [***] PERIOD PRECEDING THE DATE ON WHICH THE APPLICABLE CLAIM FOR DAMAGES AROSE. FOR THE AVOIDANCE OF DOUBT THIS

LIMITATION OF LIABILITY SHALL BE AN AGGREGATE LIMITATION OF LIABILITY WHICH IS SHARED BETWEEN LONZA AND ALL OF ITS AFFILIATES , AND IN OTHER WORDS THERE SHALL NOT BE A SEPARATE LIMIT OF LIABILITY FOR EACH SEPARATE LONZA ENTITY.

11.6 Nothing in this Agreement shall operate so as to exclude or in any way limit any liability for (i) a breach of Clause 9 (Intellectual Property) or Clause 12 (Confidentiality); (ii) Customer's indemnification obligations set forth in Section 11, (iii) fraud, gross negligence or intentional misconduct; or (iv) any liability that may not be excluded or limited as a matter of the governing law of this Agreement. Nothing in this Section 11 shall exclude or limit Customer's liability to pay invoices and/or the Cancellation Fees or agreed capital expenditure in accordance with this Agreement and as set forth in the applicable SOW.

12 Confidentiality

12.1 A Party receiving Confidential Information (the "Receiving Party") agrees to strictly keep secret any and all Confidential Information received during the Term, from or disclosed on behalf of the other Party (the "Disclosing Party") or otherwise accessed by the Receiving Party using at least the same level of measures as it uses to protect its own Confidential Information, but in any case at least commercially reasonable and customary efforts. Confidential Information shall include information disclosed in any form including but not limited to in writing, orally, graphically or in electronic or other form to the Receiving Party or its Affiliates, observed by or learned by the Receiving Party or its Affiliates, or their employees, agents, consultants, or representatives including any person in plant under or in relation to this Agreement or the Quality Agreement, which the Receiving Party knows or reasonably should know is confidential or proprietary or would in the normal course of business be considered as being confidential or proprietary, and shall include the terms of this Agreement.

12.2 Notwithstanding any other provision herein to the contrary, the Receiving Party may disclose Confidential Information that is required to be disclosed pursuant to an applicable governmental or administrative or public law, rule, regulation, order, subpoena, or other compulsory legal process, including but not limited to the rules and regulations of the U.S. Securities and Exchange Commission (SEC) or any securities exchange, and then only in accordance therewith. In such case, the Receiving Party will, to the extent legally permitted, inform the Disclosing Party [***] in writing and reasonably cooperate with the Disclosing Party in seeking to minimize the extent of the Disclosing Party's Confidential Information that has to be disclosed to the courts, authorities, or other persons and shall cooperate with the Disclosing Party, to the extent legally permitted, to seek the imposition of a protective order or of similar protective measures.

12.3 The obligation to maintain confidentiality under this Agreement does not apply to Confidential Information, which the Receiving Party can reasonably establish by contemporaneous written records:

12.3.1at the time of disclosure was publicly available; or

12.3.2is or becomes publicly available other than as a result of a breach of this Agreement by the Receiving Party or its Affiliate or their respective Representatives (as defined below); or

12.3.3was rightfully in its possession at the time of disclosure by the Disclosing Party and had not been previously received directly or indirectly from or on behalf of Disclosing Party under an obligation of confidentiality; or

12.3.4is supplied to a Party by a Third Party which was not in breach of any obligation of confidentiality to Disclosing Party or any other party; or

12.3.5is developed by the Receiving Party independently from and without access to or aid, application or use of the Disclosing Party's Confidential Information or without otherwise violating the terms of this Agreement.

12.4 The Receiving Party will use Confidential Information of the Disclosing Party only for the purposes of this Agreement and the Quality Agreement (or in the case of Customer as the Receiving Party, to exercise its rights under this Agreement). The Receiving Party agrees to return or destroy [***] (and certify such destruction) on Disclosing Party's request all written or tangible Confidential Information of the Disclosing Party, except that one copy of such Confidential Information may be kept by the Receiving Party in its confidential files for record keeping purposes only.

12.5 Each Party will restrict the disclosure of Confidential Information of the Disclosing Party to such officers, employees, consultants, contractors (including Subcontractors and External Laboratories) and representatives of itself and its Affiliates (collectively, "Representatives") who have been informed of the confidential nature of the Confidential Information, who have a need to know such Confidential Information for the purpose of performing its obligations under this Agreement and the Quality Agreement, and who are bound by a like obligation of confidentiality and restrictions on use; provided further, that Customer may disclose the terms of this Agreement and the Confidential Information of Lonza relating to the development or manufacture of Products to entities with whom Customer has (or may have) a marketing and/or development collaboration, or to bona fide actual or prospective underwriters, investors, lenders or other financing sources or to potential acquirers of the business to which this Agreement relates, and who in each case have a specific need to know such Confidential Information, who are not a Competitor of Lonza at the time such Confidential Information is shared and who are bound by a like obligation of confidentiality and restrictions on use. Prior to disclosure to Representatives, the Receiving Party shall bind its Representatives to confidentiality and non-use obligations no less stringent than those set forth herein. The Receiving Party shall notify the Disclosing Party as [***] as practicable of any unauthorized use or disclosure of the Confidential Information of the Disclosing Party.

12.6 The Receiving Party shall at all times be fully liable for any and all breaches of the confidentiality obligations in this Clause 12 by any of its Representatives, including persons in plant.

12.7 Each Party hereto expressly agrees that any breach or threatened breach of the undertakings of confidentiality provided under this Clause 12 by a Party may cause irreparable harm to the other Party and that money damages may not provide a sufficient remedy to the non-breaching Party for any breach or threatened breach. In the event of any breach and/or threatened breach, then, in addition to all other remedies available at law or, if relevant, in equity, the non-breaching Party shall be entitled to seek injunctive relief and any other relief deemed appropriate by the non-breaching Party.

12.8 Services Data. Notwithstanding the confidentiality provisions in this Clause 12 as they may relate to the use of Services Data, but subject to Clause 9.3.1, Customer acknowledges that all Services Data may be collected, aggregated, hosted, mined or otherwise stored and maintained by Lonza and its Affiliates, contractors and External Laboratories. Lonza (and its Affiliates, contractors and External Laboratories) may only use Services Data in accordance with all Applicable Laws, and only if such Services Data is anonymized and aggregated in accordance with all Applicable Laws.

13 Term and Termination

13.1 Term. This Agreement shall commence on the Effective Date and shall expire on the [***] of the Effective Date, unless terminated earlier as provided herein or extended by mutual written consent of the Parties (the "Term"); provided, however, that this Agreement will continue to remain in effect with respect to any Statements of Work already issued at the time of such termination or expiration, until such Statements of Work are themselves terminated or expire. Customer shall have the option, at its sole discretion, to extend for an additional [***] term upon notice to Lonza at least [***] prior to the expiration of the Term.

13.2 Termination. This Agreement or any SOW may be terminated as follows:

13.2.1 unless otherwise set forth in any SOW, by Customer for any reason upon [***] prior written notice to Lonza or by Lonza for any reason upon [***] prior written notice to Customer. For the avoidance of doubt, in the event of termination by Customer under this Clause 13.2.1. Customer shall remain liable for all fees for Services performed in accordance with the applicable SOW during such notice period and all Binding Purchase Orders, Batches, Development Services and all other Services shall be deemed cancelled and Customer shall pay fees calculated in accordance with Section 13.3. In the event of termination by either Party under this Clause 13.2.1, the Parties shall remain liable during the notice period for their respective obligations under this Agreement and, unless otherwise requested by Customer, Lonza will continue to perform all Services during any termination notice period. In the event any SOW contains a termination notice different than the foregoing notice requirements, the termination notice requirement of the SOW shall supersede the notice requirement of this Section 13.2.1, but only with respect to such SOW;

13.2.2 If during a Technology Transfer prior to the successful manufacture of a cGMP Batch or after a material amendment to the Manufacturing Process is implemented, it becomes apparent to Lonza in the provision of the Services that it will not be possible to complete the Services set forth in any SOW for a scientific or technical reasons despite commercially reasonable efforts, then Lonza shall promptly notify Customer, after which notification a [***] period shall be allowed for good faith discussion and attempts to mutually agree on an acceptable scientific or technical solution and modification of pricing and timelines for performance, to the extent applicable. If the Parties are unable to resolve such problems within such period despite commercially reasonable efforts, Customer and Lonza shall each have the right to terminate the applicable SOW, or if there is only one SOW at such time, then this Agreement in its entirety, forthwith by notice in writing and in any case of termination relating to this Section 13.2.2 , Customer shall not owe any Cancellation Fees. See Appendix B for Autologous Cell Therapy that shall replace this section for any Autologous Cell Therapy programs with Lonza and Customer.

13.2.3 Immediately by either Party if the other Party materially breaches a provision of this Agreement or a SOW and fails to cure such breach to the reasonable satisfaction of the non-breaching Party within [***] ([***] for non-payment) following written notification of such breach from the non-breaching party to the breaching party; provided, however, that such [***] period shall be extended as agreed by the Parties if the identified breach is incapable of cure within [***] and if the breaching Party provides a plan and timeline to cure the breach, promptly commences efforts to cure the breach and diligently prosecutes such cure (it being understood that this extended period shall be unavailable for any breach regarding non-payment or in the event of a Persistent Supply Failure);

13.2.4 by either Party, immediately, upon: (a) the dissolution, termination of existence, liquidation or business failure of the other Party; (b) the appointment of a custodian or receiver for the other Party who has not been terminated or dismissed within [***] of such appointment; (c) the institution by the other Party of any proceeding under national, federal or state bankruptcy, reorganization, receivership or other similar laws affecting the rights of creditors generally or the making by such Party of a composition or any assignment for the benefit of creditors under any national, federal or state bankruptcy, reorganization, receivership or other similar law affecting the rights of creditors generally, which proceeding is not dismissed within [***] of filing. All rights and licenses granted pursuant to this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of Title 11 of the United States Bankruptcy Code (or any same or similar provision in any jurisdiction other than the United States), licenses of rights of "intellectual property" as defined therein;

13.2.5 by either Party pursuant to Clause 14 (Force Majeure); or

13.2.6 by Customer, upon [***] prior written notice, in the event of a the event of a Persistent Supply Failure which shall not in and of itself constitute a material breach of this Agreement or a SOW.

13.3 Consequences of Termination. In the event of termination of this Agreement or any SOW and except as provided below, all Services and Batches which have been ordered or otherwise committed in accordance with this Agreement (including those in the SOW to which the Parties are committed) shall be deemed to have been cancelled effective as of the date of termination.

Except as set forth below, Customer shall, within [***] of the receipt an undisputed invoice following the date of termination, pay Lonza for:

(i) Services rendered up to the date of termination, including in respect of any Product in-process and all project-related decommissioning Services required or performed by Lonza as required by Regulatory Authorities;

(ii) subject to Clause 2.12, all otherwise unpaid costs incurred by Lonza or that are non-cancellable through the date of termination including for the purchase of agreed-upon quantities of Lonza-Procured Materials (including applicable Handling Fees) used or purchased for use or for which Lonza is irrevocably committed in connection with the SOW and External Laboratory charges (including applicable Handling Fees), solely to the extent such costs are expressly authorized in the SOW and following payment, at Customer's option and cost unless otherwise specified, such Lonza-Procured Materials will either be: (a) held by Lonza (at no charge) for future use for the production of Product if there is a Binding Purchase Order for future production; (b) delivered to Customer; or (c) disposed of by Lonza (at no charge);

(iii) any unreimbursed Capital Equipment and related decommissioning charges agreed in writing incurred pursuant to Clause 9; and

(iv) Cancellation Fees, to the extent applicable, which shall be calculated in accordance with Clause 6.5; provided, however, that Customer shall have no payment obligation under this Clause 13.3(iv) in the event of termination by Customer pursuant to Clause 13.2.3 (material breach), by Customer or Lonza for a scientific or technical reason pursuant to Clause 13.2.2, by Customer for a Persistent Supply Failure pursuant to Clause 13.2.6, or by either Party pursuant to Clause 14 (Force Majeure). In the case of termination by Lonza for Customer's

material breach, Cancellation Fees shall be calculated as of the end of the cure period set forth in Clause 13.2.3.

13.4 Survival. Neither the termination nor expiration of this Agreement shall affect the liability of a Party for breach of this Agreement. Notwithstanding anything contained in this Clause 13, the rights and obligations of each Party which by their nature survive the termination or expiration of this Agreement shall survive the termination or expiration of this Agreement, including Clauses 5, 9-12 and 16 (to the extent relevant). Termination of this Agreement (including the consequences of termination set out in this Clause 13) shall not affect the accrued rights or liabilities of either Party and shall not preclude either Party from pursuing any remedies it may have hereunder, or at law or in equity, with respect to any breach of, or default under, this Agreement (subject always to Clauses 11.4 and 11.5). All confidentiality obligations set out in this Agreement shall survive termination or expiry of this Agreement.

14 Force Majeure

14.1 If either Party and/or any of that Party's Affiliates is prevented or delayed in the performance of any of its obligations under the Agreement by Force Majeure, it shall give written notice thereof to the other Party specifying the matters constituting Force Majeure together with such evidence as it reasonably can give and specifying the period for which it is estimated that such prevention or delay will continue. The notifying Party shall then be excused from the performance or the punctual performance of such obligations, as the case may be, for so long as such cause of prevention or delay shall continue, provided that such Party uses commercially reasonable efforts to (i) mitigate any damages incurred by the other Party as a result of the prevention or delay and (ii) resume full performance of such affected obligations as soon as reasonably practicable. If such Force Majeure persists for a period of [***] or more, either Party may terminate the Agreement (if the event of Force Majeure affects the whole Agreement) or the relevant SOW(s) under this Agreement by delivering written notice to the other and in such circumstance no Cancellation Fee, if any, would be owed). "Force Majeure" shall be deemed to include any acts, events, omissions, or accidents beyond the reasonable control and without the fault or negligence of the affected Party which affects the performance by such Party of its obligations under the Agreement, including (but subject to the foregoing), any cause arising from or attributable to acts of God, earthquakes or other natural disasters, epidemic, pandemic, strike, lockouts, labor troubles (excluding labor troubles involving the work force or any part thereof of the Party in question), restrictive governmental orders or decrees, riots, insurrection, war, terrorists acts, or the inability to obtain any required Raw Materials (excluding any patient Material), energy source, equipment, labor or transportation, at prices and on terms deemed by Lonza to be reasonably practicable, from Lonza's usual sources of supply, or detection of a viral, bacterial or mycoplasmal contamination that causes a shutdown of the Facility or any part thereof. For the avoidance of doubt, Force Majeure shall not include patient delay, patient illness or conditions affecting a patient and not the Customer that results in an inability to obtain Customer Materials. Under no circumstances will an event of Force Majeure excuse a Party's obligations to make payments when due under this Agreement or an SOW.

14.2 If due to Force Majeure, the quantity of Raw Materials available to Lonza is at any time reduced so as to be insufficient to satisfy the whole of Lonza's and its Affiliates' requirements and contractual commitments, then for so long as such insufficiency shall continue, Lonza shall be entitled to apportion the quantity of Raw Materials available in an equitable pro-rata manner amongst its own and its Affiliates' requirements and contractual commitments.

14.3 With regard to Lonza, any such event of Force Majeure affecting Services or production at its Affiliates, Subcontractors, suppliers or External Laboratories shall be regarded as an event of Force Majeure, provided that Lonza first uses commercially

reasonable efforts to transition the affected Services or production to alternative Affiliates, Subcontractors, suppliers, or External Laboratories and is unsuccessful in doing so.

15 Additional Covenants

15.1 Each Party shall comply with, and shall cause its Affiliates, subsidiaries, subcontractors, directors, officers, employees, agents or any other person acting on behalf of the Party to comply with, all applicable Corruption Laws and International Trade Restrictions, and shall obtain all necessary export and re-export written consents, permits, and authorizations required by International Trade Restrictions; and

15.2 In connection with the preparation and the performance of this Agreement, each Party shall take appropriate technical and organizational measures to comply with the GDPR, as applicable. Lonza shall in compliance with GDPR as well as on Customer's request, destroy all personal data, unless Applicable Law prevents Lonza from such destruction. Lonza covenants that any personal identifiable data shared with Customer for the purposes of the Services shall be shared in accordance with all Applicable Laws, and that the preparation and the performance of this Agreement is done in accordance with the requirements of the GDPR, as applicable.

16 Miscellaneous

16.1 Independent Contractors. Each of the Parties is an independent contractor and nothing herein contained shall be deemed to constitute the relationship of partners, joint venturers, nor of principal and agent between the Parties. Neither Party shall at any time enter into, incur, or hold itself out to Third Parties as having authority to enter into or incur, on behalf of the other Party, any commitment, expense, or liability whatsoever.

16.2 No Presumption Against Drafter. Each Party and its legal counsel have reviewed and revised this Agreement. The rule of construction that requires that ambiguities in this Agreement (including any Appendix hereto) be construed against the drafter shall be waived by both Parties in the interpretation of this Agreement.

16.3 Waiver. The failure of any Party at any time or times to require performance of any provision of this Agreement (including any Appendix hereto) will in no manner affect its rights at a later time to enforce the same. No waiver by any Party of any term, provision or condition contained in this Agreement (including any Appendix hereto), whether by conduct or otherwise, in any one or more instances, shall be deemed to be or construed as a further or continuing waiver of any such term, provision or condition or of any other term, provision or condition of this Agreement (including any Appendix hereto).

16.4 Severability. If any provision hereof is or becomes at any time illegal, invalid or unenforceable in any respect, neither the legality, validity nor enforceability of the remaining provisions hereof shall in any way be affected or impaired thereby. The Parties hereto undertake to substitute any illegal, invalid or unenforceable provision by a provision which is as far as possible approximate to the intent of the Parties and/or commercially equivalent, considering the Parties' interests and the purpose of the provision.

16.5 Amendments. Modifications and/or amendments of this Agreement must be in writing and signed by the Parties. The Parties may amend this Agreement without the consent of the Affiliates of either Party.

16.6 Assignment. Subject to Clause 2.5, neither Party may assign its interest under this Agreement without the prior written consent of the other Party, such consent not to be unreasonably withheld, conditioned or delayed, provided, however that (a) either Party may assign this Agreement to (i) any Affiliate of such Party; or (ii) any Third Party in connection with the sale or transfer (by whatever method) of all or substantially all of the assets of the

business related to the subject matter of this Agreement; or (iii) in connection with a merger, consolidation, acquisition or other form of business combination, and (b) Lonza shall be entitled to sell, assign and/or transfer its trade receivables resulting from this Agreement, in each instance in respect of clauses (a) or (b), without the consent of the Customer. Notwithstanding the foregoing, any assignment by Customer under clause (a) above to a Competitor of Lonza at the time of such assignment shall require Lonza's consent (not to be unreasonably withheld, conditioned or delayed). Any purported assignment without a required consent shall be void. This Agreement will be binding on the Parties' successors and assigns. No assignment shall relieve any Party of responsibility for the performance of any obligation or liability that accrued prior to the effective date of such assignment.

16.7 Notice. Any notice required or permitted to be given under this Agreement by any Party shall be in writing and shall be (a) delivered personally, (b) sent by registered mail, return receipt requested, postage prepaid, (c) sent by a nationally-recognized courier service guaranteeing next-day or second day delivery, charges prepaid, (d) delivered by electronic mail (with documented evidence of a read receipt), to the electronic mail address of the other Party set forth below, followed by hard copy within [***]; or (e) delivered at such other addresses as may from time to time be furnished by similar notice by any Party. The effective date of any notice under this Agreement shall be the date of receipt by the receiving Party.

If to Lonza:

[***]

If to Customer:

Cabaletta Bio, Inc.

[***]

16.8 Governing Law/Jurisdiction. This Agreement or any matter, claim or dispute arising out of or in connection with this Agreement, whether contractual or non-contractual, is to be governed by and determined exclusively in accordance with the laws of the State of New York, without regard to its conflicts of laws principles. The United Nations Convention on Contracts for the International Sales of Goods is expressly disclaimed. The Parties agree to submit to the exclusive jurisdiction of the US federal courts located in the county and state of New York (and, only if such courts lack jurisdiction over the Parties), the state courts of the State of New York located in the County of New York.

16.9 Third Parties. The Parties to this Agreement do not intend that any term hereof should be enforceable by virtue of the Contracts (Rights of Third Parties) Act 1999 (or any same or similar provision in any jurisdiction other than England) by any person who is not a party to this Agreement, save that Affiliates of Lonza may rely on the indemnities granted to them and limitations and exclusions of liability contained herein and Affiliates of Lonza which have executed a Statement of Work or SOW under this Agreement shall be entitled to enforce this Agreement with respect to such SOW or Statement of Work in its own name as an intended Third Party beneficiary.

16.10 Announcements / Press Releases. Neither Party shall: (i) make any press release or announcement of any kind and in any format and on any media of any nature (including social media, photographs, video messages and any other format of media that is not in use or known as at the date of this Agreement) regarding the subject matter of this Agreement; or (ii) make any publication or promotional material of any kind in any format and on any type of media (including social media, photographs, video messages and any other format of media that is not in use or known as at the date of this Agreement) which uses or refers to any name, trademark or branding of the other; in each case without the prior written consent of the other.

For clarity, the foregoing restrictions do not apply with respect to any filings by Customer or its Affiliates necessary to comply with regulatory requirements, including filings with the U.S. Securities Exchange Commission or a Regulatory Authority.

16.11 Entire Agreement; Counterparts. This Agreement, including the Appendices attached hereto and referenced herein, contains the entire agreement between the Parties as to the Services and supersedes all prior and contemporaneous agreements, oral and written, among the Parties with respect to the Services. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, and all of which together shall constitute one and the same document. Each Party acknowledges that an original signature or a copy thereof transmitted by .pdf shall constitute an original signature for purposes of this Agreement.

16.12 If this Agreement is executed using an electronic signature program (such as DocuSign or AdobeSign), the Parties hereby agree to the terms and conditions of this Agreement by clicking the “SIGN” button. The Parties agree that an electronic signature is the legal equivalent of a manual signature on this Agreement, and that, if applicable, selecting “SIGN” constitutes such Party’s electronic signature. The Parties also agree that no certification authority or other Third Party verification is necessary to validate either Party’s electronic signature and that the lack of such certification or Third Party verification will not in any way affect the enforceability of such Party’s electronic signature or any resulting contract between the Parties. The Parties understand and agree that electronically signing and submitting this Agreement (or any amendment thereof) is the legal equivalent of having placed a handwritten signature on the submitted Agreement.

16.13 Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of the Agreement.

IN WITNESS WHEREOF, each of the Parties hereto has caused this Development and Manufacturing Services Agreement to be executed by its duly authorized representative effective as of the date written above.

LONZA Houston Inc.

By: /s/ Julie Foster
Name: Julie Foster
Title: Head of Business Development, CGT

CABALETTA BIO, INC.

By: /s/ Anup Marda
Name: Anup Marda
Title: Chief Financial Officer

APPENDIX A
SOW A - 1

[***]

APPENDIX B
Additional Terms and Conditions for [***]

[***]

APPENDIX C
Standard Safety stock levels for Product

[***]

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: August 7, 2025

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: August 7, 2025

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 June 30, 2025, 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: August 7, 2025

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 June 30, 2025 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: August 7, 2025

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