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

FORM 10-Q

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

For the quarterly period ended September 30, 2023

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: 001-37798

Cartesian Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**26-1622110**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
65 Grove Street, Watertown, MA	**02472**
(Address of principal executive offices)	**(Zip Code)**

(617) 923-1400
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	**SELB**	**The Nasdaq Stock Market LLC**

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 November 10, 2023, the registrant had 155,204,182 shares of common stock, par value $0.0001 per share, outstanding.

TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION

Item 1.	Financial Statements (unaudited)	6
	Consolidated Balance Sheets as of September 30, 2023 and December 31, 2022	6
	Consolidated Statements of Operations and Comprehensive Income (Loss) for the Three and Nine Months ended September 30, 2023 and 2022	7
	Consolidated Statements of Changes in Stockholders' Equity (Deficit) for the Three Months ended March 31, June 30, and September 30, 2023 and 2022	8
	Consolidated Statements of Cash Flows for the Nine Months ended September 30, 2023 and 2022	10
	Notes to Consolidated Financial Statements	11
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	31
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	42
Item 4.	Controls and Procedures	42

PART II. OTHER INFORMATION

Item 1.	Legal Proceedings	43
Item 1A.	Risk Factors	43
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	68
Item 3.	Defaults Upon Senior Securities	68
Item 4.	Mine Safety Disclosures	68
Item 5.	Other Information	68
Item 6.	Exhibits	69
	Signatures	70

EXPLANATORY NOTE

On November 13, 2023, Selecta Biosciences, Inc., or Selecta, announced that it had completed a merger, or the Merger, with Cartesian Therapeutics, Inc., or Cartesian, pursuant to the Agreement and Plan of Merger, or the Merger Agreement, dated as of such date, by and among Selecta, Cartesian, Sakura Merger Sub I, Inc., or First Merger Sub,, and Sakura Merger Sub II, LLC, or Second Merger Sub. In the Merger, First Merger Sub merged with and into Cartesian, followed by Cartesian merging with and into Second Merger Sub, with Second Merger Sub being the surviving entity of the Merger. In this Quarterly Report on Form 10-Q, or the Quarterly Report, references to “we,” “our,” “us” and the “Company” in the context of events occurring prior to November 13, 2023 are to Selecta Biosciences, Inc., and on and following November 13, 2023 are to Cartesian Therapeutics, Inc.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, or the Quarterly Report, contains forward-looking statements. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical facts contained in this Quarterly Report, including statements regarding the Merger, stockholder approval of the conversion of the Series A Non-Voting Convertible Preferred Stock, par value $0.0001 per share, or the Series A Preferred Stock, to be issued in the Merger into our common stock, par value $0.0001 per share, or the common stock, our future results of operations and financial position, business strategy, prospective products, product approvals, research and development costs, timing and likelihood of success, the plans and objectives of management for future operations and future results of anticipated products, the impact of the COVID-19 pandemic on our business and operations and our future financial results, and the period over which we estimate our existing cash and cash equivalents will be sufficient to fund our future operating expenses and capital expenditure requirements are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential”, or “continue” or the negative of these terms or other similar expressions. The forward-looking statements in this Quarterly Report are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Quarterly Report and are subject to a number of important factors that could cause actual results to differ materially from those in the forward-looking statements, including the factors described under the sections in this Quarterly Report titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” as well as the following:

- our expectations regarding the conversion of the Series A Preferred Stock into our common stock;
- potential litigation instituted against us or our directors challenging the Merger;
- our ability to realize any benefits or opportunities from the Merger;
- our status as a preclinical and development-stage company and our expectation to incur losses in the future;
- our future capital needs;
- our ability to maximize the value of our pipeline of product candidates;
- our unproven approach to therapeutic intervention;
- our ability to enroll patients in clinical trials, timely and successfully complete those trials and receive necessary regulatory approvals;
- our ability to continue to grow our manufacturing capabilities and resources;
- our ability to manufacture our product candidates, which in some cases are manufactured on a patient-by-patient basis;
- our ability to access manufacturing facilities and to receive or manufacture sufficient quantities of our product candidates;
- our ability to maintain our existing or future collaborations or licenses and to seek new collaborations, licenses or partnerships;
- the continuing impact of geopolitical tensions on our operations, the continuity of our business, including our preclinical studies and clinical trials, and general economic conditions;
- our ability to protect and enforce our intellectual property rights;

- federal, state, and foreign regulatory requirements, including U.S. Food and Drug Administration, or FDA, regulation of our product candidates;
- our ability to obtain and retain key executives and retain qualified personnel; and
- developments relating to our competitors and our industry, including the impact of government regulation.

Moreover, we operate in an evolving environment. New risks and uncertainties may emerge from time to time, and it is not possible for management to predict all risk and uncertainties.

You should read this Quarterly Report and the documents that we reference in this Quarterly Report completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements (unaudited)

Selecta Biosciences, Inc. and Subsidiaries

Consolidated Balance Sheets

(Amounts in thousands, except share data and par value)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 79,603	$ 106,438
Marketable securities	—	28,164
Accounts receivable	4,898	6,596
Unbilled receivables	1,875	3,162
Prepaid expenses and other current assets	3,493	3,778
Total current assets	89,869	148,138
Non-current assets:		
Property and equipment, net	2,421	2,794
Right-of-use asset, net	10,339	11,617
Long-term restricted cash	1,377	1,311
Investments	2,000	2,000
Other assets	28	26
Total assets	$ 106,034	$ 165,886
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 375	$ 316
Accrued expenses	13,637	14,084
Loan payable	—	8,476
Lease liability	1,787	1,608
Deferred revenue	4,140	593
Total current liabilities	19,939	25,077
Non-current liabilities:		
Loan payable, net of current portion	—	17,786
Lease liability	8,694	10,055
Deferred revenue	3,981	—
Warrant liabilities	13,091	19,140
Total liabilities	45,705	72,058
Commitments and contingencies (Note 17)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized; no shares issued and outstanding as of September 30, 2023 and December 31, 2022	—	—
Common stock, $0.0001 par value; 350,000,000 shares authorized; 154,854,032 and 153,042,435 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	15	15
Additional paid-in capital	501,919	493,308
Accumulated deficit	(436,989)	(394,937)
Accumulated other comprehensive loss	(4,616)	(4,558)
Total stockholders' equity	60,329	93,828
Total liabilities and stockholders' equity	$ 106,034	$ 165,886

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

Selecta Biosciences, Inc. and Subsidiaries

Consolidated Statements of Operations and Comprehensive Income (Loss)

(Amounts in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Collaboration and license revenue	$ 6,551	$ 20,710	$ 17,738	$ 93,982
Operating expenses:				
Research and development	13,002	16,539	49,408	53,410
General and administrative	6,614	5,770	18,414	17,538
Total operating expenses	19,616	22,309	67,822	70,948
Operating (loss) income	(13,065)	(1,599)	(50,084)	23,034
Investment income	1,299	710	4,024	932
Foreign currency transaction, net	(3)	15	39	(61)
Interest expense	(1,273)	(802)	(2,833)	(2,224)
Change in fair value of warrant liabilities	3,787	(6,539)	6,049	7,329
Other income, net	253	1	753	155
Loss (income) before income taxes	(9,002)	(8,214)	(42,052)	29,165
Income tax (expense) benefit	—	321	—	321
Net (loss) income	$ (9,002)	$ (7,893)	$ (42,052)	$ 29,486
Other comprehensive income (loss):				
Foreign currency translation adjustment	(20)	(21)	(69)	65
Unrealized gain on marketable securities	—	(29)	11	(29)
Total comprehensive income (loss)	$ (9,022)	$ (7,943)	$ (42,110)	$ 29,522
Net (loss) income per share:				
Basic	$ (0.06)	$ (0.05)	$ (0.27)	$ 0.21
Diluted	$ (0.06)	$ (0.05)	$ (0.27)	$ 0.15
Weighted-average common shares outstanding:				
Basic	154,804,503	152,849,992	153,870,912	141,969,449
Diluted	154,804,503	152,849,992	153,870,912	143,792,060

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

Selecta Biosciences, Inc. and Subsidiaries

Consolidated Statements of Changes in Stockholders' Equity (Deficit)

(Amounts in thousands, except share data)

	Common stock		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Stockholders' equity
	Shares	Amount				
Balance at December 31, 2022	153,042,435	$ 15	$ 493,308	$ (394,937)	$ (4,558)	$ 93,828
Issuance of common stock under Employee Stock Purchase Plan	108,068	—	149	—	—	149
Issuance of vested restricted stock units	276,480	—	—	—	—	—
Stock-based compensation expense	—	—	2,276	—	—	2,276
Currency translation adjustment	—	—	—	—	(22)	(22)
Unrealized gain on marketable securities	—	—	—	—	11	11
Net loss	—	—	—	(21,663)	—	(21,663)
Balance at March 31, 2023	153,426,983	$ 15	$ 495,733	$ (416,600)	$ (4,569)	$ 74,579
Issuance of vested restricted stock units	588	—	—	—	—	—
Stock-based compensation expense	—	—	2,283	—	—	2,283
Currency translation adjustment	—	—	—	—	(27)	(27)
Net loss	—	—	—	(11,387)	—	(11,387)
Balance at June 30, 2023	153,427,571	$ 15	$ 498,016	$ (427,987)	$ (4,596)	$ 65,448
Issuance of common stock under Employee Stock Purchase Plan	77,976	—	82	—	—	82
Issuance of vested restricted stock units	9,200	—	—	—	—	—
Issuance of common stock, license agreement	1,339,285	—	1,500	—	—	1,500
Stock-based compensation expense	—	—	2,321	—	—	2,321
Currency translation adjustment	—	—	—	—	(20)	(20)
Net loss	—	—	—	(9,002)	—	(9,002)
Balance at September 30, 2023	154,854,032	$ 15	$ 501,919	$ (436,989)	$ (4,616)	$ 60,329

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

Selecta Biosciences, Inc. and Subsidiaries

Consolidated Statements of Changes in Stockholders' Equity (Deficit)

(Amounts in thousands, except share data)

	Common stock		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Stockholders' equity
	Shares	Amount				
Balance at December 31, 2021	123,622,965	$ 12	$ 457,391	$ (430,316)	$ (4,566)	$ 22,521
Issuance of common stock under Employee Stock Purchase Plan	81,057	—	127	—	—	127
Issuance of common stock upon exercise of options	11,262	—	21	—	—	21
Issuance of vested restricted stock units	89,142	—	—	—	—	—
Issuance of common stock through at-the-market offering, net	576,418	—	1,675	—	—	1,675
Other financing fees	—	—	(79)	—	—	(79)
Stock-based compensation expense	—	—	2,753	—	—	2,753
Currency translation adjustment	—	—	—	—	(32)	(32)
Net income	—	—	—	28,778	—	28,778
Balance at March 31, 2022	124,380,844	$ 12	$ 461,888	$ (401,538)	$ (4,598)	$ 55,764
Issuance of vested restricted stock units	10,938	—	—	—	—	—
Issuance of common stock and common warrants	27,428,572	3	21,477	—	—	21,480
Issuance of common stock, license agreement	892,857	—	1,000	—	—	1,000
Other financing fees	—	—	79	—	—	79
Stock-based compensation expense	—	—	2,564	—	—	2,564
Currency translation adjustment	—	—	—	—	118	118
Net income	—	—	—	8,601	—	8,601
Balance at June 30, 2022	152,713,211	$ 15	$ 487,008	$ (392,937)	$ (4,480)	$ 89,606
Issuance of common stock under Employee Stock Purchase Plan	39,820	—	62	—	—	62
Issuance of common stock upon exercise of options	59,928	—	135	—	—	135
Issuance of vested restricted stock units	17,737	—	—	—	—	—
Issuance of common stock through at-the-market offering, net	198,126	—	446	—	—	446
Stock-based compensation expense	—	—	2,601	—	—	2,601
Currency translation adjustment	—	—	—	—	(21)	(21)
Unrealized (losses) on marketable securities	—	—	—	—	(29)	(29)
Net loss	—	—	—	(7,893)	—	(7,893)
Balance at September 30, 2022	153,028,822	$ 15	$ 490,252	$ (400,830)	$ (4,530)	$ 84,907

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

Selecta Biosciences, Inc. and Subsidiaries

Consolidated Statements of Cash Flows

(Amounts in thousands)

	Nine Months Ended September 30,	
	2023	2022
Cash flows from operating activities		
Net (loss) income	$ (42,052)	$ 29,486
Adjustments to reconcile net (loss) income to net cash used in operating activities:		
Depreciation and amortization	571	1,046
Amortization of premiums and discounts on marketable securities	(79)	(128)
Non-cash lease expense	1,278	930
Gain on disposal of property and equipment	—	(147)
Stock-based compensation expense	8,380	8,918
Non-cash interest expense	455	777
Warrant liabilities revaluation	(6,049)	(7,329)
Loss on extinguishment of debt	740	—
Changes in operating assets and liabilities:		
Accounts receivable	1,698	2,989
Unbilled receivable	1,287	—
Prepaid expenses, deposits and other assets	(30)	(304)
Accounts payable	36	(10)
Income taxes payable	—	(601)
Deferred revenue	7,528	(56,044)
Accrued expenses and other liabilities	(1,638)	635
Net cash used in operating activities	(27,875)	(19,782)
Cash flows from investing activities		
Proceeds from maturities of marketable securities	28,254	14,000
Purchases of marketable securities	—	(33,501)
Purchases of property and equipment	(142)	(990)
Net cash provided by investing activities	28,112	(20,491)
Cash flows from financing activities		
Repayments of principal, final payment fee, and prepayment penalty on debt	(27,457)	—
Debt amendment fee included in debt discount	—	(110)
Net proceeds from issuance of common stock- at-the-market offering	—	2,121
Net proceeds from issuance of common stock and common warrants	—	36,859
Proceeds from exercise of stock options	—	156
Proceeds from issuance of common stock under Employee Stock Purchase Plan	231	189
Net cash (used in) provided by financing activities	(27,226)	39,215
Effect of exchange rate changes on cash	(69)	65
Net change in cash, cash equivalents, and restricted cash	(27,058)	(993)
Cash, cash equivalents, and restricted cash at beginning of period	108,038	115,436
Cash, cash equivalents, and restricted cash at end of period	$ 80,980	$ 114,443
Supplemental cash flow information		
Cash paid for interest	$ 1,853	$ 1,616
Noncash investing and financing activities		
Issuance of common stock, license agreement in stock-based compensation expense	$ 1,500	$ 1,000
Purchase of property and equipment not yet paid	$ 65	$ 145

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

Selecta Biosciences, Inc. and Subsidiaries

Notes to Consolidated Financial Statements

1. Description of the Business

Selecta Biosciences, Inc., or the Company, was incorporated in Delaware on December 10, 2007, and is based in Watertown, Massachusetts. The Company is a clinical-stage biotechnology company leveraging the Company's ImmTOR® platform to develop tolerogenic therapies that selectively mitigate unwanted immune responses. With a proven ability to induce tolerance to highly immunogenic proteins, the Company believes ImmTOR has the potential to amplify the efficacy of biologic therapies, including redosing of life-saving gene therapies, as well as restore the body's natural self-tolerance in autoimmune diseases. The Company has several proprietary and partnered programs in its pipeline.

As discussed in further detail in Note 18 – Subsequent Events, on November 13, 2023, the Company entered into an Agreement and Plan of Merger, or the Merger Agreement, dated as of such date, by and among the Company, Cartesian Therapeutics, Inc., or Cartesian, Sakura Merger Sub I, Inc., or First Merger Sub, and Sakura Merger Sub II, LLC, or Second Merger Sub, with respect transactions referred to as the Merger. In the Merger, First Merger Sub merged with and into Cartesian, followed by Cartesian merging with and into Second Merger Sub, with Second Merger Sub being the surviving entity of the Merger.

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. 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. These efforts require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance-reporting capabilities.

The Company's product candidates are in pre-clinical and clinical development. There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's intellectual property will be obtained, or maintained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales. The Company operates in an environment of rapid change in technology and substantial competition from pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees and consultants.

Unaudited Interim Financial Information

The accompanying unaudited consolidated financial statements for the three and nine months ended September 30, 2023 and 2022 have been prepared by the Company, pursuant to the rules and regulations of the Securities and Exchange Commission, or the SEC, for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP, have been condensed or omitted pursuant to such rules and regulations. These consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements and the notes thereto for the year ended December 31, 2022 included in the Company's Annual Report on Form 10-K that was filed with the SEC on March 2, 2023. The unaudited interim financial statements have been prepared on the same basis as the audited consolidated financial statements. In the opinion of management, the accompanying unaudited interim consolidated financial statements contain all adjustments that are necessary for a fair statement of the Company's financial position as of September 30, 2023, the consolidated results of operations for the three and nine months ended September 30, 2023, and cash flows for the nine months ended September 30, 2023. Such adjustments are of a normal and recurring nature. The results of operations for the three and nine months ended September 30, 2023 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2023.

Liquidity and Management's Plan

The future success of the Company is dependent on its ability to develop its product candidates and ultimately upon its ability to attain and sustain profitable operations. The Company is subject to a number of risks similar to other early-stage life science companies, including, but not limited to, successful development of its product candidates, raising additional capital with favorable terms, protection of proprietary technology and market acceptance of any approved future products. The successful development of product candidates requires substantial working capital, which may not be available to the Company on favorable terms or at all.

To date, the Company has financed its operations primarily through public offerings and private placements of its securities, funding received from research grants, collaboration and license arrangements and its credit facility. The Company currently has no source of product revenue, and it does not expect to generate product revenue for the foreseeable future. To date, the Company's revenue has primarily been from collaboration and license agreements.

As of September 30, 2023, the Company's cash, cash equivalents and restricted cash were $81.0 million, of which $1.4 million was restricted cash related to lease commitments and $0.2 million was held by its Russian subsidiary designated solely for use in its operations. The Company believes the cash, cash equivalents and restricted cash as of September 30, 2023 will enable it to fund its current planned operations for at least the next twelve months from the date of issuance of these financial statements. Management's expectations with respect to its ability to fund current and long-term planned operations are based on estimates that are subject to risks and uncertainties. If actual results are different from management's estimates, the Company may need to seek additional strategic or financing opportunities sooner than would otherwise be expected. However, there is no guarantee that any collaboration milestones will be achieved or that any of these strategic or financing opportunities will be executed on favorable terms, and some could be dilutive to existing stockholders. If the Company is unable to obtain additional funding on a timely basis, it may be forced to significantly curtail, delay, or discontinue one or more of its planned research or development programs or be unable to expand or maintain its operations or otherwise capitalize on its commercialization of its product candidates. The Company anticipates continuing to generate operating losses for the foreseeable future due to, among other things, costs related to research and development of its product candidates and its administrative organization.

Guarantees and Indemnifications

As permitted under Delaware law, the Company indemnifies its officers, directors, consultants and employees for certain events or occurrences that happen by reason of the relationship with, or position held at the Company. Through September 30, 2023, the Company had not experienced any losses related to these indemnification obligations, and no claims were outstanding. The Company does not expect significant claims related to these indemnification obligations and, consequently, concluded that the fair value of these obligations is negligible, and no related reserves were established.

2. Summary of Significant Accounting Policies

The Company disclosed its significant accounting policies in Note 2 – Summary of Significant Accounting Policies included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022. There have been no material changes to the Company's significant accounting policies during the nine months ended September 30, 2023, with the exception of the matters discussed in recent accounting pronouncements.

Recent Accounting Pronouncements

Recently Adopted

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments-Credit Losses (Topic 326), Measurement of Credit Losses on Financial Instruments*. Subsequently, in November 2018, the FASB issued ASU 2018-19, *Codification Improvements to Topic 326, Financial Instruments-Credit Losses*. ASU 2016-13 requires entities to measure all expected credit losses for most financial assets held at the reporting date based on an expected loss model which includes historical experience, current conditions, and reasonable and supportable forecasts. ASU 2016-13 also requires enhanced disclosures to help financial statement users better understand significant estimates and judgments used in estimating credit losses. This ASU is effective for smaller reporting companies for fiscal years beginning after December 15, 2022, with early adoption permitted. The Company adopted the new standard effective January 1, 2023, using a modified retrospective transition method, and there was no impact on its consolidated financial statements or results of operations upon adoption.

3. Marketable Securities and Investments

No marketable securities were held as of September 30, 2023. The following table summarizes the marketable securities held as of December 31, 2022 (in thousands):

	Amortized cost	Unrealized losses	Fair value
December 31, 2022			
U.S. government agency securities and treasuries	$ 13,566	$ (9)	$13,557
Corporate bonds	$ 1,953	$ (2)	$ 1,951
Commercial paper	12,656	—	12,656
Total	$ 28,175	$ (11)	$28,164

Investments

As of September 30, 2023 and December 31, 2022, the Company has a $2.0 million investment in Cyrus Biotechnology, Inc., or Cyrus, pursuant to an investment agreement entered into in connection with the Collaboration and License Agreement with Cyrus. The Company's maximum exposure to loss related to this variable interest entity is limited to the carrying value of the investment.

4. Net (Loss) Income Per Share

The following table sets forth the computation of basic and diluted net (loss) income per share for the three and nine months ended September 30, 2023 and 2022 (in thousands, except share and per-share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Numerator:				
Net (loss) income	$ (9,002)	$ (7,893)	$ (42,052)	$ 29,486
Less: Change in fair value of liability warrants	—	—	—	(7,329)
Adjusted net (loss) income	$ (9,002)	$ (7,893)	$ (42,052)	$ 22,157
Denominator:				
Weighted-average common shares outstanding —basic	154,804,503	152,849,992	153,870,912	141,969,449
Dilutive effect of employee equity incentive plans and outstanding warrants	—	—	—	1,822,611
Weighted-average common shares used in per share calculations—diluted	154,804,503	152,849,992	153,870,912	143,792,060
Net (loss) income per share:				
Basic	$ (0.06)	$ (0.05)	$ (0.27)	$ 0.21
Diluted	$ (0.06)	$ (0.05)	$ (0.27)	$ 0.15

The following table represents the potential dilutive shares of common stock excluded from the computation of the diluted net (loss) income per share for all periods presented, as the effect would have been anti-dilutive:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Options, RSUs and ESPP shares	22,037,652	16,147,192	22,037,652	16,960,983
Warrants to purchase common stock	31,224,703	31,228,279	31,224,703	213,339
Total	53,262,355	47,375,471	53,262,355	17,174,322

5. Fair Value Measurements

The following tables present the Company's assets and liabilities that are measured at fair value on a recurring basis as of September 30, 2023 and December 31, 2022 (in thousands):

	September 30, 2023			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds (included in cash equivalents)	$74,340	$74,340	$ —	$ —
Total assets	$74,340	$74,340	$ —	$ —
Liabilities:				
Warrant liabilities	$13,091	$ —	$ —	$13,091
Total liabilities	$13,091	$ —	$ —	$13,091

	December 31, 2022			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds (included in cash equivalents)	$53,552	$53,552	$ —	$ —
Marketable securities:				
U.S. government agency securities and treasuries	13,557	—	13,557	—
Corporate bonds	1,951	—	1,951	—
Commercial paper	12,656	—	12,656	—
Total assets	$81,716	$53,552	$28,164	$ —
Liabilities:				
Warrant liabilities	$19,140	$ —	$ —	$19,140
Total liabilities	$19,140	$ —	$ —	$19,140

There were no transfers within the fair value hierarchy during the nine months ended September 30, 2023 or year ended December 31, 2022.

Cash, Cash Equivalents, and Restricted Cash

As of September 30, 2023 and December 31, 2022, money market funds were classified as cash and cash equivalents on the accompanying consolidated balance sheets as they mature within 90 days from the date of purchase.

As of September 30, 2023, the Company had a restricted cash balance relating to a secured letter of credit in connection with its lease for the Company's headquarters. The Company's consolidated statements of cash flows include the following as of September 30, 2023 and 2022 (in thousands):

	September 30,	
	2023	2022
Cash and cash equivalents	$79,603	$112,843
Long-term restricted cash	1,377	1,600
Total cash, cash equivalents, and restricted cash	$80,980	$114,443

Marketable Securities

No marketable securities were held as of September 30, 2023. As of December 31, 2022, marketable securities classified as Level 2 within the valuation hierarchy consist of U.S. government agency securities and treasuries, corporate bonds and commercial paper which are available-for-sale securities in accordance with the Company's investment policy. The Company estimates the fair value of these marketable securities by taking into consideration valuations that include market pricing based on real-time trade data for the same or similar securities, and other observable inputs. The amortized cost of available-for-sale debt securities is adjusted for amortization of premiums and accretion of discounts to the earliest call date for premiums or to maturity for discounts.

Warrants

In December 2019, the Company issued warrants to purchase common stock in connection with a private placement of shares of common stock, or the 2019 Warrants. Pursuant to the terms of the 2019 Warrants, the Company could be required to settle the 2019 Warrants in cash in the event of certain acquisitions of the Company and, as a result, the 2019 Warrants were required to be measured at fair value and reported as a liability on the balance sheet. On December 20, 2022, the Company amended the terms of the outstanding 2019 Warrants held by certain members of the Board, or the Amended 2019 Warrants, to remove the cash settlement provision. As a result, the Amended 2019 Warrants were remeasured at fair value on December 20, 2022 and reclassified from a liability to equity on the balance sheet. See Note 10 to the consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2022 for further discussion on the equity-classified Amended 2019 Warrants.

In April 2022, the Company issued warrants in connection with an underwritten offering of shares of common stock and warrants to purchase shares of common stock, or the 2022 Warrants. Pursuant to the terms of the 2022 Warrants, the Company could be required to settle the 2022 Warrants in cash in the event of an acquisition of the Company under certain circumstances and, as a result, the 2022 Warrants are required to be measured at fair value and reported as a liability on the balance sheet.

The Company recorded the fair value of the 2019 Warrants and the 2022 Warrants upon issuance using the Black-Scholes valuation model and is required to revalue the 2019 Warrants and the 2022 Warrants at each reporting date, with any changes in fair value recorded in the statement of operations and comprehensive income (loss). The valuations of the 2019 Warrants and the 2022 Warrants are classified as Level 3 of the fair value hierarchy due to the need to use assumptions in the valuations that are both significant to the fair value measurement and unobservable, including the stock price volatility and the expected life of the 2019 Warrants and the 2022 Warrants. Generally, increases (decreases) in the fair value of the underlying stock and estimated term would result in a directionally similar impact to the fair value measurement.

The estimated fair values of the 2019 Warrants and the 2022 Warrants were determined using the following inputs to the Black-Scholes simulation valuation:

Estimated fair value of the underlying stock. The Company estimates the fair value of the common stock based on the closing stock price at the end of each reporting period.

Risk-free interest rate. The risk-free interest rate is based on the U.S. Treasury at the valuation date commensurate with the expected remaining life assumption.

Dividend rate. The dividend rate is based on the historical rate, which the Company anticipates will remain at zero.

Expected life. The expected life of the 2019 Warrants and the 2022 Warrants is assumed to be equivalent to their remaining contractual terms which expire on December 23, 2024 and April 11, 2027, respectively.

Volatility. The Company estimates stock price volatility based on the Company's historical volatility for a period of time commensurate with the expected remaining life of the warrants.

A summary of the Black-Scholes pricing model assumptions used to record the fair value of the 2019 Warrants liability is as follows:

	September 30, 2023	December 31, 2022
Risk-free interest rate	5.46%	4.74%
Dividend yield	—	—
Expected life (in years)	1.23	1.98
Expected volatility	70.10%	79.92%

A summary of the Black-Scholes pricing model assumptions used to record the fair value of the 2022 Warrants liability is as follows:

	September 30, 2023	December 31, 2022
Risk-free interest rate	4.80%	4.22%
Dividend yield	—	—
Expected life (in years)	3.53	4.28
Expected volatility	81.78%	98.05%

Changes in Level 3 Liabilities Measured at Fair Value on a Recurring Basis

The following table reflects a roll-forward of fair value for the Company's Level 3 warrant liabilities (see Note 10 to these unaudited consolidated financial statements), for the nine months ended September 30, 2023 (in thousands):

	Warrant liabilities
Fair value as of December 31, 2022	$19,140
Change in fair value	(6,049)
Fair value as of September 30, 2023	$13,091

6. Property and Equipment

Property and equipment consists of the following (in thousands):

	September 30, 2023	December 31, 2022
Laboratory equipment	$ 6,732	$ 6,001
Computer equipment and software	701	697
Leasehold improvements	61	57
Furniture and fixtures	452	453
Office equipment	196	192
Construction in process	22	599
Total property and equipment	8,164	7,999
Less: Accumulated depreciation	(5,743)	(5,205)
Property and equipment, net	$ 2,421	$ 2,794

Depreciation expense was $0.1 million and $0.2 million for the three months ended September 30, 2023 and 2022, respectively and $0.5 million for each of the nine months ended September 30, 2023 and 2022.

7. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	September 30, 2023	December 31, 2022
Payroll and employee related expenses	$ 4,774	$ 4,242
Accrued patent fees	561	696
Accrued external research and development costs	5,655	7,274
Accrued professional and consulting services	2,287	985
Accrued interest	—	222
Other	360	665
Accrued expenses	$ 13,637	$ 14,084

8. Leases

65 Grove Street Lease

In July 2019, the Company entered into a lease with BRE-BMR Grove LLC for 25,078 square feet of laboratory and office space located at 65 Grove Street, Watertown, Massachusetts, or the Headquarters Lease. On September 1, 2022, the Company entered into an amendment, or the Lease Agreement Amendment, to the Headquarters Lease, to expand the Company's corporate headquarters located at 65 Grove Street, Watertown, Massachusetts by approximately 7,216 square feet. In connection with the Lease Agreement Amendment, the Company secured a letter of credit for the Headquarters Lease from Silicon Valley Bank, a division of First-Citizens Bank & Trust Company (successor by purchase to the Federal Deposit Insurance Corporation as Receiver for Silicon Valley Bridge Bank, N.A. (as successor to Silicon Valley Bank)), or SVB, for $1.6 million as of December 31, 2022.

In May 2023, the Company received notice from BRE-BMR Grove LLC that the requirements to reduce the amount of the letter of credit for the Headquarters Lease had been met. In connection therewith, in June 2023, the Company secured a letter of credit from JPMorgan Chase Bank, N.A. for $1.4 million, which is recognized as long-term restricted cash as of September 30, 2023, and renews automatically each year. The $1.6 million letter of credit with SVB was released from restriction and returned to the Company on July 17, 2023, and therefore was reclassified into cash and cash equivalents in the consolidated balance sheets.

For the three and nine months ended September 30, 2023 and 2022, the components of lease costs were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating lease cost	$ 696	$ 569	$2,088	$1,580
Variable lease cost	271	205	683	630
Short-term lease cost	1	3	6	8
Less: Sublease income	(250)	—	(756)	—
Total lease cost	$ 718	$ 777	$2,021	$2,218

The maturity of the Company's operating lease liabilities as of September 30, 2023 were as follows (in thousands):

	September 30, 2023
2023 (remainder)	$ 677
2024	2,740
2025	2,818
2026	2,902
2027	2,990
Thereafter	946
Total future minimum lease payments	13,073
Less: Imputed interest	2,592
Total operating lease liabilities	$ 10,481

The supplemental disclosure for the statement of cash flows related to operating leases was as follows (in thousands):

	Nine Months Ended September 30,	
	2023	2022
Cash paid for amounts included in the measurement of lease liabilities:	$1,991	$1,395

Other than the initial recording of the right-of-use asset and lease liability for the Lease Agreement Amendment in 2022, which were non-cash, the changes in the Company's right-of-use assets and lease liabilities for the nine months ended September 30, 2023 and 2022 are reflected in the non-cash lease expense and accrued expenses and other liabilities, respectively, in the consolidated statements of cash flows.

The following summarizes additional information related to operating leases:

	September 30,	
	2023	2022
Weighted-average remaining lease term	4.7 years	5.6 years
Weighted-average discount rate	9.7%	9.6%

9. Debt

2020 Term Loan

On August 31, 2020, the Company entered into a Loan and Security Agreement with Oxford Finance LLC, or Oxford, and Silicon Valley Bank, or the Loan and Security Agreement, and such facility, the 2020 Term Loan. On March 10, 2023, Silicon Valley Bank was closed by the California Department of Financial Protection and Innovation, and the Federal Deposit Insurance Corporation, or the FDIC, was appointed as receiver. On March 13, 2023, the FDIC announced that all of Silicon

Valley Bank's deposits and substantially all of its assets had been transferred to a newly created, full-service, FDIC-operated bridge bank, Silicon Valley Bridge Bank, N.A., or SVBB. SVBB assumed all loans that were previously held by Silicon Valley Bank. On March 27, 2023, First-Citizens Bank & Trust Company assumed all of SVBB's customer deposits and certain other liabilities and acquired substantially all of SVBB's loans and certain other assets from the FDIC, including the 2020 Term Loan.

On September 11, 2023, the Company entered into a payoff letter with Oxford and SVB, pursuant to which the Company paid all outstanding amounts under the 2020 Term Loan, together with accrued interest and a prepayment penalty, resulting in the full extinguishment of the 2020 Term Loan. The total payoff amount was $22.3 million, consisting of the remaining principal amount due of $19.8 million, the final payment fee of $2.3 million, the prepayment penalty of $0.2 million, and less than $0.1 million of accrued interest.

During the three and nine months ended September 30, 2023, the Company recorded a loss of $0.7 million on the extinguishment of the 2020 Term Loan, consisting of the prepayment penalty of $0.2 million and the write-off of $0.5 million of unamortized debt issuance costs and venture debt termination fee, which was included within interest expense in the consolidated statements of operations and comprehensive income (loss).

As of September 30, 2023, the Company had no outstanding borrowings, and as of December 31, 2022, the outstanding principal balance under the 2020 Term Loan was $25.0 million.

10. Equity

Equity Financings

"At-the-Market" Offerings

On October 25, 2021, the Company entered into a Sales Agreement, or the 2021 Sales Agreement, with SVB Leerink LLC (now known as Leerink Partners LLC), or Leerink Partners, pursuant to which the Company may sell shares of the Company's common stock, from time to time, through an "at the market" equity offering program under which Leerink Partners will act as sales agent. The shares of common stock sold pursuant to the 2021 Sales Agreement will be issued pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-241692), for aggregate gross sales proceeds of up to $75.0 million.

During the year ended December 31, 2022, the Company sold 774,544 shares of its common stock pursuant to the 2021 Sales Agreement for aggregate net proceeds of $2.1 million, after deducting commissions and other transaction costs.

During the nine months ended September 30, 2023, the Company sold no shares of its common stock pursuant to the 2021 Sales Agreement.

Warrants

The following is a summary of warrant activity for the three and nine months ended September 30, 2023:

	Number of Warrants			Weighted-average exercise price
	Equity classified	Liability classified	Total	
Outstanding at December 31, 2022	2,236,326	28,991,953	31,228,279	$ 1.53
Canceled	(3,576)	—	(3,576)	16.77
Outstanding at September 30, 2023	2,232,750	28,991,953	31,224,703	$ 1.53

See Note 10 to the consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022 for further discussion of the terms related to the Company's warrants.

Reserved Shares

The Company has authorized shares of common stock for future issuance as of September 30, 2023 as follows:

Exercise of warrants	31,224,703
Shares available for future stock incentive awards	8,142,893
RSUs reserved for issuance	349,750
Unvested restricted stock units	2,052,967
Outstanding common stock options	19,966,999
Total	61,737,312

11. Stock Incentive Plans

The Company maintains the 2008 Stock Incentive Plan, or the 2008 Plan, for employees, consultants, advisors, and directors. The 2008 Plan provided for the granting of incentive and non-qualified stock option and restricted stock awards as determined by the Board.

In June 2016, the Company's stockholders approved the 2016 Incentive Award Plan, or the 2016 Plan, which authorized 1,210,256 shares of common stock for future issuance under the 2016 Plan and the Company ceased granting awards under the 2008 Plan. Upon the effective date of the 2016 Plan, awards issued under the 2008 Plan remain subject to the terms of the 2008 Plan. Awards granted under the 2008 Plan that expire, lapse or terminate become available under the 2016 Plan as shares available for future grants.

Additionally, pursuant to the terms of the 2016 Plan, the Board is authorized to grant awards with respect to common stock, and may delegate to a committee of one or more members of the Board or executive officers of the Company the authority to grant options and restricted stock units. On December 9, 2020, the Board established a Stock Option Committee authorized to grant awards to certain employees and consultants subject to conditions and limitations within the 2016 Plan. In January 2023, the number of shares of common stock that may be issued under the 2016 Plan was increased by 6,121,697 shares. As of September 30, 2023, 2,734,937 shares remain available for future issuance under the 2016 Plan.

In September 2018, the Company's 2018 Employment Inducement Incentive Award Plan, or the 2018 Inducement Incentive Award Plan was adopted by the Board without stockholder approval pursuant to Rule 5635(c)(4) of the Nasdaq Stock Market LLC listing rules, which authorized 1,175,000 shares of its common stock for issuance. In March 2019, the Board approved the amendment and restatement of the 2018 Inducement Incentive Award Plan to reserve an additional 2,000,000 shares of the Company's common stock for issuance thereunder. As of September 30, 2023, there are 425,858 shares available for future grant under the 2018 Inducement Incentive Award Plan.

Stock-Based Compensation Expense

Stock-based compensation expense by classification included within the consolidated statements of operations and comprehensive income (loss), including $1.5 million recognized as stock-based compensation expense upon the achievement of a technical milestone by Ginkgo Bioworks Holdings, Inc., or Ginkgo, during the nine months ended September 30, 2023 and $1.0 million recognized as stock-based compensation expense upon the issuance of common stock to Ginkgo during the nine months ended September 30, 2022 as described in Note 14, was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Research and development	$ 1,189	$ 954	$5,058	$3,993
General and administrative	1,132	1,647	3,322	4,925
Total stock-based compensation expense	$ 2,321	$ 2,601	$8,380	$8,918

Stock Options

The estimated grant date fair values of employee stock option awards granted under the 2016 Plan and the 2018 Inducement Incentive Award Plan were calculated using the Black-Scholes option pricing model, based on the weighted-average assumptions in the following table. No stock options were granted during the three months ended September 30, 2023.

	Three Months Ended September 30,	Nine Months Ended September 30,	
	2022	2023	2022
Risk-free interest rate	3.86%	3.95%	1.79%
Dividend yield	—	—	—
Expected term	5.93	5.94	6.03
Expected volatility	93.37%	94.64%	91.97%
Weighted-average fair value of common stock	$ 1.69	$ 1.15	$ 2.99

The expected term of the Company's stock options granted to employees has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. Under the simplified method, the expected term is presumed to be the midpoint between the vesting date and the end of the contractual term. The Company utilizes this method due to lack of historical exercise data and the plain nature of its stock-based awards.

The weighted-average grant date fair value of stock options granted to employees was $1.31 during the three months ended September 30, 2022 and $0.90 and $2.26 during the nine months ended September 30, 2023 and 2022, respectively.

As of September 30, 2023, total unrecognized compensation expense related to unvested employee stock options was $11.6 million, which is expected to be recognized over a weighted-average period of 2.5 years.

The following table summarizes the stock option activity under the 2008 Plan, the 2016 Plan, and the 2018 Inducement Incentive Award Plan:

	Number of options	Weighted-average exercise price ($)	Weighted-average remaining contractual term (in years)	Aggregate intrinsic value (in thousands)
Employees				
Outstanding at December 31, 2022	15,578,412	$ 3.44	7.57	$ 4
Granted	5,477,200	$ 1.15		
Forfeited	(1,354,852)	$ 2.98		
Outstanding at September 30, 2023	19,700,760	$ 2.84	7.73	$ —
Vested at September 30, 2023	9,374,463	$ 3.87	6.60	$ —
Vested and expected to vest at September 30, 2023	18,644,435	$ 2.90	7.66	$ —
Non-employee consultants				
Outstanding at December 31, 2022	266,239	$ 8.05	5.08	$ —
Outstanding at September 30, 2023	266,239	$ 8.05	4.33	$ —
Vested at September 30, 2023	266,239	$ 8.05	4.33	$ —
Vested and expected to vest at September 30, 2023	266,239	$ 8.05	4.33	$ —

Restricted Stock Units

During the nine months ended September 30, 2023, the Company granted 1,054,600 restricted stock awards with a weighted-average fair value of $1.13 per share based on the closing price of the Company's common stock on the date of grant to employees under the 2016 Plan, which will vest over a four-year term. Forfeitures are estimated at the time of grant and are adjusted, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company has estimated a forfeiture rate of 10% for restricted stock awards to employees based on historical experience.

Unrecognized compensation expense for all restricted stock units was $2.7 million as of September 30, 2023, which is expected to be recognized over a weighted-average period of 2.5 years.

The following table summarizes the Company's restricted stock units under the 2016 Plan and 2018 Inducement Incentive Award Plan:

	Number of shares	Weighted-average grant date fair value ($)
Unvested at December 31, 2022	1,705,558	$ 2.62
Granted	1,054,600	1.13
Vested	(636,018)	2.40
Forfeited	(71,173)	1.99
Unvested at September 30, 2023	2,052,967	$ 1.95

Employee Stock Purchase Plan

In June 2016, the Company approved the 2016 Employee Stock Purchase Plan, or the ESPP, which authorized 173,076 shares of common stock for future issuance under the ESPP to participating employees. In January 2023, the number of shares of common stock authorized for issuance under the ESPP was increased by 1,530,424 shares. During the nine months ended September 30, 2023, the Company issued 186,044 shares of common stock under the ESPP. As of September 30, 2023, 4,982,098 shares remain available for future issuance under the ESPP.

The Company recognized stock-based compensation expense under the ESPP of less than $0.1 million for each of the three months ended September 30, 2023 and 2022 and $0.1 million for each of the nine months ended September 30, 2023 and 2022.

12. Revenue Arrangements

Astellas Gene Therapies

In January 2023, the Company entered into a License and Development Agreement, or the Astellas Agreement, with Audentes Therapeutics, Inc., doing business as Astellas. Under the Astellas Agreement, the Company granted Astellas an exclusive license to the Company's IdeXork technology arising from Xork (defined below), to develop and commercialize Xork for use in Pompe disease in combination with an Astellas gene therapy investigational or authorized product. Xork, Genovis' IgG Protease, is licensed by the Genovis Agreement, as described in Note 14 to these consolidated financial statements. Astellas paid a $10.0 million upfront payment to the Company upon signing of the Astellas Agreement, and the Company is entitled to receive up to $340.0 million in future additional payments over the course of the partnership that are contingent on the achievement of various development and regulatory milestones and, if commercialized, sales thresholds for annual net sales where Xork is used as a pre-treatment for an Astellas investigational or authorized product. The Company is also eligible for tiered royalty payments ranging from low to high single digits.

Pursuant to the Astellas Agreement, the Company will have the exclusive right and responsibility to complete research and development of Xork products and to conduct all preclinical studies and clinical trials for Xork for use in Pompe disease with an Astellas gene therapy investigational or authorized product, or the Xork Development Services. Astellas will reimburse the Company for 25% of all budgeted costs incurred to complete the development of Xork for use in Pompe disease with an Astellas gene therapy investigational or authorized product. The Company will have control and responsibility over regulatory filings, including any investigational drug applications, biologics license applications, and marketing authorization applications relating to the licensed product. Astellas will have the exclusive right and responsibility to research, develop, and commercialize Astellas products used in combination with Xork and will have control and responsibility over all regulatory filings, including any investigational drug applications, biologics license applications, and marketing authorization applications, relating to Astellas products and Astellas products used in combination with Xork.

The Company determined the Astellas Agreement represents a service arrangement under the scope of ASC 606. The Company determined that the sublicense of Xork to Astellas, the licensed know-how, and the Xork Development Services represent a single promise and performance obligation to be transferred to Astellas over time due to the nature of the promises in the contract. As such, the Company will recognize the transaction price as revenue utilizing the input method to measure the progress of satisfying the single performance obligation to Astellas.

In determining the transaction price, the Company concluded the upfront payment of $10.0 million and development cost reimbursements of $5.5 million will be included in the initial transaction price. All other development milestones will be fully constrained and will only be included in the transaction price when the applicable milestone is deemed probable of achievement. Each of these variable consideration items were evaluated under the most likely amount method to determine whether such amounts were probable of occurrence, or whether such amounts should be constrained until they become probable. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt and timing of such development milestones is outside the control of the Company and probability of success criteria is estimated. The Company will re-evaluate the transaction price in each reporting period, as uncertain events are resolved, or as other changes in circumstances occur. In accordance with ASC 606, the Company will only recognize revenue associated with sales-based milestones and royalties when the subsequent sales thresholds are reached and underlying sales occur, respectively. The Company determined that a significant financing component does not exist in its arrangement with Astellas. The Company also determined the options to negotiate additional fields, enter into a clinical supply agreement, and enter into a commercial supply agreement do not represent material rights under the Astellas Agreement. Astellas has the right to terminate the Astellas Agreement in its entirety or on a field-by-field basis, upon 90 days' written notice to the Company.

As of September 30, 2023, the Company recorded $4.1 million as a short-term contract liability and $4.0 million as a long-term contract liability, representing deferred revenue associated with the Astellas Agreement. As of September 30, 2023, the Company recorded a receivable of $0.5 million, representing billings for the Xork Development Services that are subject to reimbursement by Astellas. Revenue of $1.5 million and $2.9 million related to the Astellas Agreement was recognized during the three and nine months ended September 30, 2023, respectively.

Takeda Pharmaceuticals USA, Inc.

License and Development Agreement

In October 2021, the Company entered into a License Agreement, or the Takeda Agreement, with Takeda Pharmaceuticals USA, Inc., or Takeda. Under the Takeda Agreement, the Company granted Takeda an exclusive license to the Company's ImmTOR technology initially for two specified disease indications within the field of lysosomal storage disorders. Takeda paid a $3.0 million upfront payment to the Company upon signing of the Takeda Agreement, and the Company was entitled to receive up to $1.124 billion in future additional payments over the course of the partnership that were contingent on the achievement of development or commercial milestones or Takeda's election to continue its activities at specified development stages. The Company was also eligible for tiered royalties on future commercial sales of any licensed products. A more detailed description of the Takeda Agreement and the Company's evaluation of this agreement under ASC 606 can be found in Note 12 to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2022.

On March 9, 2023, the Company was notified by Takeda of the achievement of the milestone event related to the completion of a non-clinical milestone for one of the specified disease indications within the field of lysosomal storage disorders under the Takeda Agreement. Accordingly, the Company received a milestone payment of $0.5 million during the three months ended June 30, 2023.

The Takeda Agreement was terminated effective July 25, 2023, following Takeda's decision to discontinue discovery and pre-clinical activities in adeno-associated virus, or AAV, gene therapy.

As of September 30, 2023 and December 31, 2022, the Company recorded no short-term contract liability and $0.1 million as a short-term contract liability, respectively, representing deferred revenue associated with the Takeda Agreement. No revenue and revenue of $0.6 million related to the Takeda Agreement was recognized during the three and nine months ended September 30, 2023, respectively. No revenue and revenue of $1.0 million related to the Takeda Agreement was recognized during the three and nine months ended September 30, 2022, respectively.

Swedish Orphan Biovitrum AB (publ.)

License and Development Agreement

In June 2020, the Company and Sobi entered into a License and Development Agreement, or the Sobi License. Pursuant to the Sobi License, the Company agreed to grant Sobi an exclusive, worldwide (except as to Greater China) license to develop, manufacture and commercialize the Company's SEL-212 drug candidate, which is currently in development for the treatment of chronic refractory gout. The SEL-212 drug candidate is a pharmaceutical composition containing a combination of pegadricase, or the Compound, and ImmTOR. Pursuant to the Sobi License, in consideration of the license, Sobi agreed to pay the Company a one-time, upfront payment of $75.0 million. Sobi has also agreed to make milestone payments totaling up to $630.0 million to the Company upon the achievement of various development and regulatory milestones and, if commercialized, sales thresholds for annual net sales of SEL-212, and tiered royalty payments ranging from the low double digits on the lowest sales tier to the high teens on the highest sales tier. A more detailed description of the Sobi License and the Company's evaluation of this agreement under ASC 606 can be found in Note 12 to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2022.

On October 31, 2023, the Company and Sobi entered into Amendment No. 1 to the Sobi License, pursuant to which the Company granted Sobi an exclusive license to manufacture ImmTOR solely in connection with Sobi's development of SEL-212 under the Sobi License and is transferring certain contracts and manufacturing equipment to Sobi.

As of September 30, 2023 and December 31, 2022, the Company recorded a total outstanding receivable of $4.2 million and $5.0 million, respectively, representing billings for the Phase 3 DISSOLVE program that are subject to reimbursement by Sobi. Additionally, as of September 30, 2023 and December 31, 2022, the Company recorded a total unbilled receivable of $1.9 million and $3.2 million, respectively, representing revenue earned but not yet billed for the Phase 3 DISSOLVE program. Revenue of $5.0 million and $13.7 million related to the Sobi License was recognized during the three and nine months ended September 30, 2023, respectively. Revenue of $20.7 million and $73.6 million related to the Sobi License was recognized during the three and nine months ended September 30, 2022, respectively.

Sarepta Therapeutics, Inc.

Research License and Option Agreement

In June 2020, the Company and Sarepta Therapeutics, Inc., or Sarepta, entered into a Research License and Option Agreement, or the Sarepta Agreement. Pursuant to the Sarepta Agreement, the Company agreed to grant Sarepta a license under the Company's intellectual property rights covering the Company's antigen-specific biodegradable nanoparticle encapsulating ImmTOR to research and evaluate ImmTOR in combination with Sarepta's adeno-associated virus gene therapy technology, or gene editing technology, using viral or non-viral delivery, to treat Duchenne Muscular Dystrophy and certain Limb-Girdle Muscular Dystrophy subtypes, or the Indications. Sarepta initially had an option term of 24 months during which it could opt-in to obtain an exclusive license to further develop and commercialize the product to treat at least one indication, with a potential to extend the option term for an additional fee. The Company agreed to supply ImmTOR to Sarepta for clinical supply on a cost-plus basis under the Sarepta Agreement. A more detailed description of the Sarepta Agreement and the Company's evaluation of this agreement under ASC 606 can be found in Note 12 to the consolidated financial statements in our Annual Report on Form 10-K for the year ended December 31, 2022.

On March 13, 2023, the Company was notified by Sarepta that Sarepta would not be exercising its exclusive option under the Sarepta Agreement. Therefore, the remaining deferred revenue balance as of December 31, 2022 of $0.5 million was recognized as revenue during the nine months ended September 30, 2023. No revenue was recognized during the three months ended September 30, 2023. No revenue and revenue of $10.2 million was recognized during the three and nine months ended September 30, 2022, respectively.

Spark Therapeutics, Inc.

Spark License Agreement

In December 2016, the Company entered into a License and Option Agreement, or the Spark License Agreement, with Spark Therapeutics, Inc., or Spark, pursuant to which the Company and Spark agreed to collaborate on the development of gene therapies for certain targets utilizing the ImmTOR platform. The Spark License Agreement provides Spark with certain exclusive, worldwide, royalty bearing licenses to the Company's intellectual property, allowing Spark to develop and commercialize gene therapies in combination with ImmTOR for Factor VIII, an essential blood clotting protein relevant to the treatment of hemophilia A, the initial target.

On January 18, 2022, both parties agreed to mutually terminate the Spark License Agreement. Therefore, the short-term contract liability of $9.2 million as of December 31, 2021 was recognized as revenue during the nine months ended September 30, 2022. No revenue was recognized during the three months ended September 30, 2022.

Transaction Price Allocated to Future Performance Obligations

Remaining performance obligations represent the transaction price of contracts for which work has not been performed, or has been partially performed. As of September 30, 2023, the aggregate amount of the transaction price allocated to remaining performance obligations was $8.1 million.

Contract Balances from Contracts with Customers

The following table presents changes in the Company's contract liabilities during the nine months ended September 30, 2023 (in thousands):

Nine Months Ended September 30, 2023	Balance at beginning of period	Additions	Deductions	Balance at end of period
Contract liabilities:				
Deferred revenue	$ 593	$ 10,500	$ (2,972)	$ 8,121
Total contract liabilities	$ 593	$ 10,500	$ (2,972)	$ 8,121

13. Related-Party Transactions

April 2022 Offering

During the nine months ended September 30, 2022, the Company completed the underwritten offering as described in Note 10 to the consolidated financial statements within the Company's Annual Report on Form 10-K for the year ended December 31, 2022. The following table sets forth the number of shares of common stock and 2022 Warrants purchased in such offering by directors and executive officers, as of the time of such offering, and related parties thereto:

Name	Shares of common stock purchased	2022 Warrants purchased	Total aggregate purchase price
TAS Partners, LLC (affiliate of Timothy A. Springer, Ph.D.)	6,681,600	5,011,200	$ 9,421,056

During the three and nine months ended September 30, 2023, there were no related party transactions.

14. Collaboration and License Agreements

Ginkgo Bioworks Holdings, Inc.

Collaboration and License Agreements

On January 3, 2022, the Company entered into a Collaboration and License Agreement, or the Second Ginkgo Agreement, with Ginkgo Bioworks Holdings, Inc., or Ginkgo. Under this agreement, the Company will engage with Ginkgo to develop AAV, capsids designed to enhance transduction efficiency and transgene expression. In return, Ginkgo is eligible to earn both upfront research and development fees and milestone payments, including certain milestone payments in the form of shares of the Company's common stock, clinical and commercial milestone payments of up to $207 million in cash. The Second Ginkgo Agreement was assessed for collaboration components and was determined not to be within the scope of ASC 808 as the risk and rewards are not shared by both parties. The Company will expense costs related to the Second Ginkgo Agreement as incurred until regulatory approval is received in accordance with ASC 730. The Company is accounting for the contingently issuable shares of common stock to be issued in exchange for the license obtained from Ginkgo as a liability-classified, stock-based compensation arrangement with a non-employee which will be recognized when achievement of the milestones is probable. The Company will assess the capitalization of costs incurred after the receipt of regulatory approval and, if applicable, will amortize these payments based on the expected useful life of each asset, typically based on the expected commercial exclusivity period. The Company is also obligated to pay Ginkgo tiered royalties ranging from low-single digit to high-single digit percentages of annual net sales of collaboration products which will be expensed as the commercial sales occur.

In October 2021, the Company entered into a Collaboration and License Agreement, or the First Ginkgo Agreement, with Ginkgo. Under the First Ginkgo Agreement, Ginkgo will design next generation IgA proteases with potentially transformative therapeutic potential. In return, Ginkgo is eligible to earn research and development fees, clinical and commercial milestone payments of up to $85.0 million in cash, as well as certain milestone payments for fixed fair values in the form of shares of the Company's common stock. The First Ginkgo Agreement was assessed for collaboration components and was determined not to be within the scope of ASC 808 as the risk and rewards are not shared by both parties. The Company will expense costs related to the First Ginkgo Agreement as incurred until regulatory approval is received in accordance with ASC 730. The Company is accounting for the contingently issuable shares of common stock to be issued in exchange for the license obtained from Ginkgo as a liability-classified, stock-based compensation arrangement with a non-employee which will be recognized when achievement of the milestones is probable. The Company will assess the capitalization of costs incurred after the receipt of regulatory approval and, if applicable, will amortize these payments based on the expected useful life of each asset, typically based on the expected commercial exclusivity period. The Company is also obligated to pay Ginkgo tiered royalties ranging from low-single digit to high-single digit percentages of annual net sales of collaboration products which will be expensed as the commercial sales occur.

On June 13, 2022, the Company was notified of the achievement of the midpoint of the technical development plan under the First Ginkgo Agreement by Ginkgo. This milestone resulted in the payment of $0.5 million and issuance of 892,857 shares of the Company's common stock then-valued at $1.0 million to Ginkgo during the year ended December 31, 2022.

On July 19, 2023, the Company and Ginkgo mutually agreed that the completion of the technical development plan's midpoint task under the Second Ginkgo Agreement had been achieved as of June 30, 2023. This milestone resulted in the payment of $1.0 million and issuance of 1,339,285 shares of the Company's common stock then-valued at $1.5 million to Ginkgo during the three and nine months ended September 30, 2023.

Genovis AB (publ.)

License Agreement

In October 2021, the Company entered into an Exclusive License Agreement, or the Genovis Agreement, with Genovis AB (publ.), or Genovis. Under the Genovis Agreement, the Company paid to Genovis an upfront payment in exchange for an exclusive license to Genovis' IgG Protease, or Xork, enzyme technology across all therapeutic uses in humans, excluding research, preclinical, diagnostic and other potential non-therapeutic applications of the enzyme. Genovis is eligible to earn from the Company development and sales-based milestones and sublicensing fees. The Genovis Agreement was assessed for collaboration components and was determined not to be within the scope of ASC 808 as the risk and rewards are not shared by both parties. The Company will expense costs related to the Genovis Agreement as incurred until regulatory approval is received in accordance with ASC 730. The Company will assess the capitalization of costs incurred after the receipt of regulatory approval and, if applicable, will amortize these payments based on the expected useful life of each asset, typically based on the expected commercial exclusivity period. The Company is also obligated to pay Genovis tiered royalties of low double digit percentages of worldwide annual net sales of collaboration products which will be expensed as the commercial sales occur.

In February 2023, the Company made a $4.0 million payment to Genovis as a result of the sublicense of Xork to Astellas. See Note 12 to these unaudited consolidated financial statements for further discussion on the Astellas Agreement.

Cyrus Biotechnology, Inc.

Collaboration and License Agreement

In September 2021, the Company and Cyrus entered into a collaboration and license agreement, or the Cyrus Agreement. Pursuant to the Cyrus Agreement, Cyrus agreed to grant the Company an exclusive, worldwide license to certain intellectual property to form a protein engineering collaboration combining the Company's ImmTOR platform with Cyrus' ability to redesign protein therapeutics. The lead program is a proprietary interleukin-2, or IL-2, protein agonist designed to selectively promote expansion of regulatory T cells for treatment of patients with autoimmune diseases and other deleterious immune conditions. In return for the licensed intellectual property, the Company made an upfront payment and is obligated to pay certain discovery, development, and sales-based milestones which could total up to approximately $1.5 billion across multiple programs. The Cyrus Agreement was assessed for collaboration components and was determined not to be within the scope of ASC 808 as the risk and rewards are not shared by both parties. The Company will expense costs related to the Cyrus Agreement as incurred until regulatory approval is received in accordance with ASC 730. The Company will assess the capitalization of costs incurred after the receipt of regulatory approval and, if applicable, will amortize these payments based on the expected useful life of each asset, typically based on the expected commercial exclusivity period. The Company is also obligated to pay Cyrus tiered royalties ranging from mid-single digit to low-double digit percentages of annual net sales of collaboration products which will be expensed as the commercial sales occur.

On June 13, 2022, the Company and Cyrus mutually agreed that the preclinical key in-vitro success milestone had been achieved.

In October 2023, the Company notified Cyrus of its termination of the Cyrus Agreement, effective December 29, 2023.

Stock Purchase Agreement

Additionally, on September 7, 2021, the Company entered into a stock purchase agreement, or the Series B Preferred Stock Purchase Agreement, in connection with the Cyrus Agreement. Pursuant to the Series B Preferred Stock Purchase Agreement, the Company purchased 2,326,934 shares of Cyrus' Series B Preferred Stock, par value $0.0001 per share, at a purchase price of $0.8595 per share, for $2.0 million.

In accordance with ASC 810, the Company has a variable interest in Cyrus resulting from its equity investment. The Company will share in Cyrus' expected losses or receive a portion of its expected returns and absorb the variability associated with changes in the entity's net assets. However, the Company is not the primary beneficiary as it does not have the power to direct the activities most significant to Cyrus, and therefore it is not required to consolidate Cyrus. The Company has recognized the $2.0 million investment of Cyrus' Series B Preferred Stock at cost on the purchase date.

As of September 30, 2023, no impairment indicators are present and therefore the carrying value of the investment in Cyrus is $2.0 million on the accompanying consolidated balance sheet. The Company's maximum exposure to loss related to this variable interest entity is limited to the carrying value of the investment. The Company has not provided financing to Cyrus other than the amount contractually required by the Series B Preferred Stock Purchase Agreement.

Asklepios Biopharmaceutical, Inc.

Feasibility Study and License Agreement

In August 2019, the Company entered into a feasibility study and license agreement, or the AskBio Collaboration Agreement, with Asklepios Biopharmaceutical, Inc., or AskBio. Pursuant to the AskBio Collaboration Agreement, the Company and AskBio agreed to license intellectual property rights to each other as part of a collaboration to research, develop, and commercialize certain AAV gene therapy products utilizing the Company's ImmTOR platform to enable re-dosing of such AAV gene therapy products to treat serious rare and orphan genetic diseases for which there is a significant unmet medical need.

Pursuant to the AskBio Collaboration Agreement, the Company and AskBio agreed to conduct proof of concept studies to potentially validate the use of ImmTOR in conjunction with AskBio's AAV gene therapy, or SEL-302 (previously disclosed as MMA-101, in combination with ImmTOR), for the treatment of MMA to mitigate the formation of neutralizing anti-AAV capsid antibodies, or the POC Studies. On April 29, 2021, the Company was notified by AskBio that AskBio intended to opt-out of development of the MMA indication. The AskBio Collaboration Agreement otherwise remains in effect. Consequently, the Company has assumed all rights to the MMA program. The Company filed an investigational new drug application, or IND, to conduct a Phase 1/2 clinical trial of its SEL-302 product candidate in pediatric patients with MMA in the third quarter of 2021. In December 2022, the Company initiated ReiMMAgine, the Phase 1/2 clinical trial of SEL-302, however, the Company has since paused further development of SEL-302 for the treatment of MMA.

The SEL-399 program combined an empty AAV capsid (EMC-101), which is an AAV capsid containing no transgene, with ImmTOR and is being conducted in partnership with AskBio. Building on the preclinical data the Company has generated showing ImmTOR's effect on mitigating or reducing the formation of neutralizing antibodies to AAV gene therapies, the Company completed a clinical trial of SEL-399 in healthy adult volunteers in Belgium. The goal of the SEL-399 clinical trial was to demonstrate the appropriate dose of ImmTOR in humans to mitigate the formation of antibodies to AAV capsids used in gene therapies. The Company believes this promising study in healthy volunteers provides support for the potential use of ImmTOR for the inhibition of neutralizing antibodies to AAV8 in gene therapy clinical trials.

The Company and AskBio will share responsibility for the research, development and commercialization of products developed under the SEL-399 program collaboration. The parties will also share research, development, and commercialization costs equally for all collaboration products, but with a right of either party to opt out of certain products, and thereby no longer be required to share costs for such products. Each party will receive a percentage of net profits under the collaboration equal to the percentage of shared costs borne by such party in the development of such product. Pursuant to the AskBio Collaboration Agreement, AskBio is responsible for manufacturing the AAV capsids and AAV vectors and the Company is responsible for manufacturing ImmTOR.

The AskBio Collaboration Agreement is considered to be within the scope of ASC 808, as both parties are active participants and exposed to the risks and rewards of the collaborative activity. The Company evaluated the terms of the AskBio Collaboration Agreement and has identified the following promises in the arrangement (1) conducting research and development activities to develop and commercialize products under the collaboration, or the R&D Services, (2) granting a non-exclusive, non-transferable, royalty-free, fully paid up, worldwide license to certain intellectual property of the Company, or the IP Rights, for the purpose of performing the POC Studies, or the Research License, (3) granting an exclusive, nontransferable, worldwide license to the IP Rights for use in certain indications, or the Collaboration License, (4) providing manufactured supply of preclinical and clinical ImmTOR, or the Manufactured Supply, (5) participation on identified steering committees responsible for the oversight of the collaboration, or the JSC Participation, and (6) granting an exclusive option to obtain a license under the IP Rights to research, develop and commercialize licensed products. The Company determined that the R&D Services, Research License, Collaboration License, Manufactured Supply, and JSC Participation were not capable of being distinct, and therefore must be combined into a single performance obligation. Therefore, promises (1) through (5) identified above were combined into a single performance obligation. Furthermore, the Company evaluated the related option agreement and determined that it does not provide AskBio with a material right under ASC 606 as the option was not priced at a discount. The Company noted that AskBio did not meet the definition of a customer within the scope of ASC 606 for any distinct performance obligations as the Company concluded that such items were not an output of the Company's ordinary activities. As such, the Company determined that the entire arrangement would be accounted for within the scope of ASC 808. In accordance with ASC 808, collaboration expenses are recognized within research and development expense and selling, general and administrative expense on the Company's condensed consolidated statements of operations and comprehensive income (loss).

Under certain collaborative arrangements, the Company is entitled to reimbursement of certain research and development expense. Activities under collaborative arrangements for which the Company is entitled to reimbursement are considered to be collaborative activities under the scope of ASC 808. For these units of account, the Company does not analogize to ASC 606 or recognize revenue. Rather, the Company analogizes to the guidance in ASC 730, which requires that reimbursements from counterparties be recognized as an offset to the related costs. In accordance with ASC 730, the Company records reimbursement payments received from collaborators as reductions to research and development expense.

During the three and nine months ended September 30, 2023, the Company recognized less than $0.1 million and $0.1 million, respectively, of collaboration expense under the AskBio Collaboration Agreement in which actual costs incurred by both parties approximate a 50% cost share. During the three and nine months ended September 30, 2022, the Company recognized $0.2 million and $0.8 million, respectively, of collaboration expense under the AskBio Collaboration Agreement.

Massachusetts Institute of Technology

In November 2008, the Company entered into an Exclusive Patent License Agreement, or the MIT License, with the Massachusetts Institute of Technology, or MIT, under which the Company received an exclusive royalty-bearing license to utilize patents held by MIT in exchange for upfront consideration and annual license maintenance fees. Such fees are expensed as incurred and have not been material to any period presented.

In November 2023, the Company entered into a Sixth Amendment, or the Sixth Amendment, to the MIT License. Pursuant to the Sixth Amendment, the Company will be obligated to use commercially reasonable efforts to further enable the development of a licensed product thereunder.

As of September 30, 2023, and in connection with the execution of the Spark License Agreement, the Company has made contractual payments pursuant to the MIT License totaling $2.2 million. In connection with the Spark Purchase Agreement and the calculated premium paid by Spark for the equity investments made as described in Note 12 to the consolidated financial statements within the Company's Annual Report on Form 10-K for the year ended December 31, 2022, the Company has made additional contractual payments pursuant to the MIT License which totaled $0.4 million as of September 30, 2023. The Company made no additional payments during the three and nine months ended September 30, 2023.

Shenyang Sunshine Pharmaceutical Co., Ltd

In May 2014, the Company entered into a license agreement, or the 3SBio License, with Shenyang Sunshine Pharmaceutical Co., Ltd., or 3SBio. The Company has paid to 3SBio an aggregate of $7.0 million in upfront and milestone-based payments under the 3SBio License as of September 30, 2023. The Company is required to make future payments to 3SBio contingent upon the occurrence of events related to the achievement of clinical and regulatory approval milestones of up to an aggregate of $15.0 million for products containing the Company's ImmTOR platform.

15. Income Taxes

The Company provides for income taxes under ASC 740. Under ASC 740, the Company provides deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the Company's financial statement carrying amounts and the tax bases of assets and liabilities using enacted tax rates expected to be in effect in the years in which the differences are expected to reverse.

The Company has provided a full valuation allowance against its net deferred tax assets, as the Company believes that it is more likely than not that the deferred tax assets will not be realized.

Effective for tax years beginning on or after January 1, 2022, research and experimental expenditures under IRC Section 174 must be capitalized over five years when performed in the U.S. and 15 years for research and experimental expenditures performed outside of the U.S. As of September 30, 2023, the Company has performed a high-level analysis of the impact of this legislation enactment and determined the projected taxable loss position for 2023 does not result in income tax due. As of December 31, 2022, the Company has $62.4 million of federal net operating losses available, subject to an 80% limitation. The Company also has $2.3 million of federal tax credits, subject to a 75% limitation. The Company maintains its full valuation allowance.

Utilization of the net operating loss and research and development credit carryforwards may be subject to a substantial annual limitation under Section 382 and 383 of the Internal Revenue Code due to ownership change limitations that have occurred previously, or that could occur in the future. These ownership changes may limit the amount of net operating loss and research and development credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. As of December 31, 2021, the Company completed both a Section 382 and research and development tax credit study through December 31, 2020. The Company generated research credits for the years ended December 31, 2022 and 2021, but has not conducted a formal study to document its qualified activities.

The statute of limitations for assessment by the Internal Revenue Service and Massachusetts tax authorities is open for tax years since inception as the Company claimed research tax credits on its 2020 tax return which remains open for examination for the 2020 year as well as for any year in which a credit has been claimed. The Company files income tax returns in the United States and Massachusetts. There are currently no federal, state or foreign audits in progress.

16. Defined Contribution Plan

The Company maintains a defined contribution plan, or the 401(k) Plan, under Section 401(k) of the Internal Revenue Code. The 401(k) Plan covers all employees who meet defined minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pretax basis. The 401(k) Plan provides for matching contributions on a portion of participant contributions pursuant to the 401(k) Plan's matching formula. Commencing in January 2022, all matching contributions vest ratably over two years and participant contributions vest immediately. Contributions by the Company totaled $0.1 million during each of the three months ended September 30, 2023 and 2022, and $0.3 million during each of the nine months ended September 30, 2023 and 2022.

17. Commitments and Contingencies

As of September 30, 2023, the Company was not a party to any litigation that could have a material adverse effect on the Company's business, financial position, results of operations or cash flows.

Other

As permitted under Delaware law, the Company has agreed to indemnify its directors and officers for certain events or occurrences while the director or officer is, or was, serving at the Company's request in such capacity. The term of the indemnification is for the director's or officer's lifetime. The maximum potential amount of future payments the Company could be required to make is unlimited; however, the Company has directors' and officers' insurance coverage that limits its exposure and enables it to recover a portion of any future amounts paid. The Company also has indemnification arrangements under certain of its facility leases that require it to indemnify the landlord against certain costs, expenses, fines, suits, claims, demands, liabilities, and actions directly resulting from certain breaches, violations, or non-performance of any covenant or condition of the Company's lease. The term of the indemnification is for the term of the related lease agreement. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is unlimited. To date, the Company had not experienced any material losses related to any of its indemnification obligations, and no material claims with respect thereto were outstanding.

The Company is a party in various other contractual disputes and potential claims arising in the ordinary course of business. The Company does not believe that the resolution of these matters will have a material adverse effect on the Company's business, financial position, results of operations or cash flows.

18. Subsequent Events

On October 30, 2023, the Company notified Cyrus of its termination of the Cyrus Agreement, effective December 29, 2023.

On October 31, 2023, the Company and Sobi entered into Amendment No. 1 to the Sobi License, or the Amendment, pursuant to which the Company granted Sobi an exclusive license to manufacture ImmTOR solely in connection with Sobi's development of SEL-212 under the Sobi License and is transferring certain contracts and manufacturing equipment to Sobi. Additionally, in connection with entry into the Amendment, Sobi agreed to make employment offers to certain of the Company's employees engaged in ImmTOR manufacturing activities on or prior to a specified date, and the Company agreed not to terminate the employment of such employees prior to such specified date. As a result of the Amendment, the Company maintains no responsibilities to Sobi to manufacture, or supply Sobi with, ImmTOR under the Sobi License.

On November 13, 2023, the Company merged with Cartesian pursuant to the Merger Agreement. Under the terms of the Merger Agreement, at the closing of the Merger, the Company acquired all of Cartesian's assets, and the Company agreed to issue to the holders of Cartesian capital stock an aggregate of 6,723,662 shares of the Company's common stock, par value $0.0001 per share, or the common stock, and 384,930.725 shares of Series A Non-Voting Preferred Stock, par value $0.0001 per share, or the Series A Preferred Stock. The Series A Preferred Stock is convertible into the Company's common stock upon stockholder approval of such conversion.

The Certificate of Designation of Preferences, Rights and Limitations of the Series A Non-Voting Convertible Preferred Stock, or the Certificate of Designation, contains a provision granting each holder of the Series A Preferred Stock the option to require the Company to redeem any or all of such holder's preferred shares if the Company's stockholders have not voted to

approve the conversion of the Series A Preferred Stock to common stock within 18 months of the Closing Date; provided, however, that no holder will have the right to seek redemption of any shares of Series A Preferred Stock to the extent that such holder would otherwise be unable to convert such shares of Series A Preferred Stock due to the 19.9% common stock beneficial ownership limitation contained in the Certificate of Designation. The per-share redemption price is the average closing trading price of the common stock for the ten preceding trading days ending on, and including, the trading day immediately prior to the date a notice of conversion is delivered to the Company. The Company could be required to use a significant amount of its cash resources on hand to satisfy this redemption obligation, particularly if holders of Series A Preferred Stock exercise their redemption right with respect to a significant number of shares of Series A Preferred Stock or at a time when the trading price of the Company's common stock is elevated. Further, in the event that the Company does not have sufficient cash on hand to satisfy its redemption obligations, the Company may need to raise additional capital to satisfy these potential obligations. Any redemption payments could materially limit the amount of cash the Company has available to fund its operations.

Concurrently with the closing of the Merger, the Company entered into a securities purchase agreement with certain investors in a transaction exempt from the registration requirements of the Securities Act of 1933, as amended, or the Financing. In the Financing, the Company agreed to issue 149,330.115 shares of Series A Preferred Stock in exchange for aggregate gross proceeds of $60.25 million. The Company granted customary registration rights to investors in the Financing.

Additionally, on November 13, 2023, the Company announced a dividend of one contingent value right to be issued to each holder of the Company's common stock as of the close of business on December 4, 2023. When issued, a contingent value right will entitle its holder to a portion of royalties and other payments received by the Company with respect to its legacy assets, net of certain deductions.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited consolidated financial statements and related notes appearing elsewhere in this Quarterly Report and with our audited financial statements and the notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2022, which we filed with the SEC on March 2, 2023. In addition, you should read the "Risk Factors" and "Information Regarding Forward-Looking Statements" sections of this Quarterly Report and our Annual Report on Form 10-K for the year ended December 31, 2022 for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

Following the closing of the Merger described below, we are a clinical-stage biotechnology company pioneering RNA cell therapies for the treatment of autoimmune diseases. Our proprietary technology and manufacturing platform, RNA Armory®, is designed to enable precision control and optimization of engineered cells for diverse cell therapies leveraging multiple modalities, including autologous, allogeneic, and in vivo transfection. We believe our RNA approach has the potential to expand the reach of cell therapy to treat autoimmunity with safer, potent, and less expensive therapies compared a DNA approach, and potentially in the outpatient setting.

Our wholly owned pipeline includes:

- Descartes-08: Descartes-08 is an autologous anti-BCMA RNA-engineered chimeric antigen receptor T-cell therapy, or rCAR-T. Compared to conventional DNA-based CAR T-cell therapies, we believe rCAR-T does not require preconditioning chemotherapy, has predictable and controllable pharmacokinetics, and avoids the risk of genomic integration. Descartes-08 is currently in clinical development for autoimmune diseases and generalized myasthenia gravis, or MG, a chronic autoimmune disorder that causes disabling muscle weakness and fatigue. Descartes-08 has been granted Orphan Drug Designation by the U.S. Food and Drug Administration for the treatment of MG.

Cartesian previously reported positive data from the Phase 2a study of 14 patients with MG who received six weekly infusions of Descartes-08 in the outpatient setting without preconditioning chemotherapy. In the trial, the results of which were published in The Lancet Neurology, Descartes-08 was observed to be safe and well-tolerated, and to induce deep and durable responses. Enrollment is currently ongoing in a Phase 2b randomized, double-blind, placebo-controlled trial (NCT04146051) in patients with MG, with topline results expected in mid-2024.

Beyond MG, initiation of a Phase 2 study of Descartes-08 in patients with systemic lupus erythematosus, a chronic autoimmune disease that causes systemic inflammation which affects multiple organ systems, is expected in the first half of 2024. In addition, initiations of a Phase 2 ocular autoimmune basket trial and a Phase 2 vasculitic autoimmune basket trial are planned for mid-2024 and the second half of 2024, respectively.

Descartes-15: Descartes-15 is designed to be a next-generation autologous anti-BCMA rCAR-T. In preclinical studies, Descartes-15 was observed to be significantly more potent than Descartes-08. We intend to leverage its clinical observations to date from its Descartes-08 clinical program to inform the clinical strategy for Descartes-15 for the treatment of autoantibody-associated autoimmune diseases, or AAAD.

- Descartes-33: Descartes-33 is designed to be an off-the-shelf (“allogeneic”) mesenchymal stem cell therapy, or rMSC, for the treatment of AAAD. In in vitro studies, Descartes-33 was observed to induce potent degradation of neutrophil extracellular traps.

Recent Developments

Merger

On November 13, 2023, Selecta Biosciences, Inc. merged with Cartesian Therapeutics, Inc., pursuant to the Merger Agreement. Under the terms of the Merger Agreement, at the closing of the Merger, we acquired all of Cartesian’s assets, and we agreed to issue the holders of Cartesian capital stock a total of 6,723,662 shares of Selecta’s common stock and 384,930.725 shares of Selecta’s Series A Preferred Stock. Also at the closing of the Merger, each option to purchase shares of Cartesian capital stock that was outstanding and unexercised, whether or not vested, was converted into and became an option to purchase our common stock or Series A Non-Voting Convertible Preferred Stock, or the Series A Preferred Stock, and we assumed Cartesian’s 2016 Stock Incentive Plan.

The Series A Preferred Stock to be issued in the Merger is convertible into our common stock upon stockholder approval of such conversion. The proposal to approve such conversion is referred to as the conversion proposal. Pursuant to the Merger Agreement, we are required to seek stockholder approval of the conversion proposal as promptly as reasonably practicable following the Merger, at a special meeting of stockholders, and, if such approval is not obtained at that meeting, to seek to obtain such approval at an annual or special meeting to be held at least every six months thereafter until such approval is obtained.

In accordance with the Merger Agreement, each of Peter Traber, Kei Kishimoto and Lloyd Johnston resigned as Chief Medical Officer, Chief Scientific Officer and Chief Operations Officer, respectively, following which Drs. Traber, Kishimoto, and Johnston will serve as Senior Clinical Advisor, Senior Scientific Advisor, and Senior Operations Advisor, respectively, to the Company. The Board subsequently appointed Metin Kurtoglu as the Company’s Chief Operating Officer, Milos Miljkovic as Chief Medical Officer, and Chris Jewell as Chief Scientific Officer.

Immediately following the completion of the Merger, Selecta securityholders owned approximately 27% of our outstanding shares of common stock on a fully diluted basis and Cartesian securityholders owned approximately 73% of our outstanding shares on a fully diluted basis.

Support Agreements

Also on November 13, 2023, certain of our officers, directors and stockholders, collectively referred to as the Supporting Stockholders, entered into Support Agreements with us, or the Support Agreements. Under the terms of the Support Agreements, each Supporting Stockholder has agreed, among other things, to vote all shares of common stock held by such person in favor of the conversion proposal and a proposal to amend our restated certificate of incorporation, as amended, to increase our authorized share capital, until the expiration of the Support Agreements. As of November 13, 2023, the Supporting Stockholders beneficially owned an aggregate of approximately 25% of the outstanding shares of Selecta’s common stock.

Lock-up Agreements

Concurrently and in connection with the execution of the Merger Agreement, certain Cartesian stockholders as of immediately prior to the Merger, and certain of the directors and officers of Selecta as of immediately prior to the Merger entered into lock-up agreements, or the Lock-up Agreements, with the Company and Cartesian, pursuant to which each such stockholder will be subject to a 180-day lock-up on the sale or transfer of shares of Common Stock held by each such stockholder at the closing of the Merger, including those shares of common stock and Series A Preferred Stock (including the shares of common stock into which such Series A Preferred Stock is convertible) received by Cartesian stockholders in the Merger.

CVR

Additionally, on November 13, 2023, we announced that we expected to enter into a contingent value rights agreement, or the CVR Agreement, with Equiniti Trust Company, LLC, or the Trustee, within 30 days of the Merger. In connection with announcement of the CVR Agreement, we also announced that we declared a dividend of one contingent value right, or a CVR, to be issued to each holder of our common stock as of December 4, 2023, the record date. When issued, each CVR will entitle its holder, which is referred to as a Holder, to, during the period ending on the date on which the Royalty Term (as defined in our License and Development Agreement, as amended, with Swedish Orphan Biovitrum AB (publ.), or the Sobi License, ends, or the Termination Date:

(i) 100% of all milestone payments, royalties and other amounts paid to the Company or its controlled affiliates, or the Company Entities, prior to the Termination Date, under the Sobi License, or, following certain terminations of the Sobi License, any agreement a Company Entity enters into that provides for the development and commercialization of SEL-212, or a New Applicable Agreement; and

(ii) 100% of all cash consideration and the actual liquidation value of any and all non-cash consideration of any kind that is paid to or is actually received by any Company Entity prior to the Termination Date pursuant to an agreement between a Company Entity and any person who is not a Company Entity relating to a sale, license, transfer or other disposition of any transferable asset of the Company Entities existing as of immediately prior to the Merger, or a Disposition, other than those exclusively licensed under the Sobi License or which the Company Entities are required to continue to own In order to comply with the Sobi License, or a Disposition Agreement.

The distributions in respect of the CVRs will be made on a semi-annual basis, and will be subject to a number of deductions, subject to certain exceptions or limitations, including for (A) certain taxes, (B) certain out-of-pocket expenses incurred by the Company Entities including audit and accounting fees incurred in connection with reporting obligations relating to the CVRs, in respect of its performance of the Sobi License or any New Applicable Agreement, in connection with the entry into a Disposition Agreement, and under any Disposition Agreement and performance of the Company Entities' related obligations thereunder, (C) a fixed amount of $750,000 for each Distribution Period (as defined below) to account for general and administrative overhead incurred by the Company Entities, (D) in the case of a distribution that includes payments for certain milestones under clause (ii) above and for the upfront portion, if any, of the consideration payable under a Disposition Agreement, or a Trigger Distribution, the sum of payments made under any liabilities of the Company Entities arising under real property leases in effect as of immediately prior to Closing, or Lease Liabilities after the Closing and the aggregate remaining payment obligations under the Lease Liabilities outstanding as of the applicable date of measurement (but subject to a positive adjustment in case amounts held back under this clause (D) exceed the liabilities actually incurred under the Lease Liabilities at the time such a lease expires or is terminated, assigned or subleased), and (E) in the case of a Trigger Distribution, the sum of payments made after Closing under certain liabilities relating to the Company's Xork product candidate, or Xork Liabilities, after the Closing and the aggregate remaining payment obligations under Xork Liabilities outstanding as of the applicable date of measurement but subject to a positive adjustment in case amounts held back under this clause (E) exceed the liabilities actually incurred under the Xork Liabilities at such time as the development activities with respect to Xork are terminated, transferred or assigned by the Company Entities or otherwise completed in accordance with the development plan set forth in the Company's License and Development Agreement with Audentes Therapeutics, Inc., or the Astellas Agreement, when such termination, transfer, assignment or completion occurs.

We will calculate the amount of any payment due on the CVRs for each six-month period from January 1 through June 30 and each six-month period from July 1 through December 31 of each year (each such period is referred to as a Distribution Period), except that the initial Distribution Period will commence on the date of the CVR Agreement and run through June 30, 2024.

Payments on the CVRs will be cumulative and will be payable no later than the close of business on each March 15 (for Distribution Periods that end on December 31) and September 15 (for Distribution Periods that end on June 30), commencing on September 15, 2024, with each such date referred to as a Distribution Payment Date, to holders of record as of the close of business on the first day of the month of the applicable Distribution Payment Date. If a Distribution Payment Date is not a business day, payment will be made on the immediately succeeding business day, without the accumulation of additional distributions. If the amount of any per-CVR distribution is less than $0.02, we may elect to defer such distribution until the next Distribution Payment Date when the aggregate per-CVR distribution would be $0.02 or greater.

Under the CVR Agreement, as long as any CVRs are outstanding, we will not, (i) without the affirmative vote of the Holders of at least 66 and 2/3% of the then-outstanding CVRs: (i) modify in a manner adverse to the Holders any provision contained in the CVR Agreement with respect to the termination of the CVR Agreement or the CVRs, or the time for payment and amount of any distribution, or modify in any manner any provision of the CVR Agreement if such modification would reduce the amounts payable in respect of the CVRs or modify any other payment term or payment date, (ii) without the consent of each Holder of each outstanding CVR affected thereby, reduce the number of CVRs, (iii) without the consent of the affirmative vote of the Holders of a majority of the then-outstanding CVRs modify any of the foregoing provisions summarized in this paragraph, except to increase the percentage of Holders from whom consent or approval is required or to provide that certain other provisions of the CVR Agreement cannot be modified or waived without the consent of the Holders protected thereby, or alter, change, amend, or modify, in each case in any material respect or in any manner adverse to the Holders, the Sobi License, our License and Development Agreement with Astellas Gene Therapies, or the Astellas Agreement, or the Exclusive License Agreement with Genovis AB (publ.), or the Genovis Agreement, terminate the Sobi License, or sell, license, assign, transfer, enter into any monetization transaction, or otherwise dispose of or otherwise grant or suffer to exist a mortgage, pledge, lien, encumbrance or other security interest on all or a portion of (A) the patents or patent applications licensed under the Sobi License or (B) the Sobi License or any rights to receive any milestone payments, royalties or other amounts under the Sobi License, and (iv) subject to limited exceptions, will not issue CVRs, other than pursuant to the Merger Agreement and except to holders of outstanding warrants to purchase shares of common stock.

Additionally, in the event of certain terminations of the Sobi License at a time when any CVRs are outstanding, we will, and will cause our applicable related entities to, exercise our rights to obtain a “reversion license” and enforce any of our rights under the terminated Sobi License that survive the termination or expiration thereof. Further, in the event that following entry into a reversion license, we or any of such entities enter into an agreement for any sale, license, transfer or other disposition with a third party that provides for the development and commercialization of SEL-212, we will, and will cause our applicable related entities to, comply with the provisions of the CVR Agreement in connection with such new agreement.

Under the CVR Agreement, the Trustee has, and Holders of at least 20% of the CVRs then-outstanding may also instruct the Trustee to exercise, certain rights to inspection, audit, and enforcement on behalf of all Holders of the CVRs.

We estimate that peak sales of SEL-212, if approved, could reach over $700 million.

PIPE Financing

Concurrently with the closing of the Merger, we entered into a securities purchase agreement with certain investors in a transaction exempt from the registration requirements of the Securities Act of 1933, as amended, or the Financing. In the Financing, we agreed to issue 149,330.115 shares of Series A Preferred Stock in exchange for aggregate gross proceeds of $60.25 million. We granted customary registration rights to investors in the Financing.

The foregoing summaries of the Merger Agreement, form of Support Agreement, form of lock-up agreement, form of CVR Agreement, and form of securities purchase agreement are not complete and are qualified in their entirety by reference to the full texts of the Merger Agreement, form of Support Agreement, form of lock-up agreement, form of CVR Agreement, and form of securities purchase agreement, copies of which are incorporated by reference as Exhibits 2.1, 10.1, 10.2, 4.1, and 10.3, respectively, to this Quarterly Report on Form 10-Q.

Components of Results of Operations

To date, we have financed our operations primarily through public offerings and private placements of our securities, funding received from research grants, collaboration and license arrangements and our credit facility. We do not have any products approved for sale and have not generated any product sales.

Except for the year ended December 31, 2022, we have incurred significant operating losses since our inception. We incurred a net loss of $42.1 million and had net income of $29.5 million for the nine months ended September 30, 2023 and 2022, respectively. As of September 30, 2023, we had an accumulated deficit of $437.0 million.

We expect to continue to incur significant expenses and operating losses for the foreseeable future as we:

- advance Descartes-08 for MG into Phase 3 development;
- continue to develop our preclinical and clinical-stage product candidates;
- seek regulatory approvals for any product candidates that successfully complete clinical trials; and

- maintain, expand and protect our intellectual property portfolio, including through licensing arrangements.

Concurrently with the closing of the Merger, we entered into a securities purchase agreement relating to the PIPE Financing. In the Financing, we agreed to issue 149,330.115 shares of Series A Preferred Stock in exchange for aggregate gross proceeds of $60.25 million. We granted customary registration rights to investors in the Financing.

We believe that our existing cash, cash equivalents, and restricted cash as of September 30, 2023, combined with net proceeds from the Financing will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect.

We intend to seek collaboration partners for the assets in the development programs that we are no longer actively advancing.

The consolidated financial information for the nine months ended September 30, 2023 and 2022 presented below includes the accounts of Selecta Biosciences, Inc. and our wholly owned subsidiaries, Selecta (RUS) LLC, a Russian limited liability company, or Selecta (RUS), and Selecta Biosciences Security Corporation, a Massachusetts securities corporation. All intercompany accounts and transactions have been eliminated.

Collaboration and license revenue

To date, we have not generated any revenue from product sales. Our revenue consists primarily of collaboration and license revenue, which includes amounts recognized related to upfront and milestone payments for research and development funding under collaboration and license agreements. We expect that any revenue we generate will fluctuate from quarter to quarter because of the timing and amounts of fees, research and development reimbursements and other payments from collaborators. We do not expect to generate revenue from product sales for at least the next several years. If we or our collaborators fail to complete the development of our product candidates in a timely manner or fail to obtain regulatory approval as needed, our ability to generate future revenue will be harmed, and will affect the results of our operations and financial position. For further description of the agreements underlying our collaboration and license revenue, see Note 12 to our consolidated financial statements included elsewhere in this Quarterly Report.

Research and development expenses

Our research and development expenses consist of external research and development costs, which we track on a program-by-program basis and primarily include contract manufacturing organization related costs and fees paid to contract research organizations, and internal research and development costs, which are primarily compensation expenses for our research and development employees, lab supplies, analytical testing, allocated overhead costs and other related expenses. Our internal research and development costs are often devoted to expanding our programs and are not necessarily allocable to a specific target.

We expense research and development costs as incurred. Conducting a significant amount of research and development is central to our business model. Product candidates in clinical development generally have higher development costs than those in earlier stages of development, primarily due to the size, duration and cost of clinical trials. The successful development of our clinical and preclinical product candidates is highly uncertain. Clinical development timelines, the probability of success and development costs can differ materially from our expectations. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those which we currently expect will be required for the completion of clinical development of a product candidate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time to complete any clinical development.

In June 2020, we and Sobi entered into the Sobi License. Pursuant to the Sobi License, clinical trial costs incurred to complete development of SEL-212, including but not limited to costs incurred while conducting and completing the Phase 3 DISSOLVE trials, will be reimbursed by Sobi. These costs, when reimbursed, will be recognized as revenue consistent with the revenue recognition methodology disclosed in Note 12 to our unaudited consolidated financial statements included elsewhere in this Quarterly Report. The reimbursable costs exclude any costs of additional development activities required that are related to ImmTOR and that are unrelated to SEL-212.

In January 2023, we and Astellas entered into the Astellas Agreement. Pursuant to the Astellas Agreement, Astellas will reimburse us for 25% of all budgeted costs incurred to complete the development of Xork for use in Pompe disease with an Astellas gene therapy investigational or authorized product. These costs, when reimbursed, will be recognized as revenue consistent with the revenue recognition methodology disclosed in Note 12 to our unaudited consolidated financial statements included elsewhere in this Quarterly Report.

General and administrative expenses

General and administrative expenses consist primarily of salaries and related benefits, including stock-based compensation, related to our executive, finance, business development and support functions. Other general and administrative expenses include facility-related costs not otherwise allocated to research and development expenses, travel expenses for our general and administrative personnel and professional fees for auditing, tax and corporate legal services, including intellectual property-related legal services.

Investment income

Investment income consists primarily of interest income earned on our cash, cash equivalents and marketable securities.

Interest expense

Interest expense consists of interest expense on amounts borrowed under our credit facilities and loss on extinguishment of debt.

Other income, net

Other income, net consists primarily of sublease income during the three and nine months ended September 30, 2023 and was de minimis during the three and nine months ended September 30, 2022.

Change in fair value of warrant liabilities

Common warrants classified as liabilities are remeasured at fair value, utilizing a Black-Scholes valuation methodology, quarterly with the change in fair value recognized as a component of earnings.

Foreign currency transaction gain (loss)

The functional currency of our Russian subsidiary is the Russian ruble. In addition to holding cash denominated in Russian rubles, our Russian bank accounts also hold cash balances denominated in U.S. dollars to facilitate payments to be settled in U.S. dollars or other currencies. As of each of September 30, 2023 and December 31, 2022, we maintained cash of $0.2 million in Russian banks accounts in denominations of both Russian rubles and U.S. dollars. The amounts denominated in U.S. dollars and used in transacting the day-to-day operations of our Russian subsidiary are subject to transaction gains and losses, which are reported as incurred.

Results of Operations

Comparison of the Three Months Ended September 30, 2023 and 2022

Collaboration and license revenue

The following is a comparison of collaboration and license revenue for the three months ended September 30, 2023 and 2022 (in thousands, except percentages):

	Three Months Ended September 30,		Increase (decrease)	
	2023	2022		
Collaboration and license revenue	$6,551	$20,710	$(14,159)	(68)%

During the three months ended September 30, 2023, collaboration and license revenue was $6.6 million, compared to $20.7 million in 2022. During the three months ended September 30, 2023 and 2022, we recognized $5.0 million and $20.7 million, respectively, under the license agreement with Sobi resulting from the shipment of clinical supply and the reimbursement of costs incurred for the Phase 3 DISSOLVE clinical program. Additionally, during the three months ended September 30, 2023, $1.5 million was recognized under the Astellas Agreement.

Research and development expenses

The following is a comparison of research and development expenses for the three months ended September 30, 2023 and 2022 (in thousands, except percentages):

	Three Months Ended September 30,		Increase (decrease)	
	2023	2022		
Research and development	$13,002	$16,539	$(3,537)	(21)%

During the three months ended September 30, 2023, our research and development expenses decreased by $3.5 million, or 21%, as compared to the three months ended September 30, 2022. The decrease in cost was primarily the result of the strategic reprioritization.

General and administrative expenses

The following is a comparison of general and administrative expenses for the three months ended September 30, 2023 and 2022 (in thousands, except percentages):

	Three Months Ended September 30,		Increase (decrease)	
	2023	2022		
General and administrative	$ 6,614	$ 5,770	$844	15%

During the three months ended September 30, 2023, our general and administrative expenses increased by $0.8 million, or 15%, as compared to the three months ended September 30, 2022. The increase in costs was primarily the result of an increase in expenses incurred for professional fees.

Investment income

Investment income was $1.3 million and $0.7 million for the three months ended September 30, 2023 and 2022, respectively. The increase in investment income was due to increased investment and higher interest rates.

Foreign currency transaction gain (loss)

We recognized de minimis foreign currency fluctuations during each of the three months ended September 30, 2023 and 2022.

Interest expense

Interest expense was $1.3 million and $0.8 million for the three months ended September 30, 2023 and 2022, respectively, representing interest expense and amortization of the carrying costs of our credit facilities and loss on extinguishment of debt during the three months ended September 30, 2023.

Change in fair value of warrant liabilities

For the three months ended September 30, 2023, we recognized $3.8 million of income from the decrease in the fair value of warrant liabilities utilizing the Black-Scholes valuation methodology. The decrease in value was primarily driven by a driven by a decrease in the remaining expected life of the warrants and a decrease in the price of our common stock. For the three months ended September 30, 2022, we recognized a $6.5 million charge from the increase in the fair value of warrant liabilities primarily driven by an increase in the price of our common stock.

Other income, net

Other income, net consists primarily of sublease income for the three months ended September 30, 2023 and was de minimis for the three months ended September 30, 2022.

Income taxes

For the three months ended September 30, 2023, we recognized no income tax expense. For the three months ended September 30, 2022, we recognized $0.3 million in income tax benefit primarily related to the abatement of penalties and interest.

Net (loss) income

Net loss for the three months ended September 30, 2023 was $9.0 million compared to net loss of $7.9 million for the three months ended September 30, 2022.

Comparison of the Nine Months Ended September 30, 2023 and 2022

Collaboration and license revenue

The following is a comparison of collaboration and license revenue for the nine months ended September 30, 2023 and 2022 (in thousands, except percentages):

	Nine Months Ended September 30,		Increase (decrease)	
	2023	2022		
Collaboration and license revenue	$17,738	$93,982	$(76,244)	(81)%

During the nine months ended September 30, 2023 and 2022, we recognized $13.7 million and $73.6 million under the Sobi License resulting from the shipment of clinical supply and the reimbursement of costs incurred for the Phase 3 DISSOLVE clinical program. Additionally, during the nine months ended September 30, 2023, $2.9 million was recognized under the Astellas Agreement and $0.6 million was recognized under the Takeda Agreement, and $0.5 million was recognized under the Sarepta Agreement. During the nine months ended September 30, 2022, $10.2 million was recognized under the Sarepta Agreement, $9.2 million was recognized upon the mutual termination of the Spark License Agreement, and $1.0 million was recognized under the Takeda Agreement.

Research and development expenses

The following is a comparison of research and development expenses for the nine months ended September 30, 2023 and 2022 (in thousands, except percentages):

	Nine Months Ended September 30,		Increase (decrease)	
	2023	2022		
Research and development	$49,408	$53,410	$(4,002)	(7)%

During the nine months ended September 30, 2023, our research and development expenses decreased by $4.0 million, or 7%, as compared to the nine months ended September 30, 2022. The decrease in cost was primarily the result of the strategic reprioritization, partially offset by increased contract license and milestone payments and a one-time cash charge to salaries and benefits as a result of our headcount reduction in April 2023.

General and administrative expenses

The following is a comparison of general and administrative expenses for the nine months ended September 30, 2023 and 2022 (in thousands, except percentages):

	Nine Months Ended September 30,		Increase (decrease)	
	2023	2022		
General and administrative	$18,414	$17,538	$876	5%

During the nine months ended September 30, 2023, our general and administrative expenses increased by $0.9 million, or 5%, as compared to the nine months ended September 30, 2022. The increase in costs was primarily driven by a one-time cash charge to salaries and benefits as a result of our headcount reduction in April 2023 and an increase in expenses incurred for professional fees partially offset by a reduction in expenses incurred for stock compensation.

Investment income

Investment income was $4.0 million and $0.9 million, for the nine months ended September 30, 2023 and 2022, respectively. The increase in investment income was due to increased investments and higher interest rates.

Foreign currency transaction gain (loss)

We recognized de minimis foreign currency fluctuations during the nine months ended September 30, 2023 and 2022, respectively.

Interest expense

Interest expense was $2.8 million and $2.2 million for the nine months ended September 30, 2023 and 2022, respectively, representing interest expense and amortization of the carrying costs of our credit facilities and loss on extinguishment of debt during the nine months ended September 30, 2023.

Change in fair value of warrant liabilities

For the nine months ended September 30, 2023, we recognized $6.0 million of income for the decrease in the fair value of warrant liabilities utilizing a Black-Scholes valuation methodology. The decrease in value was primarily driven by a decrease in the remaining expected life of the warrants and a decrease in the price of our common stock. For the nine months ended September 30, 2022, we recognized $7.3 million of income for the decrease in the fair value of warrant liabilities primarily driven by a decrease in the price of our common stock.

Other income (expense)

Other income was $0.8 million and $0.2 million for the nine months ended September 30, 2023 and 2022, respectively. The increase was primarily driven by sublease income.

Income taxes

For the nine months ended September 30, 2023, we recognized no income tax expense. For the nine months ended September 30, 2022, we recognized $0.3 million in income tax benefit primarily related to the abatement of penalties and interest.

Net (loss) income

Net loss for the nine months ended September 30, 2023 was $42.1 million compared to net income of $29.5 million for the nine months ended September 30, 2022.

Liquidity and Capital Resources

Except for the year ended December 31, 2022, in which we had net income of $35.4 million, we have incurred recurring net losses since our inception. We expect that we will continue to incur losses and that such cumulative losses will increase for the foreseeable future.

Since inception, we have financed our operations with a combination of issuance of preferred and common stock, government grant funding, borrowings under credit facilities and proceeds from our collaboration and license agreements.

As of September 30, 2023, our cash, cash equivalents, and restricted cash were $81.0 million, of which $1.4 million was restricted cash related to lease commitments and $0.2 million was held by our Russian subsidiary designated solely for use in its operations.

In connection with the Sobi Amendment, certain of our employees agreed to transfer their employment to Sobi. Additionally, we have informed certain employees that we intend to terminate their employment later in 2023. As a result of such terminations, we expect to incur $3.0 million of cash charges related to severance and benefit costs in 2023.

In addition to our existing cash equivalents, we have from time to time, and may, in the future receive research and development funding pursuant to our collaboration and license agreements. Currently, funding from payments under our collaboration agreements represent our only source of committed external funds.

Indebtedness

On August 31, 2020, we entered into a term loan of up to $35.0 million, or the 2020 Term Loan, consisting of term loans in an aggregate amount of $25.0 million, or the Term A Loan, and term loans in an aggregate amount of $10.0 million, or the Term B Loan, governed by a loan and security agreement among us and Oxford Finance LLC, or Oxford, as collateral agent and a lender, and Silicon Valley Bank, as a lender. The Term A Loan was funded in full on August 31, 2020, or the Funding Date, and would have matured on August 1, 2025. The second draw period expired on September 30, 2021.

On March 10, 2023, Silicon Valley Bank was closed by the California Department of Financial Protection and Innovation, and the Federal Deposit Insurance Corporation, or the FDIC, was appointed as receiver. On March 13, 2023, the FDIC announced that all of Silicon Valley Bank's deposits and substantially all of its assets had been transferred to a newly created, full-service FDIC-operated bridge bank, Silicon Valley Bridge Bank, N.A., or SVBB. SVBB assumed all loans that were previously held by Silicon Valley Bank. On March 27, 2023, First-Citizens Bank & Trust assumed all of SVBB's customer deposits and certain other liabilities and acquired substantially all of SVBB's loans and certain other assets from the FDIC.

On September 11, 2023, we entered into a payoff letter with Oxford and Silicon Valley Bank, a division of First-Citizens Bank & Trust Company (successor by purchase to the Federal Deposit Insurance Corporation as Receiver for SVBB (as successor to Silicon Valley Bank)), pursuant to which we paid all outstanding amounts under the 2020 Term Loan, together with accrued interest and a prepayment penalty, resulting in the full extinguishment of the 2020 Term Loan. The total payoff amount was $22.3 million, consisting of the remaining principal amount due of $19.8 million, the final payment fee of $2.3 million, the prepayment penalty of $0.2 million, and less than $0.1 million of accrued interest.

If in the future we seek debt financing, the terms of such debt could restrict our operating and financial flexibility by imposing liens on our assets and covenants on the operation of our business.

Future funding requirements

As of the date of this Quarterly Report, we have not generated any revenue from product sales. We do not know when, or if, we will generate revenue from product sales. We will not generate significant revenue from product sales unless and until we obtain regulatory approval and commercialize one of our current or future product candidates. Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, third-party clinical research and development services, laboratory and related supplies, clinical costs, legal and other regulatory expenses, milestone and royalty payments for in-licenses, and general overhead costs. We expect that we will continue to generate losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our product candidates, and begin to commercialize any approved products. We are subject to risks in the development of our products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We expect that we will need substantial additional funding to support our continuing operations.

The Certificate of Designation of Preferences, Rights and Limitations of the Series A Non-Voting Convertible Preferred Stock, or the Certificate of Designation, contains a provision granting each holder of the Series A Preferred Stock the option to require us to redeem any or all of such holder's preferred shares if the our stockholders have not voted to approve the conversion of the Series A Preferred Stock to common stock within 18 months of the Closing Date; provided, however, that no holder will have the right to seek redemption of any shares of Series A Preferred Stock to the extent that such holder would otherwise be unable to convert such shares of Series A Preferred Stock due to the 19.9% common stock beneficial ownership limitation contained in the Certificate of Designation. The per-share redemption price is the average closing trading price of the common stock for the ten preceding trading days ending on, and including, the trading day immediately prior to the date a notice of conversion is delivered to us. We could be required to use a significant amount of its cash resources on hand to satisfy this redemption obligation, particularly if holders of Series A Preferred Stock exercise their redemption right with respect to a significant number of shares of Series A Preferred Stock or at a time when the trading price of our common stock is elevated. Further, in the event that we do not have sufficient cash on hand to satisfy its redemption obligations, we may need to raise additional capital to satisfy these potential obligations. Any redemption payments could materially limit the amount of cash we have available to fund our operations.

As of September 30, 2023, we had an accumulated deficit of $437.0 million. We anticipate operating losses to continue for the foreseeable future due to, among other things, costs related to research, development of our product candidates, conducting preclinical studies and clinical trials, and our administrative organization. We will require substantial additional financing to fund our operations and to continue to execute our strategy, and we will pursue a range of options to secure additional capital.

We believe that our existing cash, cash equivalents, and restricted cash as of September 30, 2023, combined with net proceeds from the Financing will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. Management's expectations with respect to our ability to fund current and long-term planned operations are based on estimates that are subject to risks and uncertainties. If actual results are different from management's estimates, we may need to seek additional strategic or financing opportunities sooner than would otherwise be expected. However, there is no guarantee that any collaboration milestones will be achieved or that any of these strategic or financing opportunities will be executed on favorable terms, and some could be dilutive to existing stockholders. If we are unable to obtain additional funding on a timely basis, we may be forced to further curtail, delay, or discontinue one or more of our planned research or development programs or be unable to expand our operations, meet long-term obligations or otherwise capitalize on our commercialization of our product candidates. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect.

Our future capital requirements will depend on many factors, including:

- the timing for stockholder approval of the conversion of our Series A Preferred Stock into common stock and the amount of any associated redemptions;
- our collaboration agreements remaining in effect, our entering into additional collaboration agreements and our ability to achieve milestones under these agreements;
- the manufacturability and cost of manufacturing clinical supplies of our product candidates;
- the size of our headcount and associated costs;

- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our other product candidates;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims; and
- the effect of competing technological and market developments.

Summary of Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2023 and 2022:

(In thousands)	Nine Months Ended September 30, 2023	2022
Cash (used in) and provided by:		
Operating activities	$(27,875)	$(19,782)
Investing activities	28,112	(20,491)
Financing activities	(27,226)	39,215
Effect of exchange rate changes on cash	(69)	65
Net change in cash, cash equivalents, and restricted cash	$(27,058)	$ (993)

Operating activities

Net cash used in operating activities of $27.9 million for the nine months ended September 30, 2023 included approximately $36.8 million of net loss, adjusted for non-cash items, and approximately $8.9 million cash provided by changes in operating assets and liabilities.

Net cash used in operating activities of $19.8 million for the nine months ended September 30, 2022 included approximately $33.6 million of net income, adjusted for non-cash items, and uses of cash of approximately $53.4 million for changes in operating assets and liabilities.

Investing activities

Net cash provided by investing activities for the nine months ended September 30, 2023 was $28.1 million compared to net cash used in investing activities of $20.5 million in the same period in 2022. The net cash provided by investing activities for the nine months ended September 30, 2023 was primarily proceeds from the maturities of marketable securities offset by purchases of property and equipment. The net cash used in investing activities for the nine months ended September 30, 2022 was primarily purchases of marketable securities offset by proceeds from maturities of marketable securities.

Financing activities

Net cash used in financing activities for the nine months ended September 30, 2023 was $27.2 million compared to net cash provided by financing activities of $39.2 million in the same period in 2022. The net cash used in financing activities in the nine months ended September 30, 2023 was primarily the result of repayments of principal on outstanding debt offset by proceeds from issuance of common stock under the Employee Stock Purchase Plan and in the nine months ended September 30, 2022 was primarily the result of net proceeds from underwritten and “at-the-market” offerings.

Recent Accounting Pronouncements

For a discussion of recently adopted or issued accounting pronouncements please see Note 2 to our unaudited consolidated financial statements included elsewhere in this Quarterly Report.

Off-Balance Sheet Arrangements

As of September 30, 2023, we did not have any off-balance sheet arrangements as defined in the rules and regulations of the Securities and Exchange Commission.

Critical Accounting Policies and Use of Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America, or U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates and judgements that affect the reported amounts of assets, liabilities, revenues and expenses, and disclosure of contingent assets and liabilities in our consolidated financial statements. Actual results may differ from these estimates under different assumptions or conditions. During the three and nine months ended September 30, 2023, there were no material changes to our critical accounting policies from those described in our Annual Report on Form 10-K for the year ended December 31, 2022.

Smaller Reporting Company

We qualify as a "smaller reporting company" under the rules of the Securities Act and the Exchange Act. As a result, we may choose to take advantage of certain scaled disclosure requirements available specifically to smaller reporting companies. We will remain a smaller reporting company until the last day of the fiscal year in which the aggregate market value of our common stock held by non-affiliated persons and entities, or our public float, is more than $700 million as of the last business day of our most recently completed second fiscal quarter, or until the fiscal year following the year in which we have at least $100 million in revenue and at least $250 million in public float as of the last business day of our most recently completed second fiscal quarter.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

The market risk inherent in our financial instruments and in our financial position represents the potential loss arising from adverse changes in interest rates. As of September 30, 2023 and December 31, 2022, we had cash, cash equivalents, restricted cash and marketable securities of $81.0 million and $136.2 million, respectively, consisting of non-interest and interest-bearing money market 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 and the low risk profile of our money market accounts and marketable securities, and our current policy to hold marketable securities to maturity, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents or short-term marketable securities.

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, as of the end of the period covered by this Quarterly Report, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2023.

Inherent Limitations on Effectiveness of Controls

There are inherent limitations to the effectiveness of any system of internal control over financial reporting. Accordingly, even an effective system of internal control over financial reporting can only provide reasonable assurance with respect to financial statement preparation and presentation in accordance with U.S. GAAP. Our internal controls over financial reporting are subject to various inherent limitations, including cost limitations, judgments used in decision making, assumptions about the likelihood of future events, the soundness of our systems, the possibility of human error, and the risk of fraud. Moreover, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may be inadequate because of changes in conditions and the risk that the degree of compliance with policies or procedures may deteriorate over time.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the three months ended September 30, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

RISK FACTORS SUMMARY

Investing in our common stock involves various risks. You should carefully read and consider the matters discussed in this Quarterly Report under the heading "Risk Factors," which include the following risks:

- We are a clinical-stage company and have incurred significant losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.
- We will need substantial additional funding in order to complete development of our product candidates and commercialize our products, if approved.
- Our product candidates are based on our rCAR-T and rMSC therapies, which are unproven approaches to the treatment of disease.
- Regulatory authorities in the United States and European Union have limited experience in reviewing and approving cell therapy products for autoimmune disease.
- Clinical drug development involves a lengthy and expensive process, with an uncertain outcome.
- Geopolitical events, instability and wars can adversely affect both our clinical operations and supply chains that we rely on to advance our drug candidates.
- Manufacturing our products is complex and involves new or unproven technology. Some of our products are made on a patient-by-patient basis, rendering them less predictable and requiring more demanding logistics.
- We expect to continue to grow our manufacturing capabilities and resources and we must incur significant costs to develop this expertise and/or rely on third parties to manufacture our products.
- We rely, and expect to continue to rely, on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including by failing to meet deadlines for the completion of such trials.
- If we or our licensors are unable to adequately protect our proprietary technology, or obtain and maintain issued patents that are sufficient to protect our product candidates, others could compete against us more directly, which would negatively impact our business.
- We may suffer from effects of macroeconomic instability and inflation.
- We have been in the past and may in the future be subject to securities class action lawsuits.
- The failure to successfully integrate the businesses of Cartesian would adversely affect the Company's future results.
- Our Company's future results will suffer if the combined Company does not effectively manage its expanded operations.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should consider carefully the risks described below, together with the other information included or incorporated by reference in this Quarterly Report. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. In these circumstances, the market price of our common stock could decline. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our business, prospects, financial condition and results of operations.

Risks Related to the Development of our Product Candidates

We develop our RNA-based product candidates by leveraging our proprietary technology and our manufacturing platform, RNA Armory®, which is an unproven approach to the treatment of autoimmune disease. We are early in most of our clinical development efforts and may not be successful in our efforts to build a pipeline of product candidates and develop marketable drugs.

Our RNA approach to develop product candidates for the treatment of autoimmune diseases is an unproven approach. Our most advanced product candidate, Descartes-08 is in Phase 2 clinical development. We have not demonstrated the ability to successfully complete any Phase 3 or other pivotal clinical trials, obtain regulatory approvals, manufacture a commercial product, or arrange for a third party to do so on our behalf, or conduct other sales and marketing activities necessary for successful product commercialization. We may have problems identifying new product candidates and applying our technologies to these other areas. Even if we are successful in identifying new product candidates, they may not be suitable for

clinical development, including as a result of manufacturing difficulties, harmful side effects, limited efficacy or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. The success of our product candidates will depend on several factors, including the following:

- design, initiation and completion of preclinical studies and clinical trials with positive results;
- reliance on third parties, including but not limited to collaborators, licensees, clinical research organizations and contract manufacturing organizations;
- receipt of marketing approvals from applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates and not infringing or violating patents or other intellectual property of third parties;
- manufacturability, manufacturing, logistics, and stability of our cell therapies, including autologous cell therapies;
- growing our internal current Good Manufacturing Practice (cGMP) manufacturing capabilities to support commercial manufacturing or making arrangements with third-party manufacturers;
- launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- acceptance of our products, if and when approved, by patients and the medical community;
- effectively competing with other therapies;
- obtaining and maintaining coverage and adequate reimbursement by third-party payors, including government payors, for our products, if approved;
- maintaining an acceptable safety profile of our products following approval; and
- maintaining and growing an organization of scientists and businesspeople who can develop and commercialize our product candidates and technology.

Our failure to successfully execute on of any of the foregoing for any reason would effectively prevent or delay approval of our lead and other product candidates.

Clinical drug development is inherently risky and involves a lengthy and expensive process which is subject to a number of factors, many of which are outside of our control. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Clinical development is expensive, time consuming and involves significant risk. It is impossible to predict when or if any of our product candidates will prove effective and safe in humans or will receive regulatory approval, and the risk of failure through the development process is high. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete manufacturing and preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Manufacturing cell therapies, particularly those modified with RNA, is a new field. Preclinical development is costly and inherently uncertain. Early preclinical results may not be predictive of future results, however, if our technology proves to be ineffective or unsafe as a result of, among other things, adverse side effects, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the clinical development and commercialization of our product candidates.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidate for its intended indications. Clinical testing is expensive, difficult to design and implement, can take many years to complete and its outcome is inherently uncertain. A failed clinical trial can occur at any stage of testing. Moreover, the outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, we may not be able to complete, or may be required to deviate from the current clinical trial protocol for a variety of reasons.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical trials after achieving positive results in preclinical development or early-stage clinical trials, and we cannot be certain that we will not face similar setbacks. Serious adverse events (SAEs) caused by, or other unexpected properties of, any product candidates that we may choose to develop could cause us, an institutional review board or regulatory authority to interrupt, delay or halt clinical trials of one or more of such product candidates and could result in a more restrictive label or the delay or denial of marketing approval by the FDA or comparable non-U.S. regulatory authorities. If any product candidate that we may choose to develop is associated with SAEs or other unexpected properties, we may need to abandon development or limit development of that product candidate to certain uses or subpopulations in which those undesirable characteristics would be expected to be less prevalent, less severe or more tolerable from a risk-benefit perspective. Moreover, preclinical and clinical data is 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 other regulatory authority approval. If we fail to produce positive results in clinical trials of our product candidates, the development timeline and regulatory approval and commercialization prospects for our product candidates, and, correspondingly, our business and financial prospects, would be negatively impacted.

In addition, we cannot be certain as to what type and how many clinical trials the FDA will require us to conduct before we may gain regulatory approval to market any of our product candidates in the United States or other countries, if any. Prior to approving a new therapeutic product, the FDA generally requires that safety and efficacy be demonstrated in two adequate and well-controlled clinical trials.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval for, or commercialize, our product candidates, including:

- clinical trials of our product candidates may produce unfavorable, incomplete or inconclusive results;
- we may be unable to manufacture our product candidates, which in some cases such as rCAR-T, are manufactured on a patient-by-basis basis;
- regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site or may place a clinical hold on existing clinical trials;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with contract research organizations (CROs), or clinical trial sites;
- we may be unable to recruit suitable patients to participate in a clinical trial, the number of patients required for clinical trials of our product candidates may be larger than we expect, enrollment in these clinical trials may be slower than we expect or participants may drop out of these clinical trials at a higher rate than we expect, or enrollment could be affected by the ongoing conflicts in Ukraine and the Middle East;
- the number of clinical trial sites required for clinical trials of our product candidates may be larger than we expect;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks;
- investigators, regulators, data safety monitoring boards or institutional review boards may require that we or our investigators suspend or terminate clinical research, or we may decide to do so ourselves;
- investigators may deviate from the trial protocol, fail to conduct the trial in accordance with regulatory requirements or misreport study data;
- the cost of clinical trials of our product candidates may be greater than we expect or we may have insufficient resources to pursue or complete certain aspects of our clinical trial programs or to do so within the timeframe we planned;
- the supply or quality of raw materials or manufactured product candidates (whether provided by us or third parties) or other materials necessary to conduct clinical trials of our product candidates may be insufficient, inadequate or not available at an acceptable cost, or in a timely manner, or we may experience interruptions in supply;
- laboratories that we rely upon to perform certain quality control tests may become unavailable, or their services could be delayed;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we expect;
- the FDA or comparable foreign regulatory authorities may disagree with our clinical trial design or our interpretation of data from preclinical studies and clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design of our clinical trials;
- regarding trials managed by our existing or any future collaborators, our collaborators may face any of the above issues, and may conduct clinical trials in ways they view as advantageous to them but potentially suboptimal for us; and
- geopolitical events may affect international and overseas trial sites in ways beyond our control.

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, or if we are forced to delay or abandon certain clinical trials or other testing in order to conserve capital resources, we may:

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

We could also encounter delays if a clinical trial is suspended or terminated. Authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Our product development costs will increase if we experience delays in clinical testing or in obtaining marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. In addition, from time to time our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which could cause the value of our common stock to decline and limit our ability to obtain additional financing.

We may conduct clinical trials for product candidates at sites outside the United States, and the FDA may not accept data from trials conducted in such locations or the complexity of regulatory burdens may otherwise adversely impact us.

Opening trial sites outside the United States may involve additional regulatory, administrative and financial burdens, including compliance with foreign and local requirements relating to regulatory submission and clinical trial practices. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of these data is subject to certain conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with good clinical practices (GCPs), and the FDA must be able to validate the data from the trial through an onsite inspection, if necessary. Generally, the patient population for any clinical trials conducted outside the United States must be representative of the population for which we intend to seek approval in the United States. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will be dependent upon its determination that the trials also complied with all applicable U.S. laws and regulations. Nonetheless, there can be no assurance that the FDA will accept data from trials conducted outside the United States. If the FDA does not accept the data from any trial that we conduct outside the United States, it would likely result in the need for additional clinical trials, which would be costly and time-consuming and delay or permanently halt our development of any applicable product candidates.

Additional risks inherent in conducting international clinical trials include:

- foreign regulatory requirements that could burden or limit our ability to conduct our clinical trials;
- increased costs and heightened supply constraints associated with the acquisition of standard of care drugs and/or combination or comparator agents for which we may bear responsibility in certain jurisdictions;
- administrative burdens of conducting clinical trials under multiple foreign regulatory schema;
- foreign exchange fluctuations;
- more burdensome manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research;
- lack of consistency in standard of care from country to country;
- diminished protection of intellectual property in some countries; and
- changes in country or regional regulatory requirements; and
- geopolitical instability or wars in regions outside of the United States where we conduct clinical trials may impact ongoing clinical trials.

We may not be able to qualify for or obtain various designations from regulators that would have the potential to expedite the review process of one or more of our product candidates and even if we do receive one or more such designations there is no guarantee that they will ultimately expedite the process, or aid in our obtaining marketing approval or provide market exclusivity.

There exist several designations that we can apply for from the FDA and other regulators that would provide us with various combinations of the potential for expedited regulatory review, certain financial incentives as well as the potential for post-approval exclusivity for a period of time. These designations include but are not limited to orphan drug designation, breakthrough therapy designation, accelerated approval, fast track status and priority review for our product candidates. For

example, Descartes-08 has been granted Orphan Drug Designation by the FDA for the treatment of MG. We expect to seek one or more of these designations for our other current and future product candidates. There can be no assurance that any of our other product candidates will qualify for any of these designations. There can also be no assurance that any of our product candidates that do qualify for these designations will be granted such designations or that the FDA will not revoke a designation it grants at a later date, or that Congress will not change the law about a designation. Further, there can be no assurance that any of our product candidates that are granted such designations, including Descartes-08, will ever benefit from such designations or that the FDA would not withdraw such designations once granted. Were we to receive a designation that promised a period of market exclusivity, such as orphan drug exclusivity, such exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. In particular, the scope of exclusivity afforded for RNA-modified cell therapy products may not be well defined. Further with respect to orphan drug status, even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior if it is shown to be safer, more effective or makes a major contribution to patient care.

Interim, top-line and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim, top-line or preliminary data from our clinical studies, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a full analyses of all data related to the particular 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 top-line 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. Preliminary or top-line 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. Interim data from clinical trials 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. Interim, top-line or preliminary data may not be representative of final data. If final data is not as positive as earlier interim, top-line or preliminary we have released, our business prospects would be significantly harmed.

In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed significant by you or others with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. As a result, preliminary and top-line data should not be relied upon in making an investment decision in our securities.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials, could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities and could result in decreased market acceptance of any of our product candidates, if approved. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, our trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications.

Any drug-related side effects observed in our clinical trials could also affect patient enrollment in our clinical trials or the ability of any enrolled patients to complete such trials or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;
- regulatory authorities may impose additional restrictions on the marketing of, or the manufacturing processes for, the particular product;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients, or become subject to fines, injunctions or the imposition of civil or criminal penalties;
- our reputation may suffer; and

- we could be required to develop a REMS plan to prevent, monitor and/or manage a specific serious risk by informing, educating and/or reinforcing actions to reduce the frequency and/or severity of the event.

Any of these events could prevent us from achieving or maintaining market acceptance of a particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

Risks Related to Manufacturing and our Dependence on Third Parties

We expect to continue to grow our manufacturing capabilities and resources and we must incur significant costs to develop this expertise and/or rely on third parties to manufacture our products.

We have growing manufacturing capabilities, and in order to continue to develop our current product candidates, apply for regulatory approvals and, if approved, commercialize future products, we will need to continue to develop, contract for, or otherwise arrange for any necessary external manufacturing capabilities.

We manufacture our product candidates internally. There are risks inherent in biological manufacturing and we may not meet our delivery time requirements or provide adequate amounts of material to meet our needs, and we may make errors in manufacturing, any of which could delay our clinical trials and result in additional expense to us.

Our autologous cell therapy products, including Descartes-08, are made on a patient-by-patient basis, rendering their manufacture less predictable and requiring more demanding logistics.

We rely on one or more third-party laboratories to perform certain quality control tests. These laboratories could become unavailable, or provision of their services could be delayed.

Additionally, as we scale up our manufacturing, we may encounter further challenges. Furthermore, competition for supply from our manufacturers from other companies, a breach or violation by such manufacturers of their contractual or regulatory obligations or a dispute with such manufacturers would cause delays in our discovery and development efforts, as well as additional expense to us.

In developing manufacturing capabilities by building our own manufacturing facilities, we have incurred substantial expenditures, and expect to incur significant additional expenditures in the future. Also, we have had to, and will likely need to continue to recruit, hire, and train qualified employees to staff our facilities. If we are unable to manufacture sufficient quantities of material or if we encounter problems with our facilities in the future, we may also need to secure alternative suppliers, and such alternative suppliers may not be available, or we may be unable to enter into agreements with them on reasonable terms and in a timely manner. In addition, to the extent we or our partners rely on contract manufacturing organizations, or CMOs, to supply our product candidates, any delays or disruptions in supply could have a material adverse impact on the research and development activities and potential commercialization of our or our partners' product candidates.

The manufacturing process for any products that we may develop is subject to the FDA and foreign regulatory authority approval process and we will need to meet, or will need to contract with CMOs who can meet, all applicable FDA and foreign regulatory authority requirements on an ongoing basis. Our failure or the failure of any CMO to meet required regulatory authority requirements could result in the delayed submission of regulatory applications, or delays in receiving regulatory approval for any of our or our current or future collaborator' product candidates.

To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, we depend, and will depend in the future, on these third parties to perform their obligations in a timely manner and consistent with contractual and regulatory requirements, including those related to quality control and quality assurance. The failure of any CMO to perform its obligations as expected, or, to the extent we manufacture all or a portion of our product candidates ourselves, our failure to execute on our manufacturing requirements, could adversely affect our business in a number of ways, including:

- we or our current or future collaborators may not be able to initiate or continue clinical trials of product candidates that are under development;
- we or our current or future collaborators may be delayed in submitting regulatory applications, or receiving regulatory approvals, for our product candidates;
- we may lose the cooperation of our collaborators;
- our facilities and those of our CMOs, and our products could be the subject of inspections by regulatory authorities that could have a negative outcome and result in delays in supply;
- we may be required to cease distribution or recall some or all batches of our products or take action to recover clinical trial material from clinical trial sites; and
- ultimately, we may not be able to meet the clinical and commercial demands for our products.

If we are unable to enter into future collaborations and licensing arrangements, our business could be adversely affected.

We intend to explore licenses and other strategic collaborations with pharmaceutical and biotechnology companies for development and potential commercialization of therapeutic products. However, we face significant competition in seeking appropriate collaborators. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our programs, and our business may be materially and adversely affected.

We rely, and expect to continue to rely, on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including by failing to meet deadlines for the completion of such trials.

We rely, and expect to continue to rely, on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct and manage our clinical trials, including our ongoing Phase 2 clinical program Descartes-08. We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials.

While we rely on these third parties for research and development activities, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with GCP regulations, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, safety and welfare of trial participants are protected. Other countries' regulatory agencies also have requirements for clinical trials. If we or any of our CROs or third-party contractors fail to comply with applicable GCPs, the data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, *www.ClinicalTrials.gov*, within specified timeframes. Failure to do so can result in fines, adverse publicity, and civil and criminal sanctions.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, do not comply with confidentiality obligations, do not meet expected deadlines, experience work stoppages, terminate their agreements with us or need to be replaced, or do not conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we may need to enter into new arrangements with alternative third parties, which could be difficult, costly or impossible, and our clinical trials may be extended, delayed or terminated, or may need to be repeated. If any of the foregoing occur, we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates or in commercializing our product candidates.

Risks Related to Commercialization of our Product Candidates and Legal Compliance Matters

Even if any of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If any of our product candidates receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on several factors, including:

- the efficacy, safety and potential advantages compared to alternative treatments;
- our ability to manufacture and distribute cell therapies in a timely and secure manner;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- product labeling or product insert requirements of the FDA or foreign regulatory authorities, including any limitations or warnings contained in a product's approved labeling, including any black box warning or REMS;
- the willingness of the target patient population to try new treatments and of physicians to prescribe these treatments;
- our ability to hire and retain a sales force;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement for our product candidates, once approved;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products together with other medications.

We currently have no sales organization . If we are unable to establish effective sales, marketing and distribution capabilities, or enter into agreements with third parties with such capabilities, we may not be successful in commercializing our product candidates if and when they are approved.

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any product candidate for which we obtain marketing approval, we will need to establish a sales and marketing organization or make arrangements with third parties to perform sales and marketing functions and we may not be successful in doing so. We expect to build a focused sales and marketing infrastructure to market or co-promote our product candidates in the United States and potentially elsewhere, if and when they are approved. There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

We face substantial competition, including from biosimilars, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.

The development and commercialization of new drug and biologic products and technologies is highly competitive and is characterized by rapid and substantial technological development and product innovations. We are aware that pharmaceutical and biotechnology companies, offer or are pursuing the development of pharmaceutical products or technologies that may address one or more indications that our product candidates target, as well as smaller, early-stage companies, that offer or are pursuing the development of pharmaceutical products or technologies that may address one or more indications that our product candidates target. We face competition with respect to our current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources, established presence in the market and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and reimbursement for product candidates and in marketing approved products than we do.

These third parties compete with us in recruiting and retaining qualified scientific, sales and marketing and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market, especially for any competitor developing a competing immunomodulating therapeutic that will likely share our same regulatory approval requirements. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic or biosimilar products.

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

The BPCIA was enacted as part of the Affordable Care Act 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 an approved biologic. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the reference product was approved under a BLA. The law is still being interpreted and implemented by the FDA, and as a result, its ultimate impact, implementation, and meaning are subject to uncertainty. However, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

We believe that any product candidate approved 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 approved, 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.

Even if we are able to commercialize any of our product candidates, the products may become subject to unfavorable pricing regulations or third-party coverage or reimbursement policies, any of which would have a material adverse effect on our business.

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval, especially novel products like our cell therapy product candidates, and may be particularly difficult because of the higher prices associated with such product candidates. Our ability to commercialize any product candidates successfully will depend, in part, on the extent to which coverage and adequate reimbursement for these products and related treatments 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 medications they will pay for and establish reimbursement levels.

Obtaining and maintaining adequate reimbursement for our products may be difficult. We cannot be certain if we will obtain an adequate level of reimbursement for our products by third-party payors. Even if we do obtain adequate levels of reimbursement, third-party payors, such as government or private healthcare insurers, carefully review and question the coverage of, and challenge the prices charged for, products. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Third-party payors often require that pharmaceutical companies provide them with predetermined discounts from list prices and are challenging the prices charged for products. We may also be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. Some third-party payors may require pre-approval of coverage for new and innovative therapies, such as our product candidates, before they will provide reimbursement. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining reimbursement for newly approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or similar regulatory authorities outside of the United States. Moreover, eligibility for reimbursement does not imply that a product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control, including possible price reductions, even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval. There can be no assurance that our product candidates, if they are approved for sale in the United States or in other countries, will be considered medically necessary for a specific indication or cost-effective, or that coverage or an adequate level of reimbursement will be available.

Moreover, there is heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. There can be no assurance that our product candidates, will not be subject to heightened governmental scrutiny, unfavorable regulatory inquiry or action, or Congressional inquiry.

Product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- regulatory investigations, product recalls or withdrawals, or labeling, marketing or promotional restrictions;
- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- loss of clinical trial participants or increased difficulty in enrolling future participants;
- significant costs to defend the related litigation or to reach a settlement;

- substantial payments to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy;
- the inability to commercialize any products that we may develop;
- distraction of management's attention from our primary business; and
- substantial monetary awards to patients or other claimants.

We maintain general liability, product liability and umbrella liability insurance. Our existing insurance coverage may not fully cover potential liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. A product liability claim or series of claims brought against us could cause our share price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business, including preventing or limiting the commercialization of any product candidates we develop.

Our relationships with healthcare providers, customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.

Arrangements with physicians, others who may be in a position to generate business for us, and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- the federal False Claims Act, which impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government claims for payment that are false or fraudulent. Private individuals (e.g., whistleblowers) can bring these actions on behalf of the government; in addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- HIPAA which imposes criminal and civil liability for, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- HIPAA, as amended by HITECH and its implementing regulations, which also imposes obligations, including mandatory contractual terms, on certain types of people and entities with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act, which requires applicable manufacturers of certain products for which payment is available under a federal healthcare program to report annually to the government information related to certain payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other health care professionals beginning in 2022, and teaching hospitals, as well as ownership and investment interests held by the physicians and their immediate family members;
- analogous state laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by third-party payors, including private insurers; and requirements to comply with federal and pharmaceutical industry compliance guidelines;
- state data privacy and price transparency laws, many of which differ from each other in significant ways and often are broader than and not preempted by HIPAA or the Sunshine Act, thus complicating compliance efforts; by way of example, the California Consumer Privacy Act, or CCPA, which went into effect January 1, 2020, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Although the law includes limited exceptions, including for "protected health information" maintained by a covered entity or business associate, it may regulate or impact our processing of personal information depending on the context; and

- similar healthcare laws and regulations in the European Union and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of certain protected information, such as the General Data Protection Regulation, or GDPR, which imposes obligations and restrictions on the collection and use of personal data relating to individuals located in the European Union (including health data); in addition, the United Kingdom leaving the EU could also lead to further legislative and regulatory changes. It remains unclear how the United Kingdom data protection laws or regulations will develop in the medium to longer term and how data transfer to the United Kingdom from the E.U. will be regulated. However, the United Kingdom has transposed the GDPR into domestic law with the Data Protection Act 2018, which remains in force following the United Kingdom's departure from the EU.

Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including our relationships with physicians and other healthcare providers, some of whom may recommend, purchase and/or prescribe our product candidates, if approved, may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental laws and regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, disgorgement, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing 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 marketing approval.

For example, the ACA, is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA. We cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

We expect that the ACA, 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 additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. 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.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and or approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. If a prolonged government shutdown occurs, or if global health concerns were to again prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can have a material adverse effect on our business.

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

If we or third parties we rely upon 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 our business.

We and our contract manufacturers and other third parties with whom we do business are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including biological materials and chemicals. Our operations also 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. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

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, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. The failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Risks Related to our Financial Position and Need for Additional Capital

We are a development-stage company and have incurred significant losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

Except for the year ended December 31, 2022, we have incurred significant operating losses since our inception. Our net income was $35.4 million for the year ended December 31, 2022, and net losses were $25.7 million and $68.9 million for each of the years ended December 31, 2021 and 2020, respectively, and were $9.0 million for the quarter ended September 30, 2023. As of September 30, 2023, we had an accumulated deficit of $437.0 million. To date, we have financed our operations primarily through public offerings and private placements of our securities, funding received from collaboration and license arrangements and our credit facility. We currently have no source of product revenue, and we do not expect to generate product revenue for the foreseeable future. Historically we devoted substantially all of our financial resources and efforts to developing our ImmTOR platform and following the closing of the Merger we expect to devote substantially all of our financial resources and efforts to developing our RNA-based therapies for the treatment of autoimmune diseases, identifying potential product candidates and conducting preclinical studies and our clinical trials. We are in the early stages of clinical development of most of our product candidates. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We expect that our expenses will increase substantially as we:

- continue the research and development of our product candidates;
- increase and develop our manufacturing and distribution capacities;
- discover and develop additional product candidates;
- seek to maintain and enter into collaboration, licensing and other agreements, including, but not limited to research and development, and/or commercialization agreements;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;

- potentially establish a sales, marketing and distribution infrastructure and scale up internal manufacturing capabilities to commercialize any products for which we may obtain regulatory approval;
- maintain, expand and protect our intellectual property portfolio, including through licensing arrangements;
- add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development and potential future commercialization efforts;
- experience any delays or encounter any issues with any of the above, including, but not limited to, failed studies, complex results, safety issues or other regulatory, manufacturing or scale-up challenges; and
- are exposed to broad macroeconomic conditions including inflation and supply chain tightness which could result in us paying more, or being unable, to access goods and services.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, discovering additional product candidates, obtaining regulatory approval and securing reimbursement for these product candidates, manufacturing, marketing and selling any products for which we may obtain regulatory approval, and establishing and managing our collaborations at various stages of a product candidate's development. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with pharmaceutical and biological 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. If we are required by the FDA or other regulatory authorities to perform studies in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any of our product candidates, our expenses could increase and product revenue could be further delayed.

We may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to remain profitable would depress our value and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or continue our operations.

We will need substantial additional funding in order to complete development of our product candidates and commercialize our products, if approved. If we are unable to raise capital when needed and on terms favorable to us, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue research and development for other product candidates. Additionally, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Accordingly, we will need to obtain substantial additional funding to continue operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our clinical trials, our other research and development programs or any future commercialization efforts.

We believe that our existing cash, cash equivalents, and restricted cash as of September 30, 2023, combined with net proceeds from the Financing will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months. We may pursue additional cash resources through public or private equity or debt financings, by establishing collaborations with other companies or through the monetization of potential royalty and/or milestone payments pursuant to our existing collaboration and license arrangements. Management's expectations with respect to our ability to fund current and long-term planned operations are based on estimates that are subject to risks and uncertainties. If actual results are different from management's estimates, we may need to seek additional strategic or financing opportunities sooner than would otherwise be expected. However, there is no guarantee that any of these strategic or financing opportunities will be executed on favorable terms, and some could be dilutive to existing stockholders. If we are unable to obtain additional funding on a timely basis, we may be forced to significantly curtail, delay, or discontinue one or more of our planned research or development programs or be unable to expand our operations, meet long-term obligations or otherwise capitalize on our commercialization of our product candidates. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect.

Our future capital requirements will depend on many factors, including:

- the timing for stockholder approval of the conversion of our Series A Preferred Stock into our common stock and any associated redemptions;
- the scope, progress, results and costs of our clinical trials, preclinical development, manufacturing, laboratory testing and logistics;
- the number of product candidates that we pursue and the speed with which we pursue development;
- our headcount growth and associated costs;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, from commercial sales of our product candidates for which we receive marketing approval;

- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products and technologies, including entering into licensing or collaboration arrangements for product candidates.

The Certificate of Designation contains a provision granting each holder of the Series A Preferred Stock the option to require us to redeem any or all of such holder's preferred shares if our stockholders have not voted to approve the conversion of the Series A Preferred Stock to common stock within 18 months of the Closing Date; provided, however, that no holder will have the right to seek redemption of any shares of Series A Preferred Stock to the extent that such holder would otherwise be unable to convert such shares of Series A Preferred Stock due to the 19.9% common stock beneficial ownership limitation contained in the Certificate of Designation. The per-share redemption price is the average closing trading price of the common stock for the ten preceding trading days ending on, and including, the trading day immediately prior to the date a notice of conversion is delivered to us. We could be required to use a significant amount of our cash resources on hand to satisfy this redemption obligation, particularly if holders of Series A Preferred Stock exercise their redemption right with respect to a significant number of shares of Series A Preferred Stock or at a time when the trading price of our common stock is elevated. Further, in the event that we do not have sufficient cash on hand to satisfy our redemption obligations, we may need to raise additional capital to satisfy these potential obligations. Any redemption payments could materially limit the amount of cash we have available to fund our operations.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Market volatility resulting from the ongoing conflicts in Ukraine and the Middle East and current global macroeconomic conditions or other factors could also adversely impact our ability to access capital as and when needed. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders, and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. The incurrence of indebtedness could result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborators or others at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs, including our clinical trial programs, or the commercialization of any product candidates, or be unable to sustain or expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

Our ability to use our net operating loss and research and development tax credit carryforwards to offset future taxable income may be subject to certain limitations.

We have net operating loss carryforwards, or NOLs, for federal and state income tax purposes that may be available to offset our future taxable income, if any. In general, under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to use its pre-change NOLs to offset future taxable income. If the U.S. Internal Revenue Service, or IRS, challenges our analysis that existing NOLs will not expire before utilization due to previous ownership changes, or if we undergo an ownership change in connection with or after a public offering, our ability to use our NOLs could be limited by Section 382 of the Code. Future changes in our stock ownership, some of which are outside of our control, could result in an ownership change under Sections 382 and 383 of the Code. Furthermore, our ability to use NOLs of companies that we may acquire in the future may be subject to limitations. As a result, we may not be able to use a material portion of the NOLs reflected on our balance sheet, even if we attain profitability. The reduction of the corporate tax rate under the TCJA may cause a reduction in the economic benefit of our NOLs and other deferred tax assets available to us. Under current law, NOLs that arose before January 1, 2018 may be carried forward up to 20 years. NOLs that arose after 2017 may be used to offset at most 80% of our taxable income to the extent not offset by pre-2018 NOLs and such NOLs can be carried forward indefinitely. As a result, we may become required to pay federal income taxes in future years despite having generated losses for federal income tax purposes in prior years.

Risks Related to our Intellectual Property

If we or our licensors are unable to adequately protect our proprietary technology, or obtain and maintain issued patents that are sufficient to protect our product candidates, others could compete against us more directly, which would negatively impact our business.

Our success depends in large part on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our proprietary technology and products. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and product candidates. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost, in a timely manner or in all jurisdictions. As we reach the statutory deadlines for deciding whether and where to initiate prosecution in specific foreign jurisdictions by filing national stage applications based on our Patent Cooperation Treaty, or PCT, applications, we will have to decide whether and where to pursue patent protection for the various inventions claimed in our patent portfolio, and we will only have the opportunity to obtain patents in those jurisdictions where we pursue protection. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, such as, with respect to proper priority claims, inventorship, claim scope or patent term adjustments. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business. We also cannot

guarantee that any of our patent searches or analyses, including but not limited to the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete and thorough, nor can we be certain that we have identified each and every patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction.

In some circumstances, 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 license from third parties. We may also require the cooperation of our licensors to enforce any licensed patent rights, and such cooperation may not be provided. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Moreover, we have obligations under our licenses, and any failure to satisfy those obligations could give our licensor the right to terminate the license. Termination of a necessary license could have a material adverse impact on our business.

Some of our patent licenses are non-exclusive. In those cases, a competitor could obtain a license to the same or similar technology from the licensor. We have at least one exclusive patent license that is restricted to a particular field of use. A competitor could obtain a license to a similar technology outside of that field of use.

We cannot provide any assurances that the issued patents we currently own, or any future patents, include claims with a scope sufficient to protect our product candidates or otherwise provide any competitive advantage. Further, it is possible that a patent claim may provide coverage for some but not all parts of a product candidate or third-party product. These and other factors may provide opportunities for our competitors to design around our patents.

Moreover, other parties may have developed technologies that may be related or competitive to our approach, and may have filed or may file patent applications, and may have received or may receive patents that may overlap or conflict with our patent applications, either by claiming similar methods or by claiming subject matter that could dominate our patent position. In addition, it may be some time before we understand how the patent office reacts to our patent claims and whether they identify prior art of relevance that we have not already considered.

Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in any owned patents or pending patent applications, or that we were the first to file for patent protection of such inventions, nor can we know whether those from whom we may license patents were the first to make the inventions claimed or were the first to file. For these and other reasons, the issuance, scope, validity, enforceability and commercial value of our patent rights are subject to a level of uncertainty. Our pending and future patent applications may not result in patents being issued that protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

We may be subject to a third-party preissuance submission of prior art to the U.S. Patent and Trademark Office, or USPTO or other patent office, or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize product candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Furthermore, an adverse decision in an interference proceeding can result in a third party receiving the patent right sought by us, which in turn could affect our ability to develop, market or otherwise commercialize our product candidates. The issuance, scope, validity, enforceability and commercial value of our patents are subject to a level of uncertainty.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. Due to legal standards relating to patentability, validity, enforceability and claim scope of patents covering biotechnological and pharmaceutical inventions, our ability to obtain, maintain and enforce patents is uncertain and involves complex legal and factual questions. Even if issued, a patent’s validity, inventorship, ownership or enforceability is not conclusive. Accordingly, rights under any existing patent or any patents we might obtain or license may not cover our product candidates, or may not provide us with sufficient protection for our product candidates to afford a commercial advantage against competitive products or processes, including those from branded and generic pharmaceutical companies.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how, information, or technology that is not covered by our patents. Although our agreements require all of our employees to assign their inventions to us, and we require all of our employees, consultants, advisors and any other third parties who have access to our trade secrets, proprietary know-how and other confidential information and technology to enter into appropriate confidentiality agreements, we cannot be certain that our trade secrets, proprietary know-how, and other confidential information and technology will not be subject to unauthorized disclosure or that our competitors will not otherwise gain access to or independently develop substantially equivalent trade secrets, proprietary know-how, and other information and technology. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property globally. If we are unable to prevent unauthorized disclosure of our intellectual property related to our product candidates and technology to third parties, we may not be able to establish or maintain a competitive advantage in our market, which could adversely affect our business and operations.

Any litigation to enforce or defend our patent rights, even if we were to prevail, could be costly and time-consuming and would divert the attention of our management and key personnel from our business operations. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful. Even if we are successful, domestic or foreign litigation, or USPTO or foreign patent office proceedings, may result in substantial costs and distraction to our management. We may not be able, alone or with our licensors or potential collaborators, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings. In addition, during the course of this kind of litigation or proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for our common stock could be adversely affected.

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

In addition to seeking patents for some of our technology and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also seek to enter into confidentiality and invention or patent assignment agreements with our employees, advisors and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Our trade secrets may also be obtained by third parties by other means, such as breaches of our physical or computer security systems. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, 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 any of our trade secrets were to be disclosed to, or independently developed by, a competitor, our competitive position would be harmed.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involves both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, recent patent reform legislation could further increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act America Invents Act, or the Leahy-Smith Act, included provisions that affect the way patent applications are prosecuted and may also affect patent litigation, including first-to-file provisions. A third party that files a patent application in the USPTO before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This requires us to be cognizant of the time from invention to filing of a patent application. Thus, for our U.S. patent applications containing a priority claim after March 16, 2013, the date such provisions became effective, there is a greater level of uncertainty in the patent law. Moreover, some of the patent applications in our portfolio will be subject to examination under the pre-Leahy-Smith Act law and regulations, while other patents applications in our portfolio will be subject to examination under the law and regulations, as amended by the Leahy-Smith Act. This introduces additional complexities into the prosecution and management of our portfolio.

In addition, the Leahy-Smith Act limits where a patentee may file a patent infringement suit and provides opportunities for third parties to challenge any issued patent in the USPTO. These provisions apply to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a federal court action.

Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims because it may be easier for them to do so relative to challenging the patent in a federal court action. It is not clear what, if any, impact 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 our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

In addition, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. From time to time, the U.S. Supreme Court, other federal courts, the U.S. Congress or the USPTO may change the standards of patentability, and any such changes could have a negative impact on our business.

Depending on these and other decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change or be interpreted in unpredictable ways that would weaken our ability to obtain new patents or to enforce any patents that may issue to us in the future. In addition, these events may adversely affect our ability to defend any patents that may issue in procedures in the USPTO or in courts.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability, and the ability of our collaborators, to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. While no such litigation has been brought against us and we have not been held by any court to have infringed a third party's intellectual property rights, we cannot guarantee that our technology, product candidates or use of our product candidates do not infringe third-party patents.

We are aware of numerous patents and pending applications owned by third parties, and we monitor patents and patent applications in the fields in which we are developing product candidates, both in the United States and elsewhere. However, we may have failed to identify relevant third-party patents or applications. For example, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Moreover, it is difficult for industry participants, including us, to identify all third-party patent rights that may be relevant to our product candidates and technologies because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We may fail to identify relevant patents or patent applications or may identify pending patent applications of potential interest but incorrectly predict the likelihood that such patent applications may issue with claims of relevance to our technology. In addition, we may be unaware of one or more issued patents that would be infringed by the manufacture, sale or use of a current or future product candidate, or we may incorrectly conclude that a third-party patent is invalid, unenforceable or not infringed by our activities. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our product candidates or the use of our product candidates.

The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may allege that our product candidates or the use of our technologies infringes patent claims or other intellectual property rights held by them or that we are employing their proprietary technology without authorization. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates and technology, including interference or derivation proceedings before the USPTO and similar bodies in other countries. Third parties may assert infringement claims against us based on existing intellectual property rights and intellectual property rights that may be granted in the future.

Patent and other types of intellectual property litigation can involve complex factual and legal questions, and their outcome is uncertain. If we are found, or believe there is a risk we may be found, to infringe a third party's intellectual property rights, we could be required or may choose to obtain a license from such third party to continue developing and marketing our product candidates and technology. However, we may not be able to obtain any such license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

Even if we are successful in such proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on us. Patent litigation is costly and time-consuming. We may not have sufficient resources to bring these actions to a successful conclusion. There could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

Any of these risks coming to fruition could have a material adverse impact on our business.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, and our issued patents covering our product candidates could be found invalid or unenforceable or could be interpreted narrowly if challenged in court.

Competitors may infringe our intellectual property, including our patents or the patents of our licensors. As a result, we may be required to file infringement claims to stop third-party infringement or unauthorized use. This can be expensive, particularly for a company of our size, and time-consuming. If we initiated legal proceedings against a third party to enforce a patent, if and when issued, covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include alleged failures to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement, or failure to claim patent-eligible subject matter. Grounds for unenforceability assertions include allegations that someone connected with the prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter partes review, interference proceedings and equivalent proceedings in foreign jurisdictions, such as opposition proceedings. Such proceedings could result in revocation or amendment of our patents in such a way that they no longer cover our product candidates or competitive products. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Moreover, even if not found invalid or unenforceable, the claims of our patents could be construed narrowly or in a manner that does not cover the allegedly infringing technology in question. Such a loss of patent protection would have a material adverse impact on our business.

The lives of our patents may not be sufficient to effectively protect our products and business.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its first effective non-provisional filing date. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates, proprietary technologies and their uses are obtained, once the patent life has expired, we may be open to competition. In addition, although upon issuance in the United States a patent's life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. 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. If we do not have sufficient patent life to protect our product candidates, proprietary technologies and their uses, our business and results of operations will be adversely affected.

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

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent and, in some jurisdictions, during the pendency of a patent application. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have an adverse effect on our business.

We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.

We currently have rights to certain intellectual property, through licenses from third parties and under patents and patent applications that we own, to develop our product candidates. Because we may find that our programs require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights. We may be unable to acquire or in-license compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, financial resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment.

If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of that program and our business and financial condition could suffer.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may also engage advisors and consultants who are concurrently employed at universities or other organizations or who perform services for other entities. Although we try to ensure that our employees, advisors and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, advisors or consultants have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such party's former or current employer or in violation of an agreement with another party. Although we have no knowledge of any such claims being alleged to date, if such claims were to arise, litigation may be necessary to defend against any such claims.

In addition, while it is our policy to require our employees, consultants, advisors 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. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. Similarly, we may be subject to claims that an employee, advisor or consultant performed work for us that conflicts with that person's obligations to a third party, such as an employer, and thus, that the third party has an ownership interest in the intellectual property arising out of work performed for us. Litigation may be necessary to defend against these claims. Although we have no knowledge of any such claims being alleged to date, if such claims were to arise, litigation may be necessary to defend against any such claims.

If we fail in prosecuting or 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 prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

We will not seek to protect our intellectual property rights in all jurisdictions throughout the world and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

Filing, prosecuting and defending patents on product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than in the United States, assuming that rights are obtained in the United States and assuming that rights are pursued outside the United States. In this regard, in addition to the United States, we also seek to protect our intellectual property rights in other countries. The statutory deadlines for pursuing patent protection in individual foreign jurisdictions are based on the priority date of each of our patent applications. For all of the patent families in our portfolio, including the families that may provide coverage for our lead product candidate, the relevant statutory deadlines have not yet expired. Therefore, for each of the patent families that we believe provide coverage for our lead product candidate, we will need to decide whether and where to pursue additional protection outside the United States. 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. Consequently, for our existing patent rights outside the United States and any foreign patent rights we may decide to pursue in the future, we may not be able to obtain relevant claims and/or we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, 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 do not pursue and obtain patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as in the United States. These products may compete with our product candidates and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Even if we pursue and obtain issued patents in particular jurisdictions, our patent claims or other intellectual property rights may not be effective or sufficient to prevent third parties from so competing.

If we do not obtain additional protection under the Hatch-Waxman Act and similar foreign legislation extending the terms of our patents for our product candidates, our business may be harmed.

Depending upon the timing, duration and specifics of FDA regulatory approval for our product candidates, one or more of our U.S. patents may be eligible for limited patent term restoration under the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. Patent term restorations, however, are limited to a maximum of five years and cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval by the FDA.

The application for patent term extension is subject to approval by the USPTO, in conjunction with the FDA. It takes at least six months to obtain approval of the application for patent term extension. We may not be granted 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. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened, our competitors may obtain earlier approval of competing products and our ability to generate revenues could be materially adversely affected.

Risks Related to our Operations

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

We are highly dependent on Carsten Brunn, Ph.D., our President and Chief Executive Officer, as well as the other principal members of our management, scientific and clinical teams. Although we have entered into employment agreements or offer letters with Dr. Brunn and other executive officers, each of them may terminate their employment with us at any time. We do not maintain “key person” insurance for any of our executives or other employees.

Recruiting and retaining qualified scientific, clinical, manufacturing, technology and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize product candidates. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

We have incurred increased costs as a result of operating as a public company, and our management will be required to devote substantial time to compliance initiatives and corporate governance practices.

As a public company, we have incurred and expect to continue to incur significant legal, accounting and other expenses. If we are unable to maintain effective internal control over financial reporting, we may not have adequate, accurate or timely financial information, and we may be unable to meet our reporting obligations as a public company or comply with the requirements of the SEC or Section 404. This could result in a restatement of our financial statements, the imposition of sanctions, including the inability of registered broker dealers to make a market in our common stock, or investigation by regulatory authorities. Any such action or other negative results caused by our inability to meet our reporting requirements or comply with legal and regulatory requirements or by disclosure of an accounting, reporting or control issue could adversely affect the trading price of our securities and our business. Material weaknesses in our internal control over financial reporting could also reduce our ability to obtain financing or could increase the cost of any financing we obtain. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

A variety of risks associated with maintaining our subsidiary in Russia or expanding operations internationally could adversely affect our business.

In addition to our U.S. operations, we maintain a wholly owned subsidiary in Russia, Selecta (RUS). However, we are in the process of winding down these operations. We may face risks associated with winding down the operations of our subsidiary in Russia, or with any international operations, including possible unfavorable regulatory, pricing and reimbursement, legal, political, tax and labor conditions, and risks associated with our compliance with evolving international sanctions, which could harm our business. We may also rely on collaborators to commercialize any approved product candidates outside of the United States. Doing business internationally involves a number of risks, including but not limited to:

- multiple, conflicting and changing laws and regulations, such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us to obtain and maintain regulatory approvals for the use of our product candidates in various countries;
- additional potentially relevant third-party patent rights;
- complexities and difficulties in obtaining protection of and enforcing our intellectual property rights; difficulties in staffing and managing foreign operations;
- complexities associated with managing multiple-payor reimbursement regimes, government payors or patient self-pay systems;
- limits on our ability to penetrate international markets; financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our product candidates and exposure to foreign currency exchange rate fluctuations, which could result in increased operating expenses and reduced revenues;
- natural disasters, political and economic instability, including wars, events of terrorism and political unrest, outbreak of disease, including the COVID-19 pandemic, boycotts, curtailment of trade and other business restrictions, economic sanctions, and economic weakness, including inflation;
- changes in diplomatic and trade relationships; challenges in enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- restriction on cross-border investment, including enhanced oversight by the Committee on Foreign Investment in the United States and substantial restrictions on investment from China;
- certain expenses including, among others, expenses for travel, translation and insurance;
- legal risks, including use of the legal system by the government to benefit itself or affiliated entities at our expense, including expropriation of property;
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the FCPA its books and records provisions, or its anti-bribery provisions; and
- risks that we may suffer reputational harm as a result of our operations in Russia.

Any of these factors could significantly harm our future international expansion and operations and, consequently, our results of operations.

Our business and operations, including our development programs, could be materially disrupted in the event of system failures, security breaches, violations of data protection laws or data loss or damage by us or third parties on which we rely, including our CROs or other contractors or consultants.

Our internal computer systems and those of third parties on which we rely, including our CROs and other contractors and consultants, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could have a material adverse effect on our business operations, including a material disruption of our development programs. Unauthorized disclosure of sensitive or confidential patient or employee data, including personally identifiable information, whether through breach of computer systems, systems failure, employee negligence, fraud or misappropriation, or otherwise, or unauthorized access to or through our information systems and networks, whether by our employees or third parties, could result in negative publicity, legal liability and damage to our reputation. Unauthorized disclosure of personally identifiable information could also expose us to sanctions for violations of data privacy laws and regulations around the world. To the extent that any disruption or security breach resulted in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed. For example, the loss of or damage to clinical trial data, such as from completed or ongoing clinical trials, for any of our product candidates would likely result in delays in our marketing approval efforts and significantly increased costs in an effort to recover or reproduce the data.

We have previously been, and expect to remain, the target of cyber-attacks. As we become more dependent on information technologies to conduct our operations, cyber incidents, including deliberate attacks, such as ransomware attacks, and attempts to gain unauthorized access to computer systems and networks, may increase in frequency and sophistication. These incidents pose a risk to the security of our systems and networks, the confidentiality and the availability and integrity of our data and these risks apply both to us, and to third parties on whose systems we rely for the conduct of our business. While we do not believe the effect of these incidents has historically been material to our results of operations, financial condition or prospects, cyber threats are persistent and constantly evolving. Such threats have increased in frequency, scope and potential impact in recent years, which increases the difficulty of detecting and successfully defending against them. As cyber threats continue to evolve, we may be required to incur additional expenses in order to enhance our protective measures or to remediate any information security vulnerability. There can be no assurance that we or our third-party providers will be successful in preventing cyber-attacks or mitigating their effects. Similarly, there can be no assurance that our collaborators, CROs, third-party logistics providers, distributors and other contractors and consultants will be successful in protecting our clinical and other data that is stored on their systems. Any cyber-attack or destruction or loss of data could have a material adverse effect on our business and prospects. In addition, we may suffer reputational harm or face litigation or adverse regulatory action as a result of cyber-attacks or destruction or loss of data and may incur significant additional expense to implement further data protection measures. It is also possible that unauthorized access to data may be obtained through inadequate use of security controls by our suppliers or other vendors.

Although we have general liability insurance coverage, our insurance may not cover all claims, continue to be available on reasonable terms or be sufficient in amount to cover one or more large claims. Additionally, the insurer may disclaim coverage as to any claim. The successful assertion of one or more large claims against us that exceed or are not covered by our insurance coverage or changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, could have a material adverse effect on our business, prospects, operating results and financial condition.

Acquisitions or joint ventures could disrupt our business, cause dilution to our stockholders and otherwise harm our business.

We may acquire other businesses, product candidates or technologies as well as pursue strategic alliances, joint ventures, technology licenses or investments in complementary businesses. We have not made any acquisitions to date, and our ability to do so successfully is unproven. Any of these transactions could be material to our financial condition and operating results and expose us to many risks, including:

- disruption in our relationships with future customers or with current or future distributors or suppliers as a result of such a transaction;
- unexpected liabilities related to acquired companies;
- difficulties integrating acquired personnel, technologies and operations into our existing business;
- diversion of management time and focus from operating our business to acquisition integration challenges;
- increases in our expenses and reductions in our cash available for operations and other uses;
- possible write-offs or impairment charges relating to acquired businesses; and
- inability to develop a sales force for any additional product candidates.

Foreign acquisitions involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures and languages, currency risks and the particular economic, political and regulatory risks associated with specific countries.

Also, the expected benefit of any acquisition may not materialize. 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. We cannot predict the number, timing or size of future joint ventures or acquisitions, or the effect that any such transactions might have on our operating results.

Risks Related to our Common Stock

The market price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock.

The trading price of our common stock is likely to be volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. The stock market in general and the market for smaller biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above the price at which you purchased. The market price for our common stock may be influenced by many factors, including:

- the success of competitive products or technologies;
- results or progress, or changes in approach or timelines, of clinical trials of our product candidates or those of our competitors;
- failure or discontinuation of any of our development programs;
- commencement of, termination of, or any development related to any collaboration or licensing arrangement;
- regulatory or legal developments in the United States and other countries;
- development of new product candidates that may address our markets and make our product candidates less attractive;
- changes in physician, hospital or healthcare provider practices that may make our product candidates less useful;
- announcements by us, our collaborators or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- announcement or market expectation of additional financing efforts;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- failure to meet or exceed financial estimates, projections or development timelines of the investment community or that we provide to the public;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- actual or expected changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- sale of common stock by us or our stockholders in the future as well as the overall trading volume of our common stock; changes in the composition of our stockholder base;
- activity in the options market for shares of our common stock;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

Our executive officers, directors, and principal stockholders, if they choose to act together, will continue to have the ability to control or significantly influence all matters submitted to stockholders for approval.

Our executive officers, directors and stockholders who own more than 5% of our outstanding common stock and their respective affiliates, in the aggregate, hold shares representing approximately 41.6% of our outstanding voting stock as of November 13, 2023, and assuming the conversion of all shares of Series A Preferred Stock into common stock and the completion of the Financing. As a result, if these stockholders choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control or significantly influence the election of directors, the composition of our management and approval of any merger, consolidation or sale of all or substantially all of our assets.

Future sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

Concurrently and in connection with the execution of the Merger Agreement, certain former Cartesian securityholders, as of immediately prior to the Merger, and certain of our directors and officers as of immediately prior to the Merger entered into lock-up agreements with us, pursuant to which each such stockholder, will be subject to a 180-day lockup on the sale or transfer of shares of our common stock held by each such stockholder, at the closing of the Merger, including those shares received by former Cartesian securityholders in the Merger. Upon expiration of this 180-day lockup period, these shares will become eligible for sale in the public market.

On November 13, 2023, we also entered into a registration rights agreement, or the Registration Rights Agreement, with certain parties thereto. Pursuant to the Registration Rights Agreement, we are obligated to prepare and file a resale registration statement with the SEC within 90 calendar days following the closing of the Financing, or the Filing Deadline. We agreed to use our reasonable best efforts to cause this registration statement to be declared effective by the SEC within 45 calendar days of the Filing Deadline (or within 90 calendar days if the SEC reviews the registration statement). Once such registration statement is declared effective, the shares to which the registration statement relates will no longer constitute restricted securities and may be sold freely in the public markets, subject to lapse on any related contractual restrictions related thereto of any holder party thereto, and subject to any restrictions that may be applicable to any control securities.

If our stockholders sell, indicate an intention to sell, or it is perceived that they will sell substantial amounts of our common stock in the public market after legal restrictions on resale lapse, the trading price of our common stock could decline. In addition, shares of our common stock that are subject to our outstanding options will become eligible for sale in the public market to the extent permitted by the provisions of various vesting agreements and Rules 144 and 701 under the Securities Act.

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

Provisions in our Certificate of Incorporation and Bylaws may delay or prevent an acquisition or a change in management. These provisions include a prohibition on actions by written consent of our stockholders and the ability of our Board of Directors to issue preferred stock without stockholder approval. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or the DGCL, which prohibits stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us. Although we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our Board of Directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of the Board of Directors, which is responsible for appointing the members of management.

Furthermore, our restated certificate of incorporation specifies that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for most legal actions involving claims brought against us by stockholders. We believe this provision benefits us by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. However, the provision may have the effect of discouraging lawsuits against our directors, officers, employees and agents as it may limit any stockholder's ability to bring a claim in a judicial forum that such stockholder finds favorable for disputes with us or our directors, officers, employees or agents.

In addition, the Certificate of Designation relating to our Series A Preferred Stock may delay or prevent a change in control of our company. At any time while at least 30% of the originally issued Series A Preferred Stock remains issued and outstanding, we may not consummate a Fundamental Transaction (as defined in the Certificate of Designation) or any merger or consolidation of the Company with or into another entity or any stock sale to, or other business combination in which the stockholders of the Company immediately before such transaction do not hold at least a majority of the capital stock of the Company immediately after such transaction, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series A Preferred Stock. This provision of the Certificate of Designation may make it more difficult for us to enter into any of the aforementioned transactions.

We have been in the past and may in the future be subject to securities class action lawsuits.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biopharmaceutical companies have experienced significant stock price volatility in recent years. Involvement in such litigation, could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

On August 3, 2020, a stockholder of Selecta filed a stockholder derivative action, purportedly on behalf of Selecta and against certain current and former members of the Company's Board of Directors, as well as one affiliated company owned by a current board member, in the Court of Chancery of the State of Delaware, namely Franchi v. Barabe, et al. The complaint alleges that the individual defendants breached their fiduciary duties and committed corporate waste when they authorized a private placement transaction, announced on December 19, 2019, at a price allegedly below fair value. The complaint further alleges that the four defendant directors who participated in the private placement were unjustly enriched in connection with the transaction. On September 25, 2020, the defendants filed a motion to dismiss the lawsuit. On November 6, 2020, the plaintiff filed an amended complaint, and the defendants filed a second motion to dismiss on January 8, 2021. On December 31, 2020, we received a litigation demand letter from two other putative stockholders relating to the same private placement transaction. On April 12, 2021, the Court of Chancery in the State of Delaware granted a motion to stay the litigation pending a review by a Special Committee appointed by the Company's Board of Directors. While the litigation was stayed, the parties reached an agreement in principle to settle the matter, and on March 18, 2022, they submitted a Stipulation and Agreement of Settlement and other documentation to the Court for its approval of the settlement. On July 21, 2022, the Court held a settlement hearing, at which the settlement was approved. On August 1, 2022, the Court entered an Order and Final Judgment which dismissed the action, and all claims contained therein, with prejudice. We could receive other demands or be subject to other litigation. While we intend to vigorously defend against any demands which we believe to be without merit, there can be no assurance as to the outcome of any stockholder litigation. Unfavorable outcomes in securities class action litigation could require us to pay extensive damages, which could delay or prevent our ability to develop our product candidates and harm our operations.

Risk Factors Relating to the Merger

There is no guarantee that the Merger will increase stockholder value.

In November 2023 we merged with Cartesian. We cannot guarantee that implementing the Merger and related transactions will not impair stockholder value or otherwise adversely affect our business. The Merger poses significant integration challenges between our businesses and management teams which could result in management and business disruptions, any of which could harm our results of operation, business prospects, and impair the value of the Merger to our stockholders.

Pursuant to the terms of the Merger Agreement, we are required to recommend that our stockholders approve the conversion of all outstanding shares of our Series A Preferred Stock into shares of our common stock. We cannot guarantee that our stockholders will approve this matter, and if they fail to do so we may be required to settle such shares in cash and our operations may be materially harmed.

Under the terms of the Merger Agreement, we agreed to call and hold a meeting of our stockholders to obtain the requisite approvals for the conversion of all outstanding shares of Series A Preferred Stock to be issued in the Merger and Financing into shares of our common stock, as required by the Nasdaq Stock Market LLC listing rules, and, if such approval is not obtained at that meeting, to seek to obtain such approvals at an annual or special stockholders meeting to be held at least every six months thereafter until such approval is obtained, which would be time consuming and costly. Additionally, if our stockholders do not approve the conversion of our Series A Preferred Stock within 18 months from the date of the closing of the Merger, then the holders of our Series A Preferred Stock will be entitled to elect to have their shares of Series A Preferred Stock redeemed for cash at a price per share equal to the ten-day trailing average closing trading price of the common stock at such time, as described in our Certificate of Designation relating to the Series A Preferred Stock. If we are forced to cash settle a significant amount of the Series A Preferred Stock, it could materially affect our results of operations.

The failure to successfully integrate the businesses of Selecta and Cartesian in the expected timeframe would adversely affect the combined Company's future results.

Our ability to successfully integrate the operations of Selecta and Cartesian will depend, in part, on the combined Company's ability to realize the anticipated benefits and cost savings from the Merger. If the combined Company is not able to achieve these objectives within the anticipated time frame, or at all, the anticipated benefits and cost savings of the Merger may not be realized fully, or at all, or may take longer to realize than expected, and the value of our common shares may be adversely affected. In addition, the integration of our and Cartesian's respective businesses will be a time-consuming and expensive process. Proper planning and effective and timely implementation will be critical to avoid any significant disruption to the combined Company's operations. It is possible that the integration process could result in the loss of key employees, the disruption of its ongoing business or the identification of inconsistencies in standards, controls, procedures and policies that adversely affect its ability to maintain relationships with customers, suppliers, distributors, creditors, lessors, clinical trial investigators or managers or to achieve the anticipated benefits of the Merger. Delays encountered in the integration process could have a material adverse effect on the combined Company's revenues, expenses, operating results and financial condition, including the value of its common shares.

Our future results will suffer if the combined Company does not effectively manage its expanded operations.

As a result of the Merger, we will become a larger company and our business will become more complex. There can be no assurance that we will effectively manage the increased complexity without experiencing operating inefficiencies or control deficiencies. Significant management time and effort is required to effectively manage the increased complexity of the combined Company and our failure to successfully do so could have a material adverse effect on our business, financial condition, results of operations and growth prospects. In addition, as a result of the Merger, our financial statements and results of operations in prior years may not provide meaningful guidance to form an assessment of the prospects or potential success of the combined Company's future business operations.

We expect to incur substantial expenses related to the integration of Cartesian.

We expect to incur substantial expenses in connection with the Merger and the subsequent integration of Cartesian with Selecta. There are a large number of processes, policies, procedures, operations, technologies and systems that must be integrated, including purchasing, accounting and finance, sales, billing, payroll, research and development, marketing and benefits. Both we and Cartesian have incurred significant transaction expenses in connection with the drafting and negotiation of the Merger Agreement and may potentially incur significant severance expenses as a result of the Merger. While we and Cartesian have assumed that a certain level of expenses will be incurred, there are many factors beyond their control that could affect the total amount or the timing of the integration expenses. Moreover, many of the expenses that will be incurred are, by their nature, difficult to estimate accurately. These integration expenses likely will result in our taking significant charges against earnings following the completion of the Merger, and the amount and timing of such charges are uncertain at present.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

None.

Item 6. Exhibits

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
2.1	Agreement and Plan of Merger, dated November 13, 2023, by and among Selecta Biosciences, Inc. Sakura Merger Sub I, Inc., Sakura Merger Sub II, LLC and Cartesian Therapeutics, Inc.	8-K	001-37798	2.1	11/13/2023
3.1(a)	Restated Certificate of Incorporation of Selecta Biosciences, Inc.	8-K	001-37798	3.1	6/29/2016
3.1(b)	Certificate of Amendment to the Restated Certificate of Incorporation of Selecta Biosciences, Inc., dated June 21, 2022	8-K	001-37798	3.1	6/21/2022
3.1(c)	Certificate of Amendment to the Restated Certificate of Incorporation of Selecta Biosciences, Inc., dated November 13, 2023	8-K	001-37798	3.3	11/13/2023
3.2	Amended and Restated By-laws of Cartesian Therapeutics, Inc.				Filed herewith
4.1	Form of Contingent Value Rights Agreement	8-K	001-37798	2.1	11/13/2023
10.1*	Form of Retention Bonus Letter	8-K	001-37798	10.3	11/13/2023
10.2	Form of Support Agreement	8-K	001-37798	2.1	11/13/2023
10.3	Form of Lock-up Agreement	8-K	001-37798	2.1	11/13/2023
10.4	Securities Purchase Agreement, dated as of November 13, 2023, by and among Selecta Biosciences, Inc. and each purchaser identified on Annex A thereto	8-K	001-37798	10.1	11/13/2023
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	—	—	—	Filed herewith
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	—	—	—	Filed herewith
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	—	—	—	Furnished herewith
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)	—	—	—	Filed herewith
101.SCH	Inline XBRL Taxonomy Extension Schema Document	—	—	—	Filed herewith
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document	—	—	—	Filed herewith
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document	—	—	—	Filed herewith
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document	—	—	—	Filed herewith
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document	—	—	—	Filed herewith
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)	—	—	—	Filed herewith

* Management contract or compensatory plan or arrangement.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons on behalf of the registrant in the capacities and on the dates indicated.

SELECTA BIOSCIENCES, INC.

Date: November 13, 2023

By: /s/ Carsten Brunn, Ph.D.
Carsten Brunn, Ph.D.
President and Chief Executive Officer, and Director
(Principal Executive Officer)

Date: November 13, 2023

By: /s/ Blaine Davis
Blaine Davis
Chief Financial Officer
(Principal Financial Officer)

AMENDED AND RESTATED BYLAWS OF CARTESIAN THERAPEUTICS, INC.

(a Delaware corporation)

TABLE OF CONTENTS

	Page
ARTICLE I - CORPORATE OFFICES	1
1.1 REGISTERED OFFICE	1
1.2 OTHER OFFICES	1
ARTICLE II - MEETINGS OF STOCKHOLDERS	1
2.1 PLACE OF MEETINGS	1
2.2 ANNUAL MEETING	1
2.3 SPECIAL MEETING	1
2.4 ADVANCE NOTICE PROCEDURES FOR BUSINESS BROUGHT BEFORE A MEETING	2
2.5 ADVANCE NOTICE PROCEDURES FOR NOMINATIONS OF DIRECTORS	8
2.6 NOTICE OF STOCKHOLDERS' MEETINGS	12
2.7 MANNER OF GIVING NOTICE; AFFIDAVIT OF NOTICE	12
2.8 QUORUM	12
2.9 ADJOURNED MEETING; NOTICE	13
2.10 CONDUCT OF BUSINESS	13
2.11 VOTING	13
2.12 STOCKHOLDER ACTION BY WRITTEN CONSENT WITHOUT A MEETING	14
2.13 RECORD DATE FOR STOCKHOLDER NOTICE; VOTING	14
2.14 PROXIES	15
2.15 LIST OF STOCKHOLDERS ENTITLED TO VOTE	15
2.16 POSTPONEMENT, ADJOURNMENT AND CANCELLATION OF MEETING.	15
2.17 INSPECTORS OF ELECTION	16
ARTICLE III - DIRECTORS	16
3.1 POWERS	16
3.2 NUMBER OF DIRECTORS	16
3.3 ELECTION, QUALIFICATION AND TERM OF OFFICE OF DIRECTORS	16
3.4 RESIGNATION AND VACANCIES	17
3.5 PLACE OF MEETINGS; MEETINGS BY TELEPHONE	17
3.6 REGULAR MEETINGS	17
3.7 SPECIAL MEETINGS; NOTICE	17
3.8 QUORUM	18
3.9 BOARD ACTION BY CONSENT WITHOUT A MEETING	18
3.10 FEES AND COMPENSATION OF DIRECTORS	18
3.11 REMOVAL OF DIRECTORS	18
ARTICLE IV - COMMITTEES	19
4.1 COMMITTEES OF DIRECTORS	19
4.2 COMMITTEE MINUTES	19
4.3 MEETINGS AND ACTION OF COMMITTEES	19
ARTICLE V - OFFICERS	20
5.1 OFFICERS	20
5.2 APPOINTMENT OF OFFICERS	20
5.3 SUBORDINATE OFFICERS	20
5.4 REMOVAL AND RESIGNATION OF OFFICERS	20
5.5 VACANCIES IN OFFICES	20

TABLE OF CONTENTS
(continued)

5.6 REPRESENTATION OF SHARES OF OTHER ENTITIES 21
5.7 AUTHORITY AND DUTIES OF OFFICERS 21
ARTICLE VI - RECORDS AND REPORTS 22
6.1 MAINTENANCE OF RECORDS 22
ARTICLE VII - GENERAL MATTERS 22
7.1 EXECUTION OF CORPORATE CONTRACTS AND INSTRUMENTS 22
7.2 STOCK CERTIFICATES; PARTLY PAID SHARES 22
7.3 MULTIPLES CLASSES OR SERIES OF STOCK 23
7.4 LOST CERTIFICATES 23
7.5 CONSTRUCTION; DEFINITIONS 23
7.6 DIVIDENDS 23
7.7 FISCAL YEAR 24
7.8 SEAL 24
7.9 TRANSFER OF STOCK 24
7.10 STOCK TRANSFER AGREEMENTS 24
7.11 REGISTERED STOCKHOLDERS 24
7.12 WAIVER OF NOTICE 24
7.13 INSIDER PARTICIPATION IN PRIVATE PLACEMENTS 25
ARTICLE VIII - NOTICE BY ELECTRONIC TRANSMISSION 25
8.1 NOTICE BY ELECTRONIC TRANSMISSION 25
8.2 DEFINITION OF ELECTRONIC TRANSMISSION 26
ARTICLE IX - INDEMNIFICATION AND ADVANCEMENT 26
9.1 ACTIONS, SUITS AND PROCEEDINGS OTHER THAN BY OR IN THE RIGHT OF THE CORPORATION. 26
9.2 ACTIONS OR SUITS BY OR IN THE RIGHT OF THE CORPORATION. 27
9.3 INDEMNIFICATION FOR EXPENSES OF SUCCESSFUL PARTY 27
9.4 NOTIFICATION AND DEFENSE OF CLAIM 27
9.5 ADVANCE OF EXPENSES. 28
9.6 PROCEDURE FOR INDEMNIFICATION AND ADVANCEMENT OF EXPENSES. 29
9.7 REMEDIES. 29
9.8 LIMITATIONS 30
9.9 SUBSEQUENT AMENDMENT 30
9.10 OTHER RIGHTS 30
9.11 PARTIAL INDEMNIFICATION. 31
9.12 INSURANCE 31
9.13 SAVINGS CLAUSE 31
9.14 DEFINITIONS 31
ARTICLE X - AMENDMENTS 32

AMENDED AND RESTATED
BYLAWS OF
CARTESIAN THERAPEUTICS,
INC.

ARTICLE I - CORPORATE OFFICES

1.1 REGISTERED OFFICE. The registered office of Cartesian Therapeutics, Inc. (the "Corporation") shall be fixed in the Corporation's certificate of incorporation, as the same may be amended from time to time (the "certificate of incorporation").

1.2 OTHER OFFICES. The Corporation may have other offices at any place or places, either within or outside the State of Delaware, as the board of directors (the "Board") shall from time to time determine or the business of the Corporation may from time to time require.

ARTICLE II - MEETINGS OF STOCKHOLDERS

2.1 PLACE OF MEETINGS. Meetings of stockholders shall be held at any place, within or outside the State of Delaware, designated by the Board. The Board may, in its sole discretion, determine that a meeting of stockholders shall not be held at any place, but may instead be held solely by means of remote communication as authorized by Section 211(a) of the General Corporation Law of the State of Delaware (the "DGCL"). In the absence of any such designation or determination, stockholders' meetings shall be held at the Corporation's principal executive office.

2.2 ANNUAL MEETING. The Board shall designate the date and time of the annual meeting. At the annual meeting, directors shall be elected and other proper business properly brought before the meeting in accordance with Section 2.4 of these bylaws may be transacted.

2.3 SPECIAL MEETING. A special meeting of the stockholders may be called at any time by the Board, chairperson of the Board, chief executive officer or president (in the absence of a chief executive officer), but such special meetings may not be called by any other person or persons.

No business may be transacted at such special meeting other than the business specified in such notice to stockholders. Nothing contained in this paragraph of this Section 2.3 shall be construed as limiting, fixing, or affecting the time when a meeting of stockholders called by action of the Board may be held.

2.4 ADVANCE NOTICE PROCEDURES FOR BUSINESS BROUGHT BEFORE A MEETING. At an annual meeting of the stockholders, only such business shall be conducted as shall have been properly brought before the meeting. To be properly brought before an annual meeting, business must be (i) brought before the meeting by the Corporation and specified in the notice of meeting given by or at the direction of the Board, (ii) brought before the meeting by or at the direction of the Board (or a committee thereof) or (iii) otherwise properly brought before the meeting by a stockholder who (A) was a stockholder of record of the Corporation (and, with respect to any beneficial owner, if different, on whose behalf such business is proposed, only if such beneficial owner was the beneficial owner of shares of the Corporation) both at the time of giving the notice provided for in this Section 2.4 and at the time of the meeting, (B) is entitled to vote at the meeting and (C) has complied with this Section 2.4 as to such business. Except for proposals properly made in accordance with Rule 14a-8 under the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder (as so amended and inclusive of such rules and regulations, the "Exchange Act"), and included in the notice of meeting given by or at the direction of the Board, the foregoing clause (iii) shall be the exclusive means for a stockholder to propose business to be brought before an annual meeting of the stockholders. Stockholders shall not be permitted to propose business to be brought before a special meeting of the stockholders, and the only matters that may be brought before a special meeting are the matters specified in the notice of meeting given by or at the direction of the person calling the meeting pursuant to Section 2.3 of these bylaws. Stockholders seeking to nominate persons for election to the Board must comply with Section 2.5 of these bylaws, and this Section 2.4 shall not be applicable to nominations except as expressly provided in Section 2.5 of these bylaws.

(b) Without qualification, for business to be properly brought before an annual meeting by a stockholder pursuant to clause (iii) of the second sentence of Section 2.4(a) of these bylaws, the stockholder must (i) provide Timely Notice (as defined below) thereof in writing and in proper form to the secretary of the Corporation and (ii) provide any updates or supplements to such notice at the times and in the forms required by this Section 2.4. To be timely, a stockholder's notice must be delivered to, or mailed and received by the Secretary at, the principal executive offices of the Corporation not less than ninety (90) days nor more than one hundred twenty (120) days prior to the first anniversary of the preceding year's annual meeting; *provided, however*, that (x) if the date of the annual meeting is more than thirty (30) days before or more than sixty (60) days after such anniversary date or (y) with respect to the first annual meeting held after the Company's initial public offering of its shares pursuant to a registration statement on Form S-1, notice by the stockholder to be timely must be so delivered, or mailed and received, not earlier than the close of business on the one hundred twentieth (120th) day prior to such annual meeting and not later than the later of the close of business on the ninetieth (90th) day prior to such annual meeting and the close of business on the tenth (10th) day following the day on which public disclosure of the date of such annual meeting was first made (such notice within such time periods, "Timely Notice"). In no event shall any adjournment or postponement of an annual meeting or the announcement thereof commence a new time period (or extend any time period) for the giving of Timely Notice as described above.

(c) To be in proper form for purposes of this Section 2.4, a stockholder's notice to the secretary of the Corporation shall set forth:

(i) As to each Proposing Person (as defined below), (A) the name and address of such Proposing Person (including, without limitation, if applicable, the name and address that appear on the Corporation's books and records) and (B) the class or series and number of shares of the Corporation that are, directly or indirectly, owned of record or beneficially owned (within the meaning of Rule 13d-3 under the Exchange Act) by such Proposing Person, except that such Proposing Person shall in all events be deemed to beneficially own any shares of any class or series of the Corporation as to which such Proposing Person has a right to acquire beneficial ownership at any time in the future (the disclosures to be made pursuant to the foregoing clauses (A) and (B) are referred to as "Stockholder Information");

(ii) As to each Proposing Person, (A) any derivative, swap or other transaction or series of transactions engaged in, directly or indirectly, by such Proposing Person, the purpose or effect of which is to give such Proposing Person economic risk similar to ownership of shares of any class or series of the Corporation, including, without limitation, due to the fact that the value of such derivative, swap or other transactions are determined by reference to the price, value or volatility of any shares of any class or series of the Corporation, or which derivative, swap or other transactions provide, directly or indirectly, the opportunity to profit from any increase in the price or value of shares of any class or series of the Corporation ("Synthetic Equity Interests"), which Synthetic Equity Interests shall be disclosed without regard to whether (x) the derivative, swap or other transactions convey any voting rights in such shares to such Proposing Person, (y) the derivative, swap or other transactions are required to be, or are capable of being, settled through delivery of such shares or (z) such Proposing Person may have entered into other transactions that hedge or mitigate the economic effect of such derivative, swap or other transactions, (B) any proxy (other than a revocable proxy or consent given in response to a solicitation made pursuant to, and in accordance with, Section 14(a) of the Exchange Act by way of a solicitation statement filed on Schedule 14A), agreement, arrangement, understanding or relationship pursuant to which such Proposing Person has or shares a right to vote any shares of any class or series of the Corporation, (C) any agreement, arrangement, understanding or relationship, including, without limitation, any repurchase or similar so-called "stock borrowing" agreement or arrangement, engaged in, directly or indirectly, by such Proposing Person, the purpose or effect of which is to mitigate loss to, reduce the economic risk (of ownership or otherwise) of shares of any class or series of the Corporation by, manage the risk of share price changes for, or increase or decrease the voting power of, such Proposing Person with respect to the shares of any class or series

of the Corporation, or which provides, directly or indirectly, the opportunity to profit from any decrease in the price or value of the shares of any class or series of the Corporation ("Short Interests"), (D) any rights to dividends on the shares of any class or series of the Corporation owned beneficially by such Proposing Person that are separated or separable from the underlying shares of the Corporation, (E) any performance related fees (other than an asset based fee) that such Proposing Person is entitled to based on any increase or decrease in the price or value of shares of any class or series of the Corporation, or any Synthetic Equity Interests or Short Interests, if any, (F)(x) if such Proposing Person is not a natural person, the identity of the natural person or persons associated with such Proposing Person responsible for the formulation of and decision to propose the business to be brought before the meeting (such person or persons, the "Responsible Person"), the manner in which such Responsible Person was selected, any fiduciary duties owed by such Responsible Person to the equity holders or other beneficiaries of such Proposing Person, the qualifications and background of such Responsible Person and any material interests or relationships of such Responsible Person that are not shared generally by any other record or beneficial holder of the shares of any class or series of the Corporation and that reasonably could have influenced the decision of such Proposing Person to propose such business to be brought before the meeting, and (y) if such Proposing Person is a natural person, the qualifications and background of such natural person and any material interests or relationships of such natural person that are not shared generally by any other record or beneficial holder of the shares of any class or series of the Corporation and that reasonably could have influenced the decision of such Proposing Person to propose such business to be brought before the meeting, (G) any significant equity interests or any Synthetic Equity Interests or Short Interests in any principal competitor of the Corporation held by such Proposing Persons, (H) any direct or indirect interest of such Proposing Person in any contract with the Corporation, any affiliate of the Corporation or any principal competitor of the Corporation (including, without limitation, in any such case, any employment agreement, collective bargaining agreement or consulting agreement), (I) any pending or threatened litigation in which such Proposing Person is a party or material participant involving the Corporation or any of its officers or directors, or any affiliate of the Corporation, (J) any material transaction occurring during the prior twelve months between such Proposing Person, on the one hand, and the Corporation, any affiliate of the Corporation or any principal competitor of the Corporation, on the other hand, (K) a summary of any material discussions regarding the business proposed to be brought before the meeting (x) between or among any of the Proposing Persons or (y) between or among any Proposing Person and any other record or beneficial holder of the shares of any class or series of the Corporation (including, without limitation, their names) and (L) any other information relating to such Proposing Person that would be required to be disclosed in a proxy statement or other filing required to

be made in connection with solicitations of proxies or consents by such Proposing Person in support of the business proposed to be brought before the meeting pursuant to Section 14(a) of the Exchange Act (the disclosures to be made pursuant to the foregoing clauses (A) through (L) are referred to as "Disclosable Interests"); *provided, however*, that Disclosable Interests shall not include any such disclosures with respect to the ordinary course business activities of any broker, dealer, commercial bank, trust company or other nominee who is a Proposing Person solely as a result of being the stockholder directed to prepare and submit the notice required by these bylaws on behalf of a beneficial owner; and

(iii) As to each item of business that the stockholder proposes to bring before the annual meeting, (A) a reasonably brief description of the business desired to be brought before the annual meeting, the reasons for conducting such business at the annual meeting and any material interest in such business of each Proposing Person, (B) the text of the proposal or business (including, without limitation, the text of any resolutions proposed for consideration and in the event that such business includes a proposal to amend the bylaws of the Corporation, the language of the proposed amendment), (C) a reasonably detailed description of all agreements, arrangements and understandings between or among any of the Proposing Persons or between or among any Proposing Person and any other person or entity (including, without limitation, their names) in connection with the proposal of such business by such stockholder, (D) a representation that the stockholder is a holder of record of stock of the Corporation entitled to vote at such meeting and intends to appear in person or by proxy at the meeting to propose such business, (E) a representation whether the Proposing Person intends or is part of a group which intends (1) to deliver a proxy statement and/or form of proxy to holders of at least the percentage of the Corporation's outstanding capital stock required to approve or adopt the proposal and/or (2) otherwise to solicit proxies or votes from stockholders in support of such proposal and (F) any other information relating to such item of business that would be required to be disclosed in a proxy statement or other filing required to be made in connection with solicitations of proxies in support of the business proposed to be brought before the meeting pursuant to Section 14(a) of the Exchange Act; *provided, however*, that the disclosures required by this paragraph (c)(iii) shall not include any disclosures with respect to any broker, dealer, commercial bank, trust company or other nominee who is a Proposing Person solely as a result of being the stockholder directed to prepare and submit the notice required by these bylaws on behalf of a beneficial owner.

(d) For purposes of this Section 2.4, the term "Proposing Person" shall mean (i) the stockholder providing the notice of business proposed to be brought before an annual meeting, (ii) the beneficial owner or beneficial owners, if different, on whose behalf the notice of the business proposed to be brought before the annual meeting is made, (iii) any affiliate or associate (each within the meaning of Rule 12b-2 under the Exchange Act for the purposes of these bylaws) of such stockholder or beneficial owner and (iv) any other person with whom such stockholder or beneficial owner (or any of their respective affiliates or associates) is Acting in Concert (as defined below).

(e) A person shall be deemed to be "Acting in Concert" with another person for purposes of these bylaws if such person knowingly acts (whether or not pursuant to an express agreement, arrangement or understanding) in concert with, or towards a common goal relating to the management, governance or control of the Corporation in parallel with, such other person where (i) each person is conscious of the other person's conduct or intent and this awareness is an element in their decision-making processes and (ii) at least one additional factor suggests that such persons intend to act in concert or in parallel, which such additional factors may include, without limitation, exchanging information (whether publicly or privately), attending meetings, conducting discussions, or making or soliciting invitations to act in concert or in parallel; ***provided***, that a person shall not be deemed to be Acting in Concert with any other person solely as a result of the solicitation or receipt of revocable proxies or consents from such other person in response to a solicitation made pursuant to, and in accordance with, the Section 14(a) of the Exchange Act by way of a proxy or consent solicitation statement filed on Schedule 14A. A person Acting in Concert with another person shall be deemed to be Acting in Concert with any third party who is also Acting in Concert with such other person.

(f) A stockholder providing notice of business proposed to be brought before an annual meeting shall further update and supplement such notice, if necessary, so that the information provided or required to be provided in such notice pursuant to this Section 2.4 shall be true and correct as of the record date for determining stockholders entitled to notice of the annual meeting and as of the date that is ten (10) business days prior to the meeting or any adjournment or postponement thereof, and such update and supplement shall be delivered to, or mailed and received by, the secretary of the Corporation at the principal executive offices of the Corporation not later than five (5) business days after the record date for determining stockholders entitled to notice of the annual meeting (in the case of the update and supplement required to be made as of the record date), and not later than eight (8) business days prior to the date for the meeting or, if practicable, any adjournment or postponement thereof (and, if not practicable, on the first practicable date prior to the date to which the meeting has been adjourned or postponed) (in the case of the update and supplement required to be made as of ten (10) business days prior to the meeting or any adjournment or postponement thereof).

(g) Notwithstanding anything in these bylaws to the contrary and except as otherwise expressly provided in any applicable rule or regulation promulgated under the Exchange Act, no business shall be conducted at an annual meeting except in accordance with this Section 2.4. The presiding officer of an annual meeting of stockholders shall have the power and duty (a) to determine that any business was not properly brought before the meeting in accordance with this Section 2.4 (including whether the stockholder or beneficial owner, if any,

on whose behalf the business proposed to be brought before the annual meeting is made, solicited (or is part of a group which solicited) or did not so solicit, as the case may be, proxies or votes in support of such stockholder's business in compliance with such stockholder's representation as required by clause (c)(iii)(E) of this Section 2.4); and (b) if any proposed business was not proposed in compliance with this Section 2.4 to declare to the meeting that any such business not properly brought before the meeting shall not be transacted.

(h) The foregoing notice requirements of this Section 2.4 shall be deemed satisfied by a stockholder with respect to business other than a nomination if the stockholder has notified the Corporation of his, her or its intention to present a proposal at an annual meeting in compliance with applicable rules and regulations promulgated under the Exchange Act and such stockholder's proposal has been included in a proxy statement that has been prepared by the Corporation to solicit proxies for such annual meeting. Nothing in this Section 2.4 shall be deemed to affect the rights of stockholders to request inclusion of proposals in the Corporation's proxy statement pursuant to Rule 14a-8 under the Exchange Act.

(i) For purposes of these bylaws, "public disclosure" shall mean disclosure in a press release reported by a national news service or in a document publicly filed by the Corporation with the Securities and Exchange Commission pursuant to Sections 13, 14 or 15(d) of the Exchange Act.

(j) Notwithstanding the foregoing provisions of this Section 2.4, unless otherwise required by law, if the stockholder (or a qualified representative of the stockholder) does not appear at the annual meeting to present proposed business, such proposed business shall not be transacted, notwithstanding that proxies in respect of such vote may have been received by the Corporation. For purposes of this Section 2.4, except as provided under Rule 14a-8 under the Exchange Act, to be considered a qualified representative of the stockholder, a person must be a duly authorized officer, manager or partner of such stockholder or must be authorized by a writing executed by such stockholder or an electronic transmission delivered by such stockholder to act for such stockholder as proxy at the annual meeting and such person must produce such writing or electronic transmission, or a reliable reproduction of the writing or electronic transmission, at the annual meeting.

(k) Notwithstanding the foregoing provisions of this Section 2.4, a stockholder shall also comply with all applicable requirements of the Exchange Act with respect to the matters set forth in this Section 2.4; provided however, that any references in these bylaws to the Exchange Act are not intended to and shall not limit any requirements applicable to proposals as to any business to be considered pursuant to this Section 2.4 (including paragraph (a)(iii) hereof), and compliance with paragraph (a)(iii) of this Section 2.4 shall be the exclusive means for a stockholder to submit business (other than, as provided in the first sentence of paragraph (h) of this Section 2.4, business brought properly under and in compliance with Rule 14a-8 of the Exchange Act, as may be amended from time to time).

2.5 ADVANCE NOTICE PROCEDURES FOR NOMINATIONS OF DIRECTORS.

(a) Nominations of any person for election to the Board at an annual meeting or at a special meeting (but, in the case of a special meeting, only if the election of directors is a matter specified in the notice of meeting given by or at the direction of the person calling such special meeting) may be made at such meeting only (i) by or at the direction of the Board or any committee thereof, or (ii) by a stockholder who (A) was a stockholder of record of the Corporation (and, with respect to any beneficial owner, if different, on whose behalf such nomination is proposed to be made, only if such beneficial owner was the beneficial owner of shares of the Corporation) both at the time of giving the notice provided for in this Section 2.5 and at the time of the meeting, (B) is entitled to vote at the meeting and (C) has complied with this Section 2.5 as to such nomination. The foregoing clause (ii) shall be the exclusive means for a stockholder to make any nomination of a person or persons for election to the Board to be considered by the stockholders at an annual meeting or special meeting.

(b) Without qualification, for a stockholder to make any nomination of a person or persons for election to the Board at an annual meeting, the stockholder must (i) provide Timely Notice (as defined in Section 2.4(b) of these bylaws) thereof in writing and in proper form to the secretary of the Corporation and (ii) provide any updates or supplements to such notice at the times and in the forms required by this Section 2.5. Notwithstanding anything in this paragraph to the contrary, in the event that the number of directors to be elected to the Board at an annual meeting is increased effective after the time period for which nominations would otherwise by due under this paragraph (b) and there is no public announcement by the Corporation naming the nominees for the additional directorships at least one hundred (100) days prior to the first anniversary of the preceding year's annual meeting, a stockholder's notice required by paragraph (b) of this Section 2.5 shall also be considered timely, but only with respect to nominees for the additional directorships, if it shall be delivered to the Secretary at the principal executive offices of the Corporation not later than the close of business on the tenth (10th) day following the day on which such public announcement is first made by the Corporation. Without qualification, if the election of directors is a matter specified in the notice of meeting given by or at the direction of the person calling such special meeting, then for a stockholder to make any nomination of a person or persons for election to such position(s) as specified in the notice of the special meeting, the stockholder must (i) provide timely notice thereof in writing and in proper form to the secretary of the Corporation at the principal executive offices of the Corporation and (ii) provide any updates or supplements to such notice at the times and in the forms required by this Section 2.5. To be timely, a stockholder's notice for nominations to be made at a special meeting must be delivered to, or mailed and received at, the principal executive offices of the Corporation not earlier than the close of business on the one hundred twentieth (120th) day prior to such special meeting and not later than the later of the close of business on the ninetieth (90th) day prior to such special meeting and the close of business on the tenth (10th) day following the day on which public disclosure (as defined in Section 2.4(i) of these bylaws) of the date of such special meeting was first made. In no event shall any adjournment or postponement of an annual meeting or special meeting or the announcement thereof commence a new time period (or extend any time period) for the giving of a stockholder's notice as described above.

(c) To be in proper form for purposes of this Section 2.5, a stockholder's notice to the secretary of the Corporation shall set forth:

(i) As to each Nominating Person (as defined below), the Stockholder Information (as defined in Section 2.4(c)(i) of these bylaws) except that for purposes of this Section 2.5, the term "Nominating Person" shall be substituted for the term "Proposing Person" in all places it appears in Section 2.4(c)(i);

(ii) As to each Nominating Person, any Disclosable Interests (as defined in Section 2.4(c)(ii), except that for purposes of this Section 2.5 the term "Nominating Person" shall be substituted for the term "Proposing Person" in all places it appears in Section 2.4(c)(ii) and the disclosure in clause (L) of Section 2.4(c)(ii) shall be made with respect to the election of directors at the meeting) *provided, however*, that Disclosable Interests shall not include any such disclosures with respect to the ordinary course business activities of any broker, dealer, commercial bank, trust company or other nominee who is a Nominating Person solely as a result of being the stockholder directed to prepare and submit the notice required by these bylaws on behalf of a beneficial owner; and;

(iii) As to each person whom a Nominating Person proposes to nominate for election as a director, (A) all information with respect to such proposed nominee that would be required to be set forth in a stockholder's notice pursuant to this Section 2.5 if such proposed nominee were a Nominating Person, (B) all information relating to such proposed nominee that is required to be disclosed in a proxy statement or other filings required to be made in connection with solicitations of proxies for election of directors in a contested election pursuant to Section 14(a) under the Exchange Act (including, without limitation, such proposed nominee's written consent to being named in the proxy statement as a nominee and to serving as a director if elected), (C) a description of all direct and indirect compensation and other material monetary agreements, arrangements and understandings during the past three (3) years, and any other material relationships, between or among any Nominating Person, on the one hand, and each proposed nominee, his or her respective affiliates and associates and any other persons with whom such proposed nominee (or any of his or her respective affiliates and associates) is Acting in Concert (as defined in Section 2.4(e) of these bylaws), on the other hand, including, without limitation, all information that would be required to be disclosed pursuant to Item 404 under Regulation S-K if such Nominating Person were the "registrant" for purposes of such rule and the proposed nominee were a director or executive officer of such registrant (the disclosures to be made pursuant to the foregoing clauses (A) through (C) are

referred to as "Nominee Information"), (D) a representation that the Nominating Person is a holder of record of stock of the Corporation entitled to vote at such meeting and intends to appear in person or by proxy at the meeting to propose such nomination, (E) a representation whether the Nominating Person intends or is part of a group which intends (1) to deliver a proxy statement and/or form of proxy to holders of at least the percentage of the Corporation's outstanding capital stock required to elect the nominee and/or (2) otherwise to solicit proxies or votes from stockholders in support of such nomination and (F) a completed and signed questionnaire, representation and agreement as provided in Section 2.5(g); and

(iv) The Corporation may require any proposed nominee to furnish such other information (A) as may reasonably be required by the Corporation to determine the eligibility of such proposed nominee to serve as an independent director of the Corporation in accordance with the Corporation's Corporate Governance Guidelines or (B) that could be material to a reasonable stockholder's understanding of the independence or lack of independence of such proposed nominee.

(d) For purposes of this Section 2.5, the term "Nominating Person" shall mean (i)the stockholder providing the notice of the nomination proposed to be made at the meeting,

(ii)the beneficial owner or beneficial owners, if different, on whose behalf the notice of the nomination proposed to be made at the meeting is made, (iii) any affiliate or associate of such stockholder or beneficial owner and (iv) any other person with whom such stockholder or such beneficial owner (or any of their respective affiliates or associates) is Acting in Concert.

(e) A stockholder providing notice of any nomination proposed to be made at a meeting shall further update and supplement such notice, if necessary, so that the information provided or required to be provided in such notice pursuant to this Section 2.5 shall be true and correct as of the record date for determining stockholders entitled to notice of the meeting and as of the date that is ten (10) business days prior to the meeting or any adjournment or postponement thereof, and such update and supplement shall be delivered to, or mailed and received by, the secretary of the Corporation at the principal executive offices of the Corporation not later than five (5) business days after the record date for determining stockholders entitled to notice of the meeting (in the case of the update and supplement required to be made as of the record date), and not later than eight (8) business days prior to the date for the meeting or, if practicable, any adjournment or postponement thereof (and, if not practicable, on the first practicable date prior to the date to which the meeting has been adjourned or postponed) (in the case of the update and supplement required to be made as of ten (10) business days prior to the meeting or any adjournment or postponement thereof).

(f) Notwithstanding anything in these bylaws to the contrary, no person shall be eligible for election as a director of the Corporation unless nominated in accordance with this Section 2.5, except as otherwise expressly provided in any applicable rule or regulation promulgated under the Exchange Act. The presiding officer at any meeting of stockholders shall have the power and duty to (a) determine that a nomination was not properly made in accordance with this Section 2.5 (including whether the stockholder or beneficial owner, if any, on whose behalf the nomination was made, solicited or is part of a group which solicited) or did not so solicit, as the case may be, proxies or votes in support of such stockholder's nomination in compliance with such stockholder's representation as required by clause (c)(iii)(E) of this Section 2.5); and (b) if any proposed nomination was not made in compliance with this Section 2.5 to declare such determination to the meeting that the defective nomination shall be disregarded.

(g) To be eligible to be a nominee for election as a director of the Corporation, the proposed nominee must deliver (in accordance with the time periods prescribed for delivery of notice under this Section 2.5) to the secretary of the Corporation at the principal executive offices of the Corporation a written questionnaire with respect to the background and qualification of such proposed nominee (which questionnaire shall be provided by the secretary upon written request) and a written representation and agreement (in form provided by the secretary upon written request) that such proposed nominee (i) is not and will not become a party to (A) any agreement, arrangement or understanding with, and has not given any commitment or assurance to, any person or entity as to how such proposed nominee, if elected as a director of the Corporation, will act or vote on any issue or question (a "Voting Commitment") that has not been disclosed to the Corporation or (B) any Voting Commitment that could limit or interfere with such proposed nominee's ability to comply, if elected as a director of the Corporation, with such proposed nominee's fiduciary duties under applicable law, (ii) is not, and will not become a party to, any agreement, arrangement or understanding with any person or entity other than the Corporation with respect to any direct or indirect compensation, reimbursement or indemnification in connection with candidacy, service or action as a director that has not been disclosed to the Corporation and (iii) in such proposed nominee's individual capacity and on behalf of the stockholder (and the beneficial owner, if different, on whose behalf the nomination is made) would be in compliance, if elected as a director of the Corporation, and will comply with applicable publicly disclosed corporate governance, conflict of interest, confidentiality and stock ownership and trading policies and guidelines of the Corporation.

(h) In addition to the requirements of this Section 2.5 with respect to any nomination proposed to be made at a meeting, each Nominating Person shall comply with all applicable requirements of the Exchange Act with respect to any such nominations.

(i) Notwithstanding the foregoing provisions of this Section 2.5, unless otherwise required by law, if the stockholder (or a qualified representative of the stockholder) does not appear at the meeting to present the proposed nomination, such proposed nomination shall not be considered, notwithstanding that proxies in respect of such vote may have been received by the Corporation. For purposes of this Section 2.5, to be considered a qualified representative of the stockholder, a person must be a duly authorized officer, manager or partner of such stockholder or must be authorized by a writing executed by such stockholder or an electronic transmission delivered by such stockholder to act for such stockholder as proxy at the meeting of stockholders and such person must produce such writing or electronic transmission, or a reliable reproduction of the writing or electronic transmission, at the meeting.

2.6 NOTICE OF STOCKHOLDERS' MEETINGS.

Unless otherwise provided by law, the certificate of incorporation or these bylaws, the notice of any meeting of stockholders shall be given in accordance with either Section 2.7 or Section 8.1 of these bylaws not less than ten (10) nor more than sixty (60) days before the date of the meeting to each stockholder entitled to vote at such meeting as of the record date for determining the stockholders entitled to notice of the meeting. The notice shall specify the place, if any, date and hour of the meeting, the record date for determining the stockholders entitled to vote at the meeting (if such date is different from the record date for stockholders entitled to notice of the meeting), the means of remote communication, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at such meeting, and, in the case of a special meeting, the purpose or purposes for which the meeting is called.

2.7 MANNER OF GIVING NOTICE; AFFIDAVIT OF NOTICE. Notice of any meeting of stockholders shall be deemed given:

(a) if mailed, when deposited in the United States mail, postage prepaid, directed to the stockholder at such stockholder's address as it appears on the Corporation's records; or

(b) if electronically transmitted, as provided in Section 8.1 of these bylaws.

An affidavit of the secretary or an assistant secretary of the Corporation or of the transfer agent or any other agent of the Corporation that the notice has been given by mail or by a form of electronic transmission, as applicable, shall, in the absence of fraud, be prima facie evidence of the facts stated therein.

2.8 QUORUM. Unless otherwise provided by law, the certificate of incorporation or these bylaws, the holders of a majority in voting power of the capital stock issued and outstanding and entitled to vote, present in person, or by remote communication, if applicable, or represented by proxy, shall constitute a quorum for the transaction of business at all meetings of the stockholders. A quorum, once established at a meeting, shall not be broken by the withdrawal of enough votes to leave less than a quorum. If, however, a quorum is not present or represented at any meeting of the stockholders, then either (a) the chairperson of the meeting or (b) a majority in voting power of the stockholders entitled to vote thereon, present in person, or by remote communication, if applicable, or represented by proxy, shall have power to adjourn the meeting from time to time in the manner provided in Section 2.9 of these bylaws until a quorum is present or represented. At such adjourned meeting at which a quorum is present or represented, any business may be transacted that might have been transacted at the meeting as originally noticed.

2.9 ADJOURNED MEETING; NOTICE. When a meeting is adjourned to another time or place, unless these bylaws otherwise require, notice need not be given of the adjourned meeting if the time, place, if any, thereof, and the means of remote communications, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at such adjourned meeting are announced at the meeting at which the adjournment is taken. At the adjourned meeting, the Corporation may transact any business which might have been transacted at the original meeting. If the adjournment is for more than thirty (30) days, or if after the adjournment a new record date for determining the stockholders entitled to vote is fixed for the adjourned meeting, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the adjourned meeting as of the record date for determining the stockholders entitled to notice of the adjourned meeting.

2.10 CONDUCT OF BUSINESS. The date and time of the opening and the closing of the polls for each matter upon which the stockholders will vote at a meeting shall be announced at the meeting by the person presiding over the meeting. The Board may adopt by resolution such rules and regulations for the conduct of the meeting of stockholders as it shall deem appropriate. Except to the extent inconsistent with such rules and regulations as adopted by the Board, the person presiding over any meeting of stockholders shall have the right and authority to convene and (for any or no reason) to recess and/or adjourn the meeting, to prescribe such rules, regulations and procedures (which need not be in writing) and to do all such acts as, in the judgment of such presiding person, are appropriate for the proper conduct of the meeting. Such rules, regulations or procedures, whether adopted by the Board or prescribed by the presiding person of the meeting, may include, without limitation, the following: (a) the establishment of an agenda or order of business for the meeting; (b) rules and procedures for maintaining order at the meeting and the safety of those present (including, without limitation, rules and procedures for removal of disruptive persons from the meeting); (c) limitations on attendance at or participation in the meeting to stockholders entitled to vote at the meeting, their duly authorized and constituted proxies or such other persons as the presiding person of the meeting shall determine; (d)restrictions on entry to the meeting after the time fixed for the commencement thereof; and (e)limitations on the time allotted to questions or comments by participants. The presiding person at any meeting of stockholders, in addition to making any other determinations that may be appropriate to the conduct of the meeting (including, without limitation, determinations with respect to the administration and/or interpretation of any of the rules, regulations or procedures of the meeting, whether adopted by the Board or prescribed by the person presiding over the meeting), shall, if the facts warrant, determine and declare to the meeting that a matter or business was not properly brought before the meeting and if such presiding person should so determine, such presiding person shall so declare to the meeting and any such matter or business not properly brought before the meeting shall not be transacted or considered. Unless and to the extent determined by the Board or the person presiding over the meeting, meetings of stockholders shall not be required to be held in accordance with the rules of parliamentary procedure.

2.11 VOTING. The stockholders entitled to vote at any meeting of stockholders shall be determined in accordance with the provisions of Section 2.13 of these bylaws, subject to Section 217 (relating to voting rights of fiduciaries, pledgors and joint owners of stock) and Section 218 (relating to voting trusts and other voting agreements) of the DGCL.

Except as may be otherwise provided in the certificate of incorporation or these bylaws, each stockholder shall be entitled to one (1) vote for each share of capital stock held by such stockholder.

At all duly called or convened meetings of stockholders, at which a quorum is present, for the election of directors, a plurality of the votes cast shall be sufficient to elect a director. All other elections and questions presented to the stockholders at a duly called or convened meeting, at which a quorum is present, shall, unless a different or minimum vote is required by the certificate of incorporation, these bylaws, the rules or regulations of any stock exchange applicable to the Corporation, or any law or regulation applicable to the Corporation or its securities, in which case such different or minimum vote shall be the applicable vote on the matter, be decided by the affirmative vote of the holders of a majority in voting power of the votes cast affirmatively or negatively (excluding abstentions) at the meeting by the holders entitled to vote thereon.

2.12 STOCKHOLDER ACTION BY WRITTEN CONSENT WITHOUT A MEETING. Any action required or permitted to be taken by the stockholders of the Corporation must be effected at a duly called annual or special meeting of stockholders of the Corporation and may not be effected by any consent in writing by such stockholders.

2.13 RECORD DATE FOR STOCKHOLDER NOTICE; VOTING.

In order that the Corporation may determine the stockholders entitled to notice of any meeting of stockholders or any adjournment thereof, the Board may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the Board, and which record date shall, unless otherwise required by law, not be more than sixty (60) nor less than ten (10) days before the date of such meeting. If the Board so fixes a date, such date shall also be the record date for determining the stockholders entitled to vote at such meeting unless the Board determines, at the time it fixes such record date, that a later date on or before the date of the meeting shall be the date for making such determination. If no record date is fixed by the Board, the record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be at the close of business on the day next preceding the day on which notice is given, or, if notice is waived, at the close of business on the day next preceding the day on which the meeting is held. A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting; *provided, however*, that the Board may fix a new record date for determination of stockholders entitled to vote at the adjourned meeting, and in such case shall also fix as the record date for stockholders entitled to notice of such adjourned meeting the same or an earlier date as that fixed for determination of stockholders entitled to vote in accordance herewith at the adjourned meeting.

In order that the Corporation may determine the stockholders entitled to receive payment of any dividend or other distribution or allotment of any rights, or entitled to exercise any rights in respect of any change, conversion or exchange of stock or for the purpose of any other lawful action, the Board may fix a record date, which shall not be more than sixty (60) days prior to such other action. If no such record date is fixed, the record date for determining stockholders for any such purpose shall be at the close of business on the day on which the Board adopts the resolution relating thereto.

2.14 PROXIES. Each stockholder entitled to vote at a meeting of stockholders may authorize another person or persons to act for such stockholder by proxy, but no such proxy shall be voted or acted upon after three (3) years from its date, unless the proxy provides for a longer period. The revocability of a proxy that states on its face that it is irrevocable shall be governed by the provisions of Section 212 of the DGCL. A proxy may be in the form of a telegram, cablegram or other means of electronic transmission which sets forth or is submitted with information from which it can be determined that the telegram, cablegram or other means of electronic transmission was authorized by the stockholder.

2.15 LIST OF STOCKHOLDERS ENTITLED TO VOTE. The officer who has charge of the stock ledger of the Corporation shall prepare and make, at least ten (10) days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting (*provided, however*, if the record date for determining the stockholders entitled to vote is less than ten (10) days before the date of the meeting, the list shall reflect the stockholders entitled to vote as of the tenth day before the date of the meeting), arranged in alphabetical order, and showing the address of each stockholder and the number of shares registered in the name of each stockholder. The Corporation shall not be required to include electronic mail addresses or other electronic contact information on such list. Such list shall be open to the examination of any stockholder, for any purpose germane to the meeting for a period of at least ten (10) days prior to the meeting: (a) on a reasonably accessible electronic network, provided that the information required to gain access to such list is provided with the notice of the meeting, or (b) during ordinary business hours, at the Corporation's principal executive office. In the event that the Corporation determines to make the list available on an electronic network, the Corporation may take reasonable steps to ensure that such information is available only to stockholders of the Corporation. If the meeting is to be held at a place, then the list shall be produced and kept at the time and place of the meeting during the whole time thereof, and may be inspected by any stockholder who is present. If the meeting is to be held solely by means of remote communication, then the list shall also be open to the examination of any stockholder during the whole time of the meeting on a reasonably accessible electronic network, and the information required to access such list shall be provided with the notice of the meeting. Except as otherwise provided by law, the stock ledger shall be the only evidence as to the identity of the stockholders entitled to vote in person or by proxy and the number of shares held by each of them, and as to the stockholders entitled to examine the list of stockholders.

2.16 POSTPONEMENT, ADJOURNMENT AND CANCELLATION OF MEETING.

Any previously scheduled annual or special meeting of the stockholders may be postponed or adjourned, and any previously scheduled annual or special meeting of the stockholders may be canceled, by resolution of the Board.

2.17 INSPECTORS OF ELECTION.

Before any meeting of stockholders, the Board shall appoint an inspector or inspectors of election to act at the meeting or its adjournment or postponement and make a written report thereof. The number of inspectors shall be either one (1) or three (3). If any person appointed as inspector fails to appear or fails or refuses to act, then the chairperson of the meeting may, and upon the request of any stockholder or a stockholder's proxy shall, appoint a person to fill that vacancy. Unless otherwise required by law, inspectors may be officers, employees or agents of the Corporation. Such inspectors shall have the duties prescribed by law. Each inspector, before entering upon the discharge of his or her duties, shall take and sign an oath to execute faithfully the duties of inspector with strict impartiality and according to the best of his or her ability. If there are three (3) inspectors of election, the decision, act or certificate of a majority is effective in all respects as the decision, act or certificate of all. Any report or certificate made by the inspectors of election is prima facie evidence of the facts stated therein.

ARTICLE III - DIRECTORS

3.1 POWERS. Subject to the provisions of the DGCL and any limitations in the certificate of incorporation, the business and affairs of the Corporation shall be managed and all corporate powers shall be exercised by or under the direction of the Board.

3.2 NUMBER OF DIRECTORS. The authorized number of directors shall be determined from time to time by resolution of the Board, provided the Board shall consist of at least one (1) member. No reduction of the authorized number of directors shall have the effect of removing any director before that director's term of office expires.

3.3 ELECTION, QUALIFICATION AND TERM OF OFFICE OF DIRECTORS. Except as provided in Section 3.4 of these bylaws, each director, including, without limitation, a director elected to fill a vacancy, shall hold office until the expiration of the term for which elected and until such director's successor is elected and qualified or until such director's earlier death, resignation or removal. Directors need not be stockholders unless so required by the certificate of incorporation or these bylaws. The Corporation may also have, at the discretion of the Board, a chairperson of the Board and a vice chairperson of the Board. The certificate of incorporation or these bylaws may prescribe other qualifications for directors.

3.4 RESIGNATION AND VACANCIES. Any director may resign at any time upon notice given in writing or by electronic transmission to the chairperson of the Board or the Corporation's chief executive officer, president or secretary. When one or more directors so resigns and the resignation is effective at a future date, a majority of the directors then in office, including those who have so resigned, shall have power to fill such vacancy or vacancies, the vote thereon to take effect when such resignation or resignations shall become effective, and each director so chosen shall hold office as provided in this section in the filling of other vacancies.

Unless otherwise provided in the certificate of incorporation or these bylaws, vacancies and newly created directorships resulting from any increase in the authorized number of directors shall, unless the Board determines by resolution that any such vacancies or newly created directorships shall be filled by stockholders, be filled only by a majority of the directors then in office, although less than a quorum, or by a sole remaining director. Any director elected in accordance with the preceding sentence shall hold office for the remainder of the full term of the director for which the vacancy was created or occurred and until such director's successor shall have been elected and qualified. A vacancy in the Board shall be deemed to exist under these bylaws in the case of the death, removal or resignation of any director.

3.5 PLACE OF MEETINGS; MEETINGS BY TELEPHONE. The Board may hold meetings, both regular and special, either within or outside the State of Delaware.

Unless otherwise restricted by the certificate of incorporation or these bylaws, members of the Board, or any committee designated by the Board, may participate in a meeting of the Board, or any committee, by means of conference telephone or other communications equipment by means of which all persons participating in the meeting can hear each other, and such participation in a meeting pursuant to this bylaw shall constitute presence in person at the meeting.

3.6 REGULAR MEETINGS. Regular meetings of the Board may be held without notice at such time and at such place as shall from time to time be determined by the Board; ***provided*** that any director who is absent when such determination is made shall be given notice of the determination. A regular meeting of the Board may be held without notice immediately after and at the same place as the annual meeting of stockholders.

3.7 SPECIAL MEETINGS; NOTICE. Special meetings of the Board for any purpose or purposes may be called at any time by the chairperson of the Board, the chief executive officer, the president, the secretary or a majority of the authorized number of directors.

Notice of the time and place of special meetings shall be:

(a) delivered personally by hand, by courier or by telephone;

(b) sent by United States first-class mail, postage prepaid;

(c) sent by facsimile; or

(d) sent by electronic mail, electronic transmission or other similar means,

directed to each director at that director's address, telephone number, facsimile number or electronic mail or other electronic address, as the case may be, as shown on the Corporation's records.

If the notice is (a) delivered personally by hand, by courier or by telephone, (b) sent by facsimile or (c) sent by electronic mail or electronic transmission, it shall be delivered or sent at least twenty-four (24) hours before the time of the holding of the meeting. If the notice is sent by United States mail, it shall be deposited in the United States mail at least four (4) days before the time of the holding of the meeting. Any oral notice may be communicated to the director. The notice need not specify the place of the meeting (if the meeting is to be held at the Corporation's principal executive office) nor the purpose of the meeting.

3.8 QUORUM. The greater of (a) a majority of the directors at any time in office and (b) one-third of the number of directors established by the Board pursuant to Section 3.2 of these bylaws shall constitute a quorum of the Board for the transaction of business. The vote of a majority of the directors present at any meeting at which a quorum is present shall be the act of the Board, except as may be otherwise specifically provided by statute, the certificate of incorporation or these bylaws. If a quorum is not present at any meeting of the Board, then the directors present thereat may adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum is present.

3.9 BOARD ACTION BY CONSENT WITHOUT A MEETING. Unless otherwise restricted by the certificate of incorporation or these bylaws, any action required or permitted to be taken at any meeting of the Board, or of any committee thereof, may be taken without a meeting if all members of the Board or committee, as the case may be, consent thereto in writing or by electronic transmission and the writing or writings or electronic transmission or transmissions are filed with the minutes of proceedings of the Board or committee. Such filing shall be in paper form if the minutes are maintained in paper form and shall be in electronic form if the minutes are maintained in electronic form.

3.10 FEES AND COMPENSATION OF DIRECTORS. Unless otherwise restricted by the certificate of incorporation or these bylaws, the Board shall have the authority to fix the compensation of directors.

3.11 REMOVAL OF DIRECTORS. Subject to the rights of the holders of the shares of any series of Preferred Stock, the Board or any individual director may be removed from office only for cause and only by the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock of the Corporation entitled to vote thereon.

ARTICLE IV - COMMITTEES

4.1 COMMITTEES OF DIRECTORS. The Board may designate one (1) or more committees, each committee to consist of one (1) or more of the directors of the Corporation. The Board may designate one (1) or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee. In the absence or disqualification of a member of a committee, the member or members thereof present at any meeting and not disqualified from voting, whether or not such member or members constitute a quorum, may unanimously appoint another member of the Board to act at the meeting in the place of any such absent or disqualified member. Any such committee, to the extent provided in the resolution of the Board or in these bylaws, shall have and may exercise all the powers and authority of the Board in the management of the business and affairs of the Corporation, and may authorize the seal of the Corporation to be affixed to all papers that may require it; but no such committee shall have the power or authority to (a) approve or adopt, or recommend to the stockholders, any action or matter (other than the election or removal of directors) expressly required by the DGCL to be submitted to stockholders for approval, or (b) adopt, amend or repeal any bylaw of the Corporation.

4.2 COMMITTEE MINUTES. Each committee shall keep regular minutes of its meetings and report the same to the Board when required.

4.3 MEETINGS AND ACTION OF COMMITTEES. Meetings and actions of committees shall be governed by, and held and taken in accordance with, the provisions of:

(a) Section 3.5 of these bylaws (place of meetings and meetings by telephone);

(b) Section 3.6 of these bylaws (regular meetings);

(c) Section 3.7 of these bylaws (special meetings and notice);

(d) Section 3.8 of these bylaws (quorum);

(e) Section 7.12 of these bylaws (waiver of notice); and

(f) Section 3.9 of these bylaws (action without a meeting),

with such changes in the context of those bylaws as are necessary to substitute the committee and its members for the Board and its members. *However*:

(i) the time of regular meetings of committees may be determined either by resolution of the Board or by resolution of the committee;

(ii) special meetings of committees may also be called by resolution of the Board; and

(iii) notice of special meetings of committees shall also be given to all alternate members, who shall have the right to attend all meetings of the committee. The Board may adopt rules for the governance of any committee not inconsistent with the provisions (or any part thereof) of these bylaws.

ARTICLE V - OFFICERS

5.1 OFFICERS. The officers of the Corporation shall be a president and a secretary. The Corporation may also have, at the discretion of the Board, a chief executive officer, a chief financial officer or treasurer, one (1) or more vice presidents, one (1) or more assistant vice presidents, one (1) or more assistant treasurers, one (1) or more assistant secretaries, and any such other officers as may be appointed in accordance with the provisions of these bylaws. Any number of offices may be held by the same person.

5.2 APPOINTMENT OF OFFICERS. The Board shall appoint the officers of the Corporation, except such officers as may be appointed in accordance with the provisions of Section 5.3 of these bylaws, subject to the rights, if any, of an officer under any contract of employment.

5.3 SUBORDINATE OFFICERS. The Board may appoint, or empower the chief executive officer or, in the absence of a chief executive officer, the president, to appoint, such other officers and agents as the business of the Corporation may require. Each of such officers shall hold office for such period, as is provided in these bylaws or as the Board may from time to time determine.

5.4 REMOVAL AND RESIGNATION OF OFFICERS. Subject to the rights, if any, of an officer under any contract of employment, any officer may be removed, either with or without cause, by the Board at any regular or special meeting of the Board or, except in the case of an officer chosen by the Board, by any officer upon whom such power of removal may be conferred by the Board.

Any officer may resign at any time by giving written notice to the Corporation. Any resignation shall take effect at the date of the receipt of that notice or at any later time specified in that notice. Unless otherwise specified in the notice of resignation, the acceptance of the resignation shall not be necessary to make it effective. Any resignation is without prejudice to the rights, if any, of the Corporation under any contract to which the officer is a party.

5.5 VACANCIES IN OFFICES. Any vacancy occurring in any office of the Corporation shall be filled by the Board or as provided in Section 5.3 of these bylaws.

5.6 REPRESENTATION OF SHARES OF OTHER ENTITIES. The chairperson of the Board, the president, any vice president, the treasurer, the secretary or assistant secretary of this Corporation, or any other person authorized by the Board or the president or a vice president, is authorized to vote, represent and exercise on behalf of this Corporation all rights incident to any and all securities of any other entity or entities standing in the name of this Corporation. The authority granted herein may be exercised either by such person directly or by any other person authorized to do so by proxy or power of attorney duly executed by such person having the authority.

5.7 AUTHORITY AND DUTIES OF OFFICERS. All officers of the Corporation shall respectively have such authority and perform such duties in the management of the business of the Corporation as may be designated from time to time by the Board and, to the extent not so provided, as generally pertain to their respective offices, subject to the control of the Board.

ARTICLE VI - RECORDS AND REPORTS

6.1 MAINTENANCE OF RECORDS. Subject to applicable law, the Corporation shall, either at its principal executive office or at such place or places as designated by the Board, keep a record of its stockholders listing their names and addresses and the number and class of shares held by each stockholder, a copy of these bylaws as amended to date, accounting books and other records.

ARTICLE VII - GENERAL MATTERS

7.1 EXECUTION OF CORPORATE CONTRACTS AND INSTRUMENTS. The Board, except as otherwise provided in these bylaws, may authorize any officer or officers, or agent or agents, to enter into any contract or execute any instrument in the name of and on behalf of the Corporation; such authority may be general or confined to specific instances. Unless so authorized or ratified by the Board or within the agency power of an officer, no officer, agent or employee shall have any power or authority to bind the Corporation by any contract or engagement or to pledge its credit or to render it liable for any purpose or for any amount.

7.2 STOCK CERTIFICATES; PARTLY PAID SHARES. The shares of the Corporation shall be represented by certificates provided that the Board may provide by resolution or resolutions that some or all of any or all classes or series of stock shall be uncertificated shares. Certificates for the shares of stock, if any, shall be in such form as is consistent with the certificate of incorporation and applicable law. Every holder of stock represented by a certificate shall be entitled to have a certificate signed by, or in the name of the Corporation by the chairperson or vice-chairperson of the Board, or the president or vice- president, and by the treasurer or an assistant treasurer, or the secretary or an assistant secretary of the Corporation representing the number of shares registered in certificate form. Any or all of the signatures on the certificate may be a facsimile. In case any officer, transfer agent or registrar who has signed or whose facsimile signature has been placed upon a certificate has ceased to be such officer, transfer agent or registrar before such certificate is issued, it may be issued by the Corporation with the same effect as if he were such officer, transfer agent or registrar at the date of issue.

The Corporation may issue the whole or any part of its shares as partly paid and subject to call for the remainder of the consideration to be paid therefor. Upon the face or back of each stock certificate issued to represent any such partly paid shares, or upon the books and records of the Corporation in the case of uncertificated partly paid shares, the total amount of the consideration to be paid therefor and the amount paid thereon shall be stated. Upon the declaration of any dividend on fully paid shares, the Corporation shall declare a dividend upon partly paid shares of the same class, but only upon the basis of the percentage of the consideration actually paid thereon.

7.3 MULTIPLES CLASSES OR SERIES OF STOCK. If the Corporation is authorized to issue more than one class of stock or more than one series of any class, then the powers, the designations, the preferences and the relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights shall be set forth in full or summarized on the face or back of the certificate that the Corporation shall issue to represent such class or series of stock; ***provided***, ***however***, that, except as otherwise provided in Section 202 of the DGCL, in lieu of the foregoing requirements, there may be set forth on the face or back of the certificate that the Corporation shall issue to represent such class or series of stock a statement that the Corporation will furnish without charge to each stockholder who so requests the powers, the designations, the preferences and the relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights. Within a reasonable time after the issuance or transfer or uncertificated stock, the Corporation shall send to the registered owner thereof a written notice containing the information required to be set forth or stated on certificates pursuant to the DGCL or a statement that the Corporation will furnish without charge to each stockholder who so requests the powers, designations, preferences and relative participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights.

7.4 LOST CERTIFICATES. Except as provided in this Section 7.4, no new certificates for shares shall be issued to replace a previously issued certificate unless the latter is surrendered to the Corporation in accordance with applicable law. The Corporation may issue a new certificate of stock or uncertificated shares in the place of any certificate theretofore issued by it, alleged to have been lost, stolen or destroyed, and the Corporation may require the owner of the lost, stolen or destroyed certificate, or such owner's legal representative, to give the Corporation a bond sufficient to indemnify it against any claim that may be made against it on account of the alleged loss, theft or destruction of any such certificate or the issuance of such new certificate or uncertificated shares.

7.5 CONSTRUCTION; DEFINITIONS. Unless the context requires otherwise, the general provisions, rules of construction and definitions in the DGCL shall govern the construction of these bylaws. Without limiting the generality of this provision, the singular number includes the plural, the plural number includes the singular, and the term "person" includes both a corporation and a natural person.

7.6 DIVIDENDS. The Board, subject to any restrictions contained in either (a) the DGCL or (b) the certificate of incorporation, may declare and pay dividends upon the shares of its capital stock. Dividends may be paid in cash, in property or in shares of the Corporation's capital stock.

The Board may set apart out of any of the funds of the Corporation available for dividends a reserve or reserves for any proper purpose and may abolish any such reserve. Such purposes shall include but not be limited to equalizing dividends, repairing or maintaining any property of the Corporation, and meeting contingencies.

7.7 FISCAL YEAR. The fiscal year of the Corporation shall be fixed by resolution of the Board and may be changed by the Board.

7.8 SEAL. The Corporation may adopt a corporate seal, which shall be adopted and which may be altered by the Board. The Corporation may use the corporate seal by causing it or a facsimile thereof to be impressed or affixed or in any other manner reproduced.

7.9 TRANSFER OF STOCK. Shares of the Corporation shall be transferable in the manner prescribed by law and in these bylaws. Shares of stock of the Corporation shall be transferred on the books of the Corporation only by the holder of record thereof or by such holder's attorney duly authorized in writing, upon surrender to the Corporation of the certificate or certificates representing such shares endorsed by the appropriate person or persons (or by delivery of duly executed instructions with respect to uncertificated shares), with such evidence of the authenticity of such endorsement or execution, transfer, authorization and other matters as the Corporation may reasonably require, and accompanied by all necessary stock transfer stamps. To the fullest extent permitted by law, no transfer of stock shall be valid as against the Corporation for any purpose until it shall have been entered in the stock records of the Corporation by an entry showing the names of the persons from and to whom it was transferred.

7.10 STOCK TRANSFER AGREEMENTS. The Corporation shall have power to enter into and perform any agreement with any number of stockholders of any one or more classes of stock of the Corporation to restrict the transfer of shares of stock of the Corporation of any one or more classes owned by such stockholders in any manner not prohibited by the DGCL.

7.11 REGISTERED STOCKHOLDERS. The Corporation, to the fullest extent permitted by law,:

(a) shall be entitled to recognize the exclusive right of a person registered on its books as the owner of shares to receive dividends and to vote as such owner;

(b) shall be entitled to hold liable for calls and assessments the person registered on its books as the owner of shares; and

(c) shall not be bound to recognize any equitable or other claim to or interest in such share or shares on the part of another person, whether or not it shall have express or other notice thereof, except as otherwise provided by the laws of Delaware.

7.12 WAIVER OF NOTICE. Whenever notice is required to be given under any provision of the DGCL, the certificate of incorporation or these bylaws, a written waiver, signed by the person entitled to notice, or a waiver by electronic transmission by the person entitled to notice, whether before or after the time of the event for which notice is to be given, shall be deemed equivalent to notice. Attendance of a person at a meeting shall constitute a waiver of notice of such meeting, except when the person attends a meeting for the express purpose of

objecting at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Neither the business to be transacted at, nor the purpose of, any regular or special meeting of the stockholders need be specified in any written waiver of notice or any waiver by electronic transmission unless so required by the certificate of incorporation or these bylaws.

7.13 INSIDER PARTICIPATION IN PRIVATE PLACEMENTS. The Corporation may, at times, choose to issue stock and/or other securities by means of a private placement rather than a public offering. The Corporation's directors and officers may participate as investors in the Corporation's private placement transactions, provided that their participation is expressly authorized by the Board, or any standing or special committee of the Board designated and empowered for such purpose. The Board, or relevant committee, shall review the proposed investment to ensure that it is consistent with the Corporation's Corporate Governance Guidelines and in the best interests of the Corporation and its stockholders.

ARTICLE VIII - NOTICE BY ELECTRONIC TRANSMISSION

8.1 NOTICE BY ELECTRONIC TRANSMISSION. Without limiting the manner by which notice otherwise may be given effectively to stockholders pursuant to the DGCL, the certificate of incorporation or these bylaws, any notice to stockholders given by the Corporation under any provision of the DGCL, the certificate of incorporation or these bylaws shall be effective if given by a form of electronic transmission consented to by the stockholder to whom the notice is given. Any such consent shall be revocable by the stockholder by written notice to the Corporation. Any such consent shall be deemed revoked if:

(a) the Corporation is unable to deliver by electronic transmission two (2) consecutive notices given by the Corporation in accordance with such consent; and

(b) such inability becomes known to the secretary or an assistant secretary of the Corporation or to the transfer agent, or other person responsible for the giving of notice.

However, the inadvertent failure to treat such inability as a revocation shall not invalidate any meeting or other action.

Any notice given pursuant to the preceding paragraph shall be deemed given:

(a) if by facsimile telecommunication, when directed to a number at which the stockholder has consented to receive notice;

(b) if by electronic mail, when directed to an electronic mail address at which the stockholder has consented to receive notice;

(c) if by a posting on an electronic network together with separate notice to the stockholder of such specific posting, upon the later of (i) such posting and (ii) the giving of such separate notice; and

(d) if by any other form of electronic transmission, when directed to the stockholder.

An affidavit of the secretary or an assistant secretary of the Corporation or of the transfer agent or other agent of the Corporation that the notice has been given by a form of electronic transmission shall, in the absence of fraud, be prima facie evidence of the facts stated therein.

8.2 DEFINITION OF ELECTRONIC TRANSMISSION. For the purposes of these bylaws, an "electronic transmission" means any form of communication, not directly involving the physical transmission of paper, that creates a record that may be retained, retrieved and reviewed by a recipient thereof, and that may be directly reproduced in paper form by such a recipient through an automated process.

ARTICLE IX - INDEMNIFICATION AND ADVANCEMENT

9.1 ACTIONS, SUITS AND PROCEEDINGS OTHER THAN BY OR IN THE RIGHT OF THE CORPORATION.

The Corporation shall indemnify each person who was or is a party or threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the Corporation) by reason of the fact that he or she is or was, or has agreed to become, a director or officer of the Corporation, or, while a director or officer of the Corporation, is or was serving, or has agreed to serve, at the request of the Corporation, as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (including, without limitation, any employee benefit plan) (all such persons being referred to hereafter as an "Indemnitee"), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including, without limitation, attorneys' fees), liabilities, losses, judgments, fines (including, without limitation, excise taxes and penalties arising under the Employee Retirement Income Security Act of 1974), and amounts paid in settlement actually and reasonably incurred by or on behalf of Indemnitee in connection with such action, suit or proceeding and any appeal therefrom, if Indemnitee acted in good faith and in a manner which Indemnitee reasonably believed to be in, or not opposed to, the best interests of the Corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful. The termination of any action, suit or proceeding by judgment, order, settlement, conviction or upon a plea of nolo contendere or its equivalent, shall not, of itself, create a presumption that Indemnitee did not act in good faith and in a manner which Indemnitee reasonably believed to be in, or not opposed to, the best interests of the Corporation, and, with respect to any criminal action or proceeding, had reasonable cause to believe that his or her conduct was unlawful.

9.2 ACTIONS OR SUITS BY OR IN THE RIGHT OF THE CORPORATION.

The Corporation shall indemnify any Indemnitee who was or is a party to or threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the Corporation to procure a judgment in its favor by reason of the fact that Indemnitee is or was, or has agreed to become, a director or officer of the Corporation, or, while a director or officer of the Corporation, is or was serving, or has agreed to serve, at the request of the Corporation, as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (including, without limitation, any employee benefit plan), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including, without limitation, attorneys' fees) actually and reasonably incurred by or on behalf of Indemnitee in connection with such action, suit or proceeding and any appeal therefrom, if Indemnitee acted in good faith and in a manner which Indemnitee reasonably believed to be in, or not opposed to, the best interests of the Corporation, except that no indemnification shall be made under this Section 9.2 in respect of any claim, issue or matter as to which Indemnitee shall have been adjudged to be liable to the Corporation, unless, and only to the extent, that the Court of Chancery of Delaware or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of such liability but in view of all the circumstances of the case, Indemnitee is fairly and reasonably entitled to indemnity for such expenses (including, without limitation, attorneys' fees) which the Court of Chancery of Delaware or such other court shall deem proper.

9.3 INDEMNIFICATION FOR EXPENSES OF SUCCESSFUL PARTY.

Notwithstanding any other provisions of this Article IX, to the extent that an Indemnitee has been successful, on the merits or otherwise, in defense of any action, suit or proceeding referred to in Sections 9.1 and 9.2 of these bylaws, or in defense of any claim, issue or matter therein, or on appeal from any such action, suit or proceeding, Indemnitee shall be indemnified to the fullest extent permitted by law against all expenses (including, without limitation, attorneys' fees) actually and reasonably incurred by or on behalf of Indemnitee in connection therewith.

9.4 NOTIFICATION AND DEFENSE OF CLAIM.

As a condition precedent to an Indemnitee's right to be indemnified, such Indemnitee must notify the Corporation in writing as soon as practicable of any action, suit, proceeding or investigation involving such Indemnitee for which indemnity will or could be sought. With respect to any action, suit, proceeding or investigation of which the Corporation is so notified, the Corporation will be entitled to participate therein at its own expense and/or to assume the defense thereof at its own expense, with legal counsel reasonably acceptable to Indemnitee. After notice from the Corporation to Indemnitee of its election so to assume such defense, the Corporation shall not be liable to Indemnitee for any legal or other expenses subsequently

incurred by Indemnitee in connection with such action, suit, proceeding or investigation, other than as provided below in this Section 9.4. Indemnitee shall have the right to employ his or her own counsel in connection with such action, suit, proceeding or investigation, but the fees and expenses of such counsel incurred after notice from the Corporation of its assumption of the defense thereof shall be at the expense of Indemnitee unless (a) the employment of counsel by Indemnitee has been authorized by the Corporation, (b) counsel to Indemnitee shall have reasonably concluded that there may be a conflict of interest or position on any significant issue between the Corporation and Indemnitee in the conduct of the defense of such action, suit, proceeding or investigation or (c) the Corporation shall not in fact have employed counsel to assume the defense of such action, suit, proceeding or investigation, in each of which cases the fees and expenses of counsel for Indemnitee shall be at the expense of the Corporation, except as otherwise expressly provided by this Article IX. The Corporation shall not be entitled, without the consent of Indemnitee, to assume the defense of any claim brought by or in the right of the Corporation or as to which counsel for Indemnitee shall have reasonably made the conclusion provided for in clause (b) above. The Corporation shall not be required to indemnify Indemnitee under this Article IX for any amounts paid in settlement of any action, suit, proceeding or investigation effected without its written consent. The Corporation shall not settle any action, suit, proceeding or investigation in any manner which would impose any penalty or limitation on Indemnitee without Indemnitee's written consent. Neither the Corporation nor Indemnitee will unreasonably withhold or delay its consent to any proposed settlement.

9.5 ADVANCE OF EXPENSES.

Subject to the provisions of Sections 9.4 and 9.6 of these bylaws, in the event of any threatened or pending action, suit, proceeding or investigation of which the Corporation receives notice under this Article IX, any expenses (including, without limitation, attorneys' fees) incurred by or on behalf of Indemnitee in defending an action, suit, proceeding or investigation or any appeal therefrom shall be paid by the Corporation in advance of the final disposition of such matter to the fullest extent permitted by law; *provided, however*, that, to the extent required by law, the payment of such expenses incurred by or on behalf of Indemnitee in advance of the final disposition of such matter shall be made only upon receipt of an undertaking by or on behalf of Indemnitee to repay all amounts so advanced in the event that it shall ultimately be determined by final judicial decision from which there is no further right to appeal that Indemnitee is not entitled to be indemnified by the Corporation as authorized in this Article IX or otherwise; and *provided further* that no such advancement of expenses shall be made under this Article IX if it is determined (in the manner described in Section 9.6 of these bylaws) that (a) Indemnitee did not act in good faith and in a manner he or she reasonably believed to be in, or not opposed to, the best interests of the Corporation, or (b) with respect to any criminal action or proceeding, Indemnitee had reasonable cause to believe his or her conduct was unlawful. Such undertaking shall be accepted without reference to the financial ability of Indemnitee to make such repayment.

9.6 PROCEDURE FOR INDEMNIFICATION AND ADVANCEMENT OF EXPENSES.

In order to obtain indemnification or advancement of expenses pursuant to Section 9.1, 9.2, 9.3 or 9.5 of these bylaws, an Indemnitee shall submit to the Corporation a written request. Any such advancement of expenses shall be made promptly, and in any event within 60 days after receipt by the Corporation of the written request of Indemnitee, unless (a) the Corporation has assumed the defense pursuant to Section 9.4 of these bylaws (and none of the circumstances described in Section 9.4 of these bylaws that would nonetheless entitle the Indemnitee to indemnification for the fees and expenses of separate counsel have occurred) or (b) the Corporation determines within such 60-day period that Indemnitee did not meet the applicable standard of conduct set forth in Section 9.1, 9.2 or 9.5 of these bylaws, as the case may be. Any such indemnification, unless ordered by a court, shall be made with respect to requests under Section 9.1 or 9.2 of these bylaws only as authorized in the specific case upon a determination by the Corporation that the indemnification of Indemnitee is proper because Indemnitee has met the applicable standard of conduct set forth in Section 9.1 or 9.2 of these bylaws, as the case may be. Such determination shall be made in each instance (a) by a majority vote of the directors of the Corporation consisting of persons who are not at that time parties to the action, suit or proceeding in question ("disinterested directors"), whether or not a quorum, (b) by a committee of disinterested directors designated by majority vote of disinterested directors, whether or not a quorum, (c) if there are no disinterested directors, or if the disinterested directors so direct, by independent legal counsel (who may, to the extent permitted by law, be regular legal counsel to the Corporation) in a written opinion or (d) by the stockholders of the Corporation.

9.7 REMEDIES.

To the fullest extent permitted by law, the right to indemnification or advancement of expenses as granted by this Article IX shall be enforceable by Indemnitee in any court of competent jurisdiction. Neither the failure of the Corporation to have made a determination prior to the commencement of such action that indemnification is proper in the circumstances because Indemnitee has met the applicable standard of conduct, nor an actual determination by the Corporation pursuant to Section 9.6 of these bylaws that Indemnitee has not met such applicable standard of conduct, shall be a defense to the action or create a presumption that Indemnitee has not met the applicable standard of conduct. In any suit brought by Indemnitee to enforce a right to indemnification or advancement, or brought by the Corporation to recover an advancement of expenses pursuant to the terms of an undertaking, the Corporation shall have the burden of proving that Indemnitee is not entitled to be indemnified, or to such advancement of expenses, under this Article IX. Indemnitee's expenses (including, without limitation, attorneys' fees) reasonably incurred in connection with successfully establishing Indemnitee's right to indemnification or advancement, in whole or in part, in any such proceeding shall also be indemnified by the Corporation to the fullest extent permitted by law. Notwithstanding the foregoing, in any suit brought by Indemnitee to enforce a right to indemnification hereunder it shall be a defense that the Indemnitee has not met any applicable standard for indemnification set forth in the DGCL.

9.8 LIMITATIONS.

Notwithstanding anything to the contrary in this Article IX, except as set forth in Section 9.7 of these bylaws, the Corporation shall not indemnify an Indemnitee pursuant to this Article IX in connection with a proceeding (or part thereof) initiated by such Indemnitee unless the initiation thereof was approved by the Board. Notwithstanding anything to the contrary in this Article IX, the Corporation shall not indemnify (or advance expenses to) an Indemnitee to the extent such Indemnitee is reimbursed (or advanced expenses) from the proceeds of insurance, and in the event the Corporation makes any indemnification (or advancement) payments to an Indemnitee and such Indemnitee is subsequently reimbursed from the proceeds of insurance, such Indemnitee shall promptly refund indemnification (or advancement) payments to the Corporation to the extent of such insurance reimbursement.

9.9 SUBSEQUENT AMENDMENT.

No amendment, termination or repeal of this Article IX or of the relevant provisions of the DGCL or any other applicable laws shall adversely affect or diminish in any way the rights of any Indemnitee to indemnification or advancement of expenses under the provisions hereof with respect to any action, suit, proceeding or investigation arising out of or relating to any actions, transactions or facts occurring prior to the final adoption of such amendment, termination or repeal.

9.10 OTHER RIGHTS.

The indemnification and advancement of expenses provided by this Article IX shall not be deemed exclusive of any other rights to which an Indemnitee seeking indemnification or advancement of expenses may be entitled under any law (common or statutory), agreement or vote of stockholders or disinterested directors or otherwise, both as to action in Indemnitee’s official capacity and as to action in any other capacity while holding office for the Corporation, and shall continue as to an Indemnitee who has ceased to be a director or officer, and shall inure to the benefit of the estate, heirs, executors and administrators of Indemnitee. Nothing contained in this Article IX shall be deemed to prohibit, and the Corporation is specifically authorized to enter into, agreements with officers and directors providing indemnification and advancement rights and procedures different from those set forth in this Article IX. In addition, the Corporation may, to the extent authorized from time to time by the Board, grant indemnification and advancement rights to other employees or agents of the Corporation or other persons serving the Corporation and such rights may be equivalent to, or greater or less than, those set forth in this Article IX.

9.11 PARTIAL INDEMNIFICATION.

If an Indemnitee is entitled under any provision of this Article IX to indemnification by the Corporation for some or a portion of the expenses (including, without limitation, attorneys' fees), liabilities, losses, judgments, fines (including, without limitation, excise taxes and penalties arising under the Employee Retirement Income Security Act of 1974, as amended) or amounts paid in settlement actually and reasonably incurred by or on behalf of Indemnitee in connection with any action, suit, proceeding or investigation and any appeal therefrom but not, however, for the total amount thereof, the Corporation shall nevertheless indemnify Indemnitee for the portion of such expenses (including, without limitation, attorneys' fees), liabilities, losses, judgments, fines (including, without limitation, excise taxes and penalties arising under the Employee Retirement Income Security Act of 1974, as amended) or amounts paid in settlement to which Indemnitee is entitled.

9.12 INSURANCE.

The Corporation may purchase and maintain insurance, at its expense, to protect itself and any director, officer, employee or agent of the Corporation or another corporation, partnership, joint venture, trust or other enterprise (including, without limitation, any employee benefit plan) against any expense, liability or loss incurred by him or her in any such capacity, or arising out of his or her status as such, whether or not the Corporation would have the power to indemnify such person against such expense, liability or loss under the DGCL.

9.13 SAVINGS CLAUSE.

If this Article IX or any portion hereof shall be invalidated on any ground by any court of competent jurisdiction, then the Corporation shall nevertheless indemnify each Indemnitee as to any expenses (including, without limitation, attorneys' fees), liabilities, losses, judgments, fines (including, without limitation, excise taxes and penalties arising under the Employee Retirement Income Security Act of 1974, as amended) and amounts paid in settlement in connection with any action, suit, proceeding or investigation, whether civil, criminal or administrative, including, without limitation, an action by or in the right of the Corporation, to the fullest extent permitted by any applicable portion of this Article IX that shall not have been invalidated and to the fullest extent permitted by applicable law.

9.14 DEFINITIONS.

Terms used in this Article IX and defined in Section 145(h) and Section 145(i) of the DGCL shall have the respective meanings assigned to such terms in such Section 145(h) and Section 145(i).

ARTICLE X - AMENDMENTS.

Subject to the limitations set forth in Section 9.9 of these bylaws or the provisions of the certificate of incorporation, the Board is expressly empowered to adopt, amend or repeal the bylaws of the Corporation. The stockholders also shall have power to adopt, amend or repeal the bylaws of the Corporation; ***provided***, ***however***, that, in addition to any vote of the holders of any class or series of stock of the Corporation required by law or by the certificate of incorporation, such action by stockholders shall require the affirmative vote of the holders of at least a majority in voting power of the outstanding shares of capital stock of the Corporation entitled to vote thereon.

Exhibit 31.1

CERTIFICATIONS

I, Carsten Brunn, Ph.D., certify that:

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

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

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

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

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

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

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

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

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

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

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

November 13, 2023

/s/ Carsten Brunn, Ph.D.

Carsten Brunn, Ph.D.
President and Chief Executive Officer, and Director
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Blaine Davis, certify that:

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

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

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

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

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

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

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

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

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

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

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

November 13, 2023

/s/ Blaine Davis

Blaine Davis
Chief Financial Officer
(Principal Financial 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 on Form 10-Q of Selecta Biosciences, Inc. (the "Company") for the period ended September 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

1. The Quarterly Report on Form 10-Q of the Company for the period ended September 30, 2023 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

November 13, 2023

/s/ Carsten Brunn, Ph.D.

Carsten Brunn, Ph.D.
President and Chief Executive Officer, and Director
(Principal Executive Officer)

November 13, 2023

/s/ Blaine Davis

Blaine Davis
Chief Financial Officer
(Principal Financial Officer)