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

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended June 30, 2022
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 001-37418

Sio Gene Therapies Inc.
(Exact name of registrant as specified in its charter)

Delaware	**85-3863315**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
130 West 42nd St., 26th Floor, New York, NY	**10036**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(877) 746-4891**

N/A

(Former name, former address and former fiscal year, if changed since last report)

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

Title of each Class	Trading Symbol	Name of each exchange on which registered
Common Stock, par value $0.00001 per share	SIOX	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: None

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 o

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 o

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

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 ☒

The number of shares outstanding of the Registrant's common stock, $0.00001 par value per share, on August 9, 2022, was 73,975,196.

SIO GENE THERAPIES INC.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED JUNE 30, 2022

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Summary of the Material Risks Associated with Our Business

Our business is subject to numerous risks and uncertainties that you should be aware of in evaluating our business. These risks include, but are not limited to, the following:

- We may not be successful in identifying and implementing any strategic business combination or other transaction and any strategic transactions that we may consummate in the future could have negative consequences.
- If we are successful in completing a strategic transaction, we may be exposed to other operational and financial risks.
- If a strategic transaction is not consummated, our Board may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.
- We have a limited operating history and have never generated any product revenues.
- Our business, operations and future prospects could continue to be adversely impacted by the effects of health epidemics, including the recent COVID-19 pandemic.
- We expect to incur significant losses for the foreseeable future and may never achieve or maintain profitability.
- The market price of our common stock has been and is likely to continue to be highly volatile, and you may lose some or all of your investment.
- The intended tax effects of our corporate structure prior to and following the Domestication (as defined below) and our corporate reorganization to align our corporate structure with current and future business activity (the "Reorganization"), and intercompany arrangements prior to the Domestication and Reorganization, depend on the application of the tax laws of various jurisdictions and on how we operate our business.

The summary risk factors described above should be read together with the text of the full risk factors below, in the section titled “Risk Factors” in Part II, Item 1A. and the other information set forth in this Quarterly Report on Form 10-Q, including our unaudited condensed consolidated financial statements and the related notes, as well as in other documents that we file with the Securities and Exchange Commission. The risks summarized above or described in full below are not the only risks that we face. Additional risks and uncertainties not precisely known to us, or that we currently deem to be immaterial, may also harm our business, financial condition, results of operations and future growth prospects.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

SIO GENE THERAPIES INC.
Condensed Consolidated Balance Sheets
(Unaudited, in thousands, except share and per share amounts)

	June 30, 2022	March 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 54,771	$ 63,729
Restricted cash	1,184	1,184
Prepaid expenses and other current assets	2,821	5,214
Income tax receivable	355	1,609
Total current assets	59,131	71,736
Operating lease right-of-use assets	2,267	2,444
Property and equipment, net	1,084	900
Total assets	$ 62,482	$ 75,080
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,240	$ 3,984
Accrued expenses	6,101	8,232
Current portion of operating lease liabilities	808	786
Total current liabilities	9,149	13,002
Operating lease liabilities, net of current portion	1,554	1,730
Total liabilities	10,703	14,732
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Common stock, par value $0.00001 per share, 1,000,000,000 shares authorized, 73,975,196 and 73,739,378 issued and outstanding at June 30, 2022 and March 31, 2022, respectively	1	1
Additional paid-in capital	922,807	922,966
Accumulated deficit	(871,362)	(862,956)
Accumulated other comprehensive income	333	337
Total stockholders' equity	51,779	60,348
Total liabilities and stockholders' equity	$ 62,482	$ 75,080

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

SIO GENE THERAPIES INC.
Condensed Consolidated Statements of Operations
(Unaudited, in thousands, except share and per share amounts)

	Three Months Ended June 30,	
	2022	**2021**
Operating expenses:		
Research and development expenses		
(includes stock-based compensation (benefit) expense of $(401) and $432 for the three months ended June 30, 2022 and 2021, respectively)	$ 5,542	$ 8,058
General and administrative expenses		
(includes stock-based compensation expense of $242 and $889 for the three months ended June 30, 2022 and 2021, respectively)	2,992	3,859
Total operating expenses	8,534	11,917
Other (income) expenses:		
Other income, net	(124)	(19)
Loss before income tax benefit	(8,410)	(11,898)
Income tax benefit	(4)	(28)
Net loss	$ (8,406)	$ (11,870)
Net loss per share of common stock — basic and diluted	$ (0.11)	$ (0.16)
Weighted-average shares of common stock outstanding — basic and diluted	73,765,292	72,861,870

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

SIO GENE THERAPIES INC.
Condensed Consolidated Statements of Comprehensive Loss
(Unaudited, in thousands)

	Three Months Ended June 30,	
	2022	2021
Net loss	$ (8,406)	$ (11,870)
Other comprehensive (loss) income:		
Foreign currency translation adjustment	(4)	2
Total other comprehensive (loss) income	(4)	2
Comprehensive loss	$ (8,410)	$ (11,868)

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

SIO GENE THERAPIES INC.
Condensed Consolidated Statements of Stockholders' Equity
(Unaudited, in thousands, except share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Shares	Amount				
Balance at March 31, 2021	69,377,567	$ 1	$ 914,100	$ (791,069)	$ 335	$ 123,367
Shares issued upon settlement of restricted stock units	82,542	—	—	—	—	—
Shares sold in connection with at-the-market offering, net of brokerage fees and offering expenses of $0.0 million	179,400	—	479	—	—	479
Stock-based compensation expense	—	—	1,321	—	—	1,321
Foreign currency translation adjustment	—	—	—	—	2	2
Net loss	—	—	—	(11,870)	—	(11,870)
Balance at June 30, 2021	69,639,509	$ 1	$ 915,900	$ (802,939)	$ 337	$ 113,299

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Shares	Amount				
Balance at March 31, 2022	73,739,378	$ 1	$ 922,966	$ (862,956)	$ 337	$ 60,348
Shares issued upon settlement of restricted stock units	235,818	—	—	—	—	—
Stock-based compensation benefit	—	—	(159)	—	—	(159)
Foreign currency translation adjustment	—	—	—	—	(4)	(4)
Net loss	—	—	—	(8,406)	—	(8,406)
Balance at June 30, 2022	73,975,196	$ 1	$ 922,807	$ (871,362)	$ 333	$ 51,779

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

SIO GENE THERAPIES INC.
Condensed Consolidated Statements of Cash Flows
(Unaudited, in thousands)

	Three Months Ended June 30,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (8,406)	$ (11,870)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of operating lease right-of-use assets	177	49
Stock-based compensation (benefit) expense	(159)	1,321
Depreciation and non-cash amortization	94	61
Change in operating lease liabilities	(154)	(53)
Other	(5)	4
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	2,393	1,072
Income tax receivable	1,254	(25)
Accounts payable	(1,744)	(404)
Accrued expenses	(2,131)	(2,807)
Net cash used in operating activities	(8,681)	(12,652)
Cash flows from investing activities:		
Cash proceeds from sale of long-term investment	—	4,343
Purchases of property and equipment	(277)	(180)
Net cash (used in) provided by investing activities	(277)	4,163
Cash flows from financing activities:		
Cash proceeds from issuance of shares of common stock, net of issuance costs	—	479
Net cash provided by financing activities	—	479
Net change in cash and cash equivalents, restricted cash and long-term restricted cash	(8,958)	(8,010)
Total cash and cash equivalents, restricted cash and long-term restricted cash—beginning of period	64,913	120,170
Total cash and cash equivalents, restricted cash and long-term restricted cash—end of period	$ 55,955	$ 112,160
Cash and cash equivalents —beginning of period	63,729	118,986
Restricted cash included in current assets—beginning of period	1,184	—
Restricted cash included in long-term assets—beginning of period	—	1,184
Total cash and cash equivalents, restricted cash and long-term restricted cash—beginning of period	$ 64,913	$ 120,170
Cash and cash equivalents—end of period	54,771	110,976
Restricted cash included in current assets—end of period	1,184	—
Restricted cash included in long-term assets—end of period	—	1,184
Total cash and cash equivalents, restricted cash and long-term restricted cash—end of period	$ 55,955	$ 112,160

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

Note 1—Description of Business

Historically, Sio Gene Therapies Inc. ("Sio"), together with its wholly owned subsidiaries (the "Company"), was a clinical-stage company focused on developing gene therapies to radically transform the lives of patients with neurodegenerative diseases.

Sio is a Delaware corporation, which was originally an exempted limited company incorporated under the laws of Bermuda in October 2014 and was named Axovant Gene Therapies Ltd. ("AGT") from March 2019 until November 2020. During November 2020, the Company completed a corporate transformation, changing its jurisdiction of incorporation from Bermuda to the State of Delaware, changing its name to Sio Gene Therapies Inc., and changing its ticker symbol on The Nasdaq Global Select Market ("Nasdaq") to "SIOX" (collectively, these events comprise the "Domestication"). The Company continues to be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, and applicable rules of Nasdaq.

Since its initial public offering in 2015, the Company has devoted substantially all of its efforts to raising capital, acquiring product candidates and advancing its product candidates into clinical development. The Company has determined that it has one operating and reporting segment as it allocates resources and assesses financial performance on a consolidated basis.

Note 2—Summary of Significant Accounting Policies

(A) Basis of Presentation:

The Company's fiscal year ends on March 31, and its fiscal quarters end on June 30, September 30 and December 31.

These unaudited condensed consolidated financial statements and accompanying notes have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by U.S. GAAP for complete financial statements. These unaudited condensed consolidated financial statements and accompanying notes should be read in conjunction with the Company's audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended March 31, 2022 (the "Annual Report"), filed with the SEC on June 14, 2022. The unaudited condensed consolidated balance sheet at March 31, 2022 has been derived from the audited consolidated financial statements at that date. In the opinion of management, all adjustments (consisting of normal recurring adjustments) considered necessary to present fairly the financial position of the Company and its results of operations and cash flows for the periods presented have been included. Operating results for the three months ended June 30, 2022 are not necessarily indicative of the results that may be expected for the year ending March 31, 2023, for any other interim period, or for any other future year.

Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification ("ASC"), and as amended by Accounting Standards Updates ("ASU"), issued by the Financial Accounting Standards Board ("FASB"). These unaudited condensed consolidated financial statements and accompanying notes include the accounts of the Company and its wholly owned subsidiaries. The Company has no unconsolidated subsidiaries. All intercompany balances and transactions have been eliminated in consolidation. Certain prior period balances have been reclassified to conform to the current period presentation.

During November 2020, the historical financial statements and subsidiaries of AGT became the historical financial statements and subsidiaries of Sio upon consummation of the Domestication. As a result, these unaudited condensed consolidated financial statements and accompanying notes reflect (i) the historical operating results of AGT and its subsidiaries prior to the Domestication; (ii) the operating results of the Company following the Domestication; and (iii) the Company's equity structure for all periods presented.

There have been no significant changes in the Company's accounting policies from those disclosed in its Annual Report.

(B) Going Concern and Management's Plans:

The Company assesses and determines its ability to continue as a going concern in accordance with the provisions of ASC Subtopic 205-40, "*Presentation of Financial Statements—Going Concern*", which requires the Company to evaluate whether there are conditions or events that raise substantial doubt about its ability to continue as a going concern within one year after the date that its annual and interim consolidated financial statements and accompanying notes are issued. Certain additional financial statement disclosures are required if such conditions or events are identified. If and when an entity's liquidation becomes imminent, financial statements should be prepared under the liquidation basis of accounting. Determining the extent, if any, to which conditions or events raise substantial doubt about the Company's ability to continue as a going concern, or the extent to which mitigating plans sufficiently alleviate any such substantial doubt, as well as whether or not liquidation is imminent, requires judgment by management. The Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the consolidated financial statements and accompanying notes are issued.

The Company is currently a development stage company, and thus, has not yet achieved profitability. The Company expects to continue to incur significant operating and net losses, as well as negative cash flows from operations, for the foreseeable future. The Company has not generated any revenue to date.

For the three months ended June 30, 2022 and the fiscal year ended March 31, 2022, the Company incurred net losses of $8.4 million and $71.9 million, respectively. As of June 30, 2022, the Company's cash and cash equivalents totaled $54.8 million and its accumulated deficit was $871.4 million. The Company estimates that its current cash and cash equivalents balance is sufficient to support operations beyond the twelve month period following the date that these unaudited condensed consolidated financial statements were issued. These estimates are based on assumptions that may prove to be wrong, and the Company could use its available capital resources sooner than it currently expects.

The Company's future funding requirements, both near and long-term, will depend on many factors, including, but not limited to, the timing and outcome of its exploration of, and execution upon any, potential strategic alternatives, the cost of obtaining necessary intellectual property and defending potential intellectual property disputes, realization of the anticipated benefits of the Company's headcount reduction, and the costs of operating as a public company.

(C) Use of Estimates:

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. The Company regularly evaluates estimates and assumptions related to certain assets and liabilities, including its research and development accruals, as well as assumptions used to estimate the fair value of its stock option awards, estimate its income tax expense and estimate its ability to continue as a going concern. Specifically, the Company's assessment of the completeness of the information for research and development accruals is subject to variability and uncertainty. In addition, in certain circumstances, the determination of the nature and amount of research and development services that have been received during the reporting period requires judgment as the timing and pattern of vendor invoicing does not correspond to the level of services provided. The Company estimates the grant date fair value of stock option awards with only time-based vesting requirements using a Black-Scholes valuation model and uses a Monte Carlo Simulation method under the income approach to estimate the grant date fair value of stock option awards with market-based performance conditions. The Company bases its estimates and assumptions on historical experience and on various other factors that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from those estimates.

Additionally, the Company assessed the impact that the COVID-19 pandemic has had on its operations and financial results as of June 30, 2022 and through the date of issuance of these unaudited condensed consolidated financial statements. The Company's analysis was informed by the facts and circumstances as they were known to the Company. This assessment considered the impact COVID-19 may have on financial estimates and assumptions that affect the reported amounts of assets and liabilities and expenses.

(D) Net Loss per Share of Common Stock:

Basic net loss per share of common stock is computed by dividing the net loss applicable to shareholders of common stock by the weighted-average number of shares of common stock and 3,301,998 pre-funded warrants (see Note 6(B)) outstanding during the period, without further consideration for potentially dilutive securities. The pre-funded warrants were fully exercised in July 2021 (See Note 6(B)). In accordance with ASC Topic 260, *Earnings Per Share*, the pre-funded warrants were included in the computation of basic net loss per share because the exercise price was negligible and they were fully vested and exercisable at any time after the original issuance date. Diluted net loss per share of common stock is computed by dividing the net loss applicable to shareholders of common stock by the diluted weighted-average number of shares of common stock outstanding during the period calculated in accordance with the treasury stock method. In periods in which the Company reports a net loss, all common stock equivalents are deemed anti-dilutive such that basic net loss per share of common stock and diluted net loss per share of common stock are equivalent. Potentially dilutive shares of common stock have been excluded from the diluted net loss per share of common stock computations in all periods presented because such securities have an anti-dilutive effect on net loss per share of common stock due to the Company's net loss. Restricted Stock Units ("RSUs") and stock options outstanding for a total of 2.1 million and 5.6 million shares of common stock were not included in the calculation of diluted weighted-average shares of common stock outstanding for the three months ended June 30, 2022 and June 30, 2021, respectively, because they were anti-dilutive given the net loss of the Company.

(E) Financial Instruments and Fair Value Measurement:

The Company utilizes fair value measurement guidance prescribed by accounting standards to value its financial instruments.

The guidance establishes a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances.

Fair value is defined as the exchange price, or exit price, representing the amount that would be received from the sale of an asset or paid to transfer a liability in an orderly transaction between market participants. As a basis for considering market participant assumptions in fair value measurements, the guidance establishes a three-tier fair value hierarchy that distinguishes among the following:

- Level 1-Valuations are based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access.
- Level 2-Valuations are based on quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active and models for which all significant inputs are observable, either directly or indirectly.
- Level 3-Valuations are based on inputs that are unobservable (supported by little or no market activity) and significant to the overall fair value measurement.

To the extent the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The Company's financial instruments include cash and cash equivalents and restricted cash. Cash consists of non-interest-bearing deposits denominated in the U.S. dollar, Swiss franc and Euro, while cash equivalents consists of interest-bearing money market fund deposits denominated in the U.S. dollar, which are invested in debt securities issued or guaranteed by the U.S. government and repurchase agreements fully collateralized by U.S. Treasury and U.S. government securities, and restricted cash consists of interest-bearing deposits denominated in the U.S. dollar. Cash and restricted cash are stated at their historical carrying amounts, which approximate fair value due to their short-term nature. The carrying values of the Company's money market fund included in cash and cash equivalents of $50.0 million and $61.0 million at June 30, 2022 and March 31, 2022, respectively, approximated their fair values, which are based on quoted prices in active markets for identical securities.

The following table summarizes the fair value of the Company's money market fund included in cash equivalents based on the inputs used at June 30, 2022 and March 31, 2022 in determining such values (in thousands):

	As of June 30, 2022				As of March 31, 2022			
	Fair Value	Price Quotations (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Fair Value	Price Quotations (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Money market fund	$ 50,000	$ 50,000	$ —	$ —	$ 61,000	$ 61,000	$ —	$ —

(F) Recent Accounting Pronouncements:

In June 2016, the FASB issued ASU No. 2016-13, "*Financial Instruments — Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*" ("ASU No. 2016-13"). ASU 2016-13 requires that financial assets measured at amortized cost, such as loans, accounts and trade receivables and investments, be represented net of expected credit losses, which may be estimated based on relevant information such as historical experience, current conditions, and future expectation for each pool of similar financial asset. ASU No. 2016-13 requires enhanced disclosures related to trade receivables and associated credit losses. In May 2019, the FASB issued ASU No. 2019-05, *"Financial Instruments — Credit Losses (Topic 326): Targeted Transition Relief*", which allows for a transition election on certain instruments and is effective for smaller reporting companies for fiscal years beginning after December 15, 2022 and interim periods in those fiscal years. In November 2019, the FASB issued ASU No. 2019-11, "*Codification Improvements to Topic 326, Financial Instruments — Credit Losses*", which amends certain aspects of ASU No. 2016-13, including transition relief for troubled debt restructuring ("TDR"), among other topics. In March 2022, the FASB issued ASU No. 2022-02, "*Financial Instruments — Credit Losses (Topic 326): Troubled Debt Restructurings and Vintage Disclosures*" ("ASU No. 2022-02"), which eliminates the accounting guidance on TDRs for creditors in ASC Subtopic 310-40 and amends the guidance on "vintage disclosures" to require disclosure of current-period gross write-offs by year of origination. ASU No. 2022-02 also updates the requirements related to accounting for credit losses under ASC Topic 326 and adds enhanced disclosures for creditors with respect to loan refinancings and restructurings for borrowers experiencing financial difficulty. While the Company does not expect the adoption of this guidance to materially impact the Company's consolidated financial statements and related disclosures because it does not currently have any investments or trade receivables, the impact on the Company's consolidated financial statements and disclosures will depend on the facts and circumstances of any specific future transactions.

In August 2020, the FASB issued ASU No. 2020-06, "*Debt — Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40)*" ("ASU No. 2020-06"). ASU No. 2020-06 simplifies the accounting for convertible debt instruments by removing the beneficial conversion and cash conversion separation models for convertible instruments. Under ASU No. 2020-06, the embedded conversion features are no longer separated from the host contract for convertible instruments with conversion features that are not required to be accounted for as derivatives or that do not result in substantial premiums accounted for as paid-in capital. ASU No. 2020-06 also amends the accounting for certain contracts in an entity's own equity that are currently accounted for as derivatives because of specific settlement provisions. In addition, the new guidance modifies how particular convertible instruments and certain contracts that may be settled in cash or shares impact the computation of diluted earnings or loss per share. The provisions of ASU No. 2020-06 are effective for fiscal years beginning after December 15, 2021, and interim periods within those fiscal years, with early adoption permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. The Company's adoption of ASU No. 2020-06 on April 1, 2022 did not impact the Company's consolidated financial statements and related disclosures because it did not maintain any debt instruments accounted for in accordance with ASC Subtopic 470-20, "*Debt — Debt with Conversion and Other Options*" or instruments accounted for as derivatives in accordance with ASC Subtopic 815-40, "*Derivatives and Hedging — Contracts in Entity's Own Equity*", and the Company had also included outstanding pre-funded warrants in the computation of basic net loss per share (see Note 2(D)).

In May 2021, the FASB issued ASU No. 2021-04, "*Earnings Per Share (Topic 260), Debt — Modifications and Extinguishments (Subtopic 470-50), Compensation — Stock Compensation (Topic 718), and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options*" ("ASU No. 2021-04"). ASU No. 2021-04 provides a principles-based framework for issuers to account for a modification or exchange of freestanding equity-classified written call options. To the extent applicable, issuers first reference other U.S. GAAP to account for the effect of the modification. In the absence of other U.S. GAAP, ASU No. 2021-04 clarifies whether to account for the effect as an adjustment to equity, and the related EPS implications, or as an expense, and if so the manner and pattern of recognition. The provisions of ASU No. 2021-04 are effective for annual periods beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption is permitted. The Company's adoption of ASU No. 2021-04 on April 1, 2022 did not impact the Company's consolidated financial statements and related disclosures because it did not modify outstanding equity-classified written call options upon adoption.

In March 2022, the FASB issued ASU No. 2022-01, "*Derivatives and Hedging (Topic 815) — Fair Value Hedging — Portfolio Layer Method*" ("ASU No. 2022-01"). ASU No. 2022-01 clarifies the guidance in ASC Topic 815 on fair value hedge accounting of interest rate risk for portfolios of financial assets, and amends the guidance in ASU 2017-12, "*Derivatives and Hedging (Topic 815): Targeted Improvements to Accounting for Hedging Activities*", that, among other things, established the "last-of-layer" method for making the fair value hedge accounting for these portfolios more accessible. ASU 2022-01 renames that method the "portfolio layer" method. The provisions of ASU No. 2022-01 are effective for annual periods beginning after December 15, 2022, including interim periods within those fiscal years. Early adoption is permitted. While the Company does not expect the adoption of this guidance to materially impact the Company's consolidated financial statements and related disclosures because it does not currently have any financial instruments designated as fair value hedges, the impact on the Company's consolidated financial statements and disclosures will depend on the facts and circumstances of any specific future transactions or circumstances.

Other recent accounting pronouncements issued by the FASB (including its Emerging Issues Task Force), the American Institute of Certified Public Accountants, and the SEC did not, or are not believed by management to, have a material impact on the Company's present or future consolidated financial position, results of operations or cash flows.

Note 3—License and Collaboration Agreements

(A) The University of Massachusetts Medical School Exclusive License Agreement:

In December 2018, the Company entered into an exclusive license agreement (the "UMMS Agreement") with the University of Massachusetts Medical School ("UMMS"), pursuant to which the Company received a worldwide, royalty-bearing, sub-licensable license under certain patent applications and any patents issuing therefrom, biological materials and know-how controlled by UMMS to develop and commercialize gene therapy product candidates, including AXO-AAV-GM1 and AXO-AAV-GM2, for the treatment of GM1 gangliosidosis and GM2 gangliosidosis (including Tay-Sachs disease and Sandhoff disease), respectively. In April 2022, the Company provided notice of termination of the UMMS Agreement to UMMS, which termination is expected to become effective August 31, 2022. The Company incurred a total of $3.4 million and $3.4 million of program-specific costs related to its AXO-AAV-GM1 and AXO-AAV-GM2 programs within research and development expenses in its unaudited condensed consolidated statements of operations during the three months ended June 30, 2022 and June 30, 2021, respectively. The Company paid a total of $0.2 million and $1.6 million to UMMS during the three months ended June 30, 2022 and June 30, 2021, respectively.

(B) Oxford Biomedica License Agreement:

In June 2018, the Company entered into an exclusive license agreement (the "Oxford Agreement") with Oxford Biomedica (UK) Ltd. ("Oxford"), pursuant to which the Company received a worldwide, exclusive, royalty-bearing, sub-licensable license under certain patents and other intellectual property controlled by Oxford to develop and commercialize AXO-Lenti-PD and related gene therapy products for all diseases and conditions. In February 2022, the Company provided notice of termination of the Oxford Agreement to Oxford, which termination became effective June 30, 2022. The Company incurred $0.1 million and $0.6 million of AXO-Lenti-PD program-specific costs within research and development expenses in its unaudited condensed consolidated statement of operations during the three months ended June 30, 2022 and June 30, 2021, respectively. The Company paid Oxford a total of $0.6 million and $22 thousand during the three months ended June 30, 2022 and June 30, 2021, respectively.

Note 4—Investment in Arvelle Therapeutics B.V.

In February 2021, the Company sold its investment of 8.1 million shares of nonredeemable preferred stock (the "Arvelle Shares") of Arvelle Therapeutics B.V. ("Arvelle") to a third party as part of that third party's cash acquisition of all of the outstanding equity of Arvelle. In exchange, the Company received an upfront payment of approximately $11.6 million, in addition to a future payment to be received of approximately $1.2 million that is being held in escrow and that is recorded as restricted cash in the Company's unaudited condensed consolidated balance sheet at June 30, 2022, as well as the right to receive up to an additional total of $7.0 million in potential future regulatory and sales milestone payments (collectively, the "Arvelle Sale"). The Company originally purchased its Arvelle Shares in February 2019 and May 2020 in exchange for €0.00001 per share paid in cash, as well as certain goods and services provided by the Company to Arvelle. The Company recorded a net gain of approximately $4.7 million to other non-operating income in the Company's consolidated statement of operations upon the closing of the Arvelle Sale in February 2021, as well as a gain of approximately $4.3 million recorded to other non-operating income in the Company's consolidated statement of operations and to receivable from sale of long-term investment in its consolidated balance sheet upon the achievement of a regulatory milestone in March 2021 that was collected during the three months ended June 30, 2021.

Note 5—Accrued Expenses

As of June 30, 2022, and March 31, 2022, accrued expenses consisted of the following (in thousands):

	June 30, 2022	March 31, 2022
Research and development expenses	$ 4,254	$ 4,392
Bonuses and other compensation expenses	655	2,113
Other expenses	1,192	1,727
Total accrued expenses	$ 6,101	$ 8,232

Note 6—Stockholders' Equity

(A) Overview:

Sio's Certificate of Incorporation filed with the State of Delaware on November 12, 2020 authorizes the issuance of up to a total of 1,010,000,000 shares, of which 1,000,000,000 shares are common stock with a par value of $0.00001 per share and 10,000,000 shares are preferred stock with a par value of $0.00001 per share.

(B) Transactions:

In February 2020, as part of a follow-on public offering, the Company issued and sold pre-funded warrants to purchase up to 3,301,998 shares of common stock at an offering price of $3.74999 and an exercise price of $0.00001 per pre-funded warrant, which were fully exercised in July 2021. The pre-funded warrants were classified as equity and the fair value of the pre-funded warrants was recorded as a credit to additional paid-in capital and was not subject to remeasurement.

The Company has engaged SVB Securities LLC as its agent to sell shares of the Company's common stock from time to time through an at-the-market equity offering program. SVB Securities LLC receives compensation for its services in an amount equal to 3% of the gross proceeds of any of the Company's common stock sold. During the three months ended June 30, 2022, the Company did not sell any shares of its common stock under this program. During the three months ended June 30, 2021, the Company sold approximately 0.2 million shares of its common stock for total proceeds of approximately $0.5 million, net of brokerage fees, under this program. As of June 30, 2022, the Company had sold a total of approximately $30.4 million shares of its common stock for aggregate proceeds of approximately $92.0 million, net of brokerage fees, under and since the inception of this program.

Note 7—Stock-Based Compensation

(A) Amended and Restated 2015 Equity Incentive Plan:

In March 2015, the Company adopted its 2015 Equity Incentive Plan, which was (i) amended and restated in June 2017 by its Board of Directors and became effective upon shareholder approval in August 2017, (ii) further amended and restated in October 2020 by its Board of Directors, and (iii) further amended and restated in August 2021 by its Board of Directors and became effective upon stockholder approval in September 2021 (the "2015 Plan"). In April 2022 and April 2021, the number of shares of common stock authorized for issuance under the 2015 Plan increased automatically by 2.9 million and 2.8 million, respectively, in accordance with the terms of the 2015 Plan. Upon amendment and restatement by the Company's Board of Directors and stockholder approval of the 2015 Plan in August 2021 and September 2021, respectively, the number of shares of common stock authorized for issuance under the 2015 Plan increased by 5.0 million. At June 30, 2022, totals of 16.3 million shares of common stock were authorized for issuance and 13.2 million shares of common stock were available for future issuance under the 2015 Plan.

(B) Stock Options:

Time-based stock options granted to the Company's employees vest over a period of either (i) four years with 25% of the shares of common stock underlying the option vesting on the first anniversary of the vesting commencement date and the remainder vesting in 12 equal quarterly installments thereafter for such stock options granted prior to April 2021, or (ii) three years with one-third of the shares of common stock underlying the stock option vesting on the first anniversary of the vesting commencement date and the remainder vesting in 8 equal quarterly installments thereafter for such stock options granted since April 2021, each subject to continuing service. Initial stock options granted to the Company's non-employee directors vest in equal installments on the first, second and third anniversaries of the vesting commencement date, and stock options subsequently granted annually to the Company's non-employee directors vest fully on the first anniversary of the vesting commencement date, each subject to continuous service. Options with market-based performance conditions vest based on the trading price for the Company's shares of common stock exceeding certain closing price thresholds.

Stock options granted under the 2015 Plan provide option holders, if provided for by the terms of the option agreement or if approved by the Board of Directors, the right to exercise their options prior to vesting. In the event that an option holder exercises the unvested portion of any option, such unvested portion will be subject to a repurchase option held by the Company at the lower of (i) the fair market value of its common stock on the date of repurchase and (ii) the exercise price of the options. Any shares of common stock underlying such unvested portion will continue to vest in accordance with the original vesting schedule of the option.

The Company did not grant any stock options during the three months ended June 30, 2022. During the three months ended June 30, 2021, the Company granted options to purchase a total of 1.6 million shares of its common stock, with a weighted-average exercise price of $2.47 and estimated grant date fair value of $3.3 million under the 2015 Plan. There were no options with market-based performance conditions granted during the three months ended June 30, 2022 and June 30, 2021 under the 2015 Plan. At June 30, 2022, options to purchase a total of 1.2 million shares of common stock were outstanding under the 2015 Plan with a weighted-average exercise price of $8.82 per share, including options with market-based performance conditions to purchase 0.1 million shares of common stock at a weighted average exercise price of $6.42 per share. At June 30, 2022, vested options to purchase a total of 0.8 million shares of common stock were outstanding under the 2015 Plan, with no options with market-based performance conditions vested and outstanding. During the three months ended June 30, 2022 and June 30, 2021, the total grant date fair values of stock options that vested under the 2015 Plan were $0.7 million and $0.9 million, respectively.

(C) Restricted Stock Units:

RSUs granted during the three months ended June 30, 2022 and June 30, 2021 vest in three equal annual installments commencing on the first anniversary of the vesting commencement date, subject to continuing service. Of the total number of RSUs granted in September 2019 representing approximately 0.3 million shares of the Company's common stock, one-half vested on January 31, 2020 and the remaining one-half vested on July 31, 2020, subject to continuing service. The Company did not grant any RSUs during the three months ended June 30, 2022. During the three months ended June 30, 2021, the Company granted RSUs for a total of 1.1 million shares of common stock, with an aggregate grant date fair value of $2.8 million to its employees under the 2015 Plan. At June 30, 2022, RSUs for approximately 0.9 million shares of common stock were outstanding, of which approximately 39 thousand were vested. During the three months ended June 30, 2022 and June 30, 2021, the total grant date fair values of RSUs that vested under the 2015 Plan were $0.7 million and $0.6 million, respectively.

(D) Stock-based Compensation Expense:

The Company recorded total stock-based compensation (benefit) expense of $(0.2) million and 1.3 million for the three months ended June 30, 2022 and 2021, respectively, related to options and RSUs granted to its employees and directors, excluding stock-based compensation expense allocated to the Company from RSL (see Note 7(E)). The stock-based compensation expense was included in research and development and general and administrative expenses in the Company's unaudited condensed consolidated statements of operations. At June 30, 2022, total unrecognized compensation expense for unvested outstanding option and RSU equity awards of the Company's common stock granted to its employees and directors under the 2015 Plan was $1.5 million, which is expected to be recognized over the remaining weighted-average service period of 1.91 years.

(E) RSL Common Share Awards and Options:

Certain employees of the Company have been granted RSL common share awards and options for which stock-based compensation expense is allocated to the Company from RSL. The Company recorded such total allocated stock-based compensation expense of $0 thousand and $6 thousand during the three months ended June 30, 2022 and 2021, respectively.

Note 8—Commitments and Contingencies

As of June 30, 2022, the Company had entered into commitments under the Services Agreements with certain of RSL's wholly owned subsidiaries and agreements to rent office and research and development laboratory spaces. In addition, the Company has entered into services agreements with third parties for pharmaceutical manufacturing and research activities in the normal course of business, which can generally be terminated by the Company with 30- to 60-days' written notice, unless otherwise indicated. Further, certain of the Company's manufacturing agreements could require early termination and wind-down payments due from the Company as a result of the recent termination of its clinical trials.

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

The following discussion and analysis of our financial condition, results of operations and cash flows should be read in conjunction with (i) the interim unaudited condensed consolidated financial statements and the related notes thereto included elsewhere in this Quarterly Report on Form 10-Q, and (ii) the audited consolidated financial statements and notes thereto and management's discussion and analysis of financial condition and results of operations for the fiscal year ended March 31, 2021, included in our Annual Report on Form 10-K, filed with the Securities and Exchange Commission (the "SEC") on June 9, 2021.

This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These statements are often identified by the use of words such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "project," "will," "would" or the negative or plural of these words or similar expressions or variations, although not all forward-looking statements contain these identifying words. We cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. The forward-looking statements appearing in a number of places throughout this Quarterly Report on Form 10-Q include, but are not limited to, statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things:

- the timing and outcome of our exploration of potential strategic alternatives;
- our anticipated uses of cash, cash runway and future cash position;
- the timing, cost and anticipated savings benefits of internal restructurings that we have conducted or may conduct in the future, including headcount reductions;
- our public securities' potential liquidity and trading;
- continued service of, or changes required in, our officers or other key personnel;
- our estimates regarding our results of operations, financial condition, liquidity, capital requirements, prospects, growth and strategies;
- our lack of profitability and the need for additional capital;
- the impact of laws and government regulations; and
- our ability to maintain and operate our business in light of the COVID-19 pandemic;

We have based these forward-looking statements largely on our current expectations and projections about future events, including the responses we expect from the FDA and other regulatory authorities and financial trends that we believe may affect our financial condition, results of operations, business strategy, nonclinical studies and clinical trials and financial needs. Such forward-looking statements are subject to a number of risks, uncertainties, assumptions and other factors known and unknown that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified herein, and those discussed in the section titled "Risk Factors" set forth in Part II, Item 1A of this Quarterly Report on Form 10-Q and in our other filings with the SEC. These risks are not exhaustive. You should not rely upon forward-looking statements as predictions of future events. Furthermore, such forward-looking statements speak only as of the date of this report. New risk factors emerge from time to time and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely upon these statements as predictions of future events.

Overview

Historically, we were a clinical-stage company focused on developing gene therapies to radically transform the lives of patients with neurodegenerative diseases. We previously had three clinical-stage programs: AXO-AAV-GM1 for the treatment of GM1 gangliosidosis, AXO-AAV-GM2 for the treatment of GM2 gangliosidosis (including Tay-Sachs and Sandhoff diseases) and AXO-Lenti-PD for the treatment of Parkinson's disease.

Currently, we are winding down these three clinical-stage programs while also working on one pre-clinical program.

In June 2018, we entered into the Oxford Agreement with Oxford pursuant to which we received a worldwide, royalty-bearing, sub-licensable license under certain patents and other intellectual property controlled by Oxford to develop and commercialize AXO-Lenti-PD and related gene therapy products. In February 2022, we provided notice to Oxford to terminate the Oxford Agreement to develop and commercialize AXO-Lenti-PD and related gene therapy product candidates. We determined to terminate the Oxford Agreement and redirect resources to our AXO-AAV-GM1 and -GM2 programs, as well as other strategic initiatives, due to several factors, including the resource requirements and development timelines to reach meaningful value inflection for the program and an increasingly challenging market and regulatory environment for Parkinson's disease. We continued to incur immaterial expenses in connection with the Oxford Agreement until its termination became effective on June 30, 2022.

In December 2018, we entered into the UMMS Agreement with UMMS pursuant to which we received a worldwide, royalty-bearing, sub-licensable license under certain patent applications and any patents issuing therefrom, biological materials and know-how controlled by UMMS to develop and commercialize gene therapy product candidates, including AXO-AAV-GM1 and AXO-AAV-GM2, for the treatment of GM1 gangliosidosis and GM2 gangliosidosis (including Tay-Sachs disease and Sandhoff disease). In April 2022, we provided notice to UMMS to terminate the UMMS Agreement, which termination is expected to become effective August 31, 2022. We will continue to conduct clinical operations for the AXO-AAV-GM1 and AXO-AAV-GM2 programs under the UMMS Agreement during the 90-day wind-down/termination period.

In parallel with our decision to terminate the AXO-AAV-GM1 and -GM2 programs, in April 2022, our board of directors approved and we announced the strategic decision to explore and review a range of strategic alternatives focused on maximizing stockholder value from our existing cash and cash equivalents, including a potential sale, merger, business combination or similar transaction. In connection with these actions, and as approved by our board of directors, we began implementing a significant headcount reduction, which is expected to conclude in August 2022.

While we continue to conduct certain pre-clinical research and development initiatives in gene therapy, we expect to devote substantial time and resources to exploring strategic alternatives. Despite devoting significant efforts to identify and evaluate potential strategic alternatives, there can be no assurance that this strategic review process will result in us pursuing any transaction or that any transaction, if pursued, will be completed on attractive terms or at all. We have not set a timetable for completion of this strategic review process, and our board of directors has not approved a definitive course of action. Additionally, there can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated or lead to increased stockholder value or that we will make any additional cash distribution to our stockholders. In addition, we expect to incur additional operating expenses associated with the wind-down of the UMMS Agreement and the execution of certain other cost-saving measures.

COVID-19 Business Update

We are continuing to closely monitor the impact of the global COVID-19 pandemic on our business and operations. We believe that the measures we have previously implemented are appropriate, reflecting both regulatory and public health guidance, to maintain business continuity. We will continue to closely monitor and seek to comply with guidance from governmental authorities and adjust our activities as appropriate.

In the conduct of our business activities during the pandemic, we took actions designed to protect the safety and well-being of patients, healthcare workers and employees. For patients previously enrolled in our clinical trials, we worked closely with clinical trial investigators and site staff to continue treatment in compliance with trial protocols and to uphold trial integrity, while working to observe government and institutional guidelines designed to safeguard the health and safety of patients, clinical trial investigators and site staff. While the COVID-19 pandemic has not resulted in a significant delay to our prior clinical development timelines to-date and has not had a significant impact to our historical operations, the COVID-19 pandemic continues to evolve, including as a result of variants. The effects of the COVID-19 pandemic, together with recent macroeconomic uncertainty, could materially impact our strategic goals to explore and review a range of strategic alternatives focused on maximizing stockholder value from our existing cash and cash equivalents, including a potential sale, merger, business combination or similar transaction. The COVID-19 pandemic and related impacts (including inflationary pressures and macroeconomic uncertainty) could result in significant and prolonged disruption of global financial markets, which has negatively impacted and may continue to reduce our ability to access capital, limiting the financial resources available to us as well as to any potential strategic counterparty.

We do not yet know the full extent of potential impacts on our business, operations, strategic goals, or the global economy as a whole. However, these effects could harm our operations, and we will continue to monitor the COVID-19 situation closely. For additional information about risks and uncertainties related to the COVID-19 pandemic that may impact our business, financial condition and results of operations, see the section titled "Risk Factors" under Part II, Item 1A in this Quarterly Report on Form 10-Q.

Financial Operations Overview

Revenue

We have not generated any revenue from the sale of any products, and we do not expect to generate any revenue unless and until we obtain regulatory approval of and begin to commercialize any product candidates.

Research and Development Expense

Since our inception, our operations have historically been focused primarily on organizing and staffing our company, raising capital, and acquiring, preparing for and advancing our product candidates into clinical development. Our research and development expenses include program-specific costs, as well as unallocated internal costs.

Program-specific costs include:

- direct third-party costs, which include expenses incurred under agreements with CROs and contract manufacturing organizations, the cost of consultants who assist with the development of our product candidates on a program-specific basis, investigator grants, sponsored research, manufacturing costs in connection with producing materials for use in conducting nonclinical and clinical studies, and any other third-party expenses directly attributable to the development of our prior product candidates; and
- payments for research and development milestones, which include costs incurred under our agreements with UMMS and Oxford.

Unallocated internal costs include:

- stock-based compensation expense for research and development personnel;
- personnel-related expenses, which include employee-related expenses, such as salaries, benefits and recruiting expenses, for research and development personnel; and
- other expenses, which include research and development software costs, travel expenses, laboratory facility rental costs and research and development equipment depreciation expenses, as well as the cost of consultants who assist with our research and development but are not allocated to a specific program.

Our research and development expenses are expected to decrease substantially in the near term, following the previously announced discontinuation of our AXO-AAV-GM1, AXO-AAV-GM2 and AXO-Lenti-PD programs, as well as the significant reduction in workforce that we implemented in April 2022. The AXO-Lenti-PD program was wound down by July 31, 2022 and the AXO-AAV-GM1 and AXO-AAV-GM2 programs are expected to be wound down by August 31, 2022, after which our research and development activities will be concentrated on one preclinical program.

General and Administrative Expense

General and administrative expenses consist primarily of employee-related expenses such as salaries, benefits and travel expenses for our general and administrative personnel; stock-based compensation, including stock-based compensation allocated to us from our affiliate, Roivant Sciences Ltd. ("RSL"), for certain RSL equity instruments granted to certain of our employees (primarily our former CEO (the "RSL Equity Instruments"), who resigned as our CEO in January 2022); non-employee benefit insurance premiums; third-party legal and accounting fees; information technology costs; office rent, fixed asset depreciation and other overhead costs; and consulting services.

During the fiscal year ending March 31, 2023, we anticipate that our general and administrative expenses will decrease compared to the fiscal year ended March 31, 2022, primarily as a result of stock-based compensation expense associated with the RSL Equity Instruments, for which expensing commenced upon the liquidity event vesting condition being met upon the closing of RSL's business combination with Montes Archimedes Acquisition Corp. ("MAAC") on September 30, 2021 and ended by March 31, 2022.

Results of Operations for the Three Months Ended June 30, 2022 and 2021

The following table summarizes our results of operations for the three months ended June 30, 2022 and 2021 (in thousands):

	Three Months Ended June 30,		
	2022	2021	Change
Operating expenses:			
Research and development expenses (includes stock-based compensation (benefit) expense of $(401) and $432 for the three months ended June 30, 2022 and 2021, respectively)	$ 5,542	$ 8,058	$ (2,516)
General and administrative expenses (includes stock-based compensation expense of $242 and $889 for the three months ended June 30, 2022 and 2021, respectively)	2,992	3,859	(867)
Total operating expenses	8,534	11,917	(3,383)
Other income, net	(124)	(19)	(105)
Loss before income tax (benefit) expense	(8,410)	(11,898)	3,488
Income tax benefit	(4)	(28)	24
Net loss	$ (8,406)	$ (11,870)	$ 3,464

Research and Development Expenses

Our research and development expenses during the three-months ended June 30, 2022 and 2021 consisted of the following (in thousands):

	Three Months Ended June 30,		
	2022	2021	Change
Program-specific costs	$ 3,484	$ 3,976	$ (492)
Unallocated internal costs:			
Personnel-related	1,542	2,500	(958)
Stock-based compensation expense	(401)	432	(833)
Other	917	1,150	(233)
Total research and development expenses	$ 5,542	$ 8,058	$ (2,516)

Research and development expenses were $5.5 million for the three months ended June 30, 2022 and $8.1 million for the three months ended June 30, 2021. The $2.5 million decrease was primarily related to decreases in:

(i) program-specific costs relating to our prior AXO-Lenti-PD and AXO-AAV-GM1 and AXO-AAV-GM2 programs, which decreased $0.5 million as we began winding down clinical-stage programs subsequent to our termination of the Oxford Agreement and the UMMS Agreement; and

(ii) unallocated internal costs, which decreased $2.0 million primarily due to reductions in personnel-related and stock-based compensation costs after announcing the discontinuation of clinical-stage programs and initiating a significant reduction in workforce in April 2022. Costs incurred during the quarter ended June 30, 2022 included $0.6 million of severance expense.Further, the costs incurred during the quarter ended June 30, 2022 benefitted from the reversal of $0.4 million in stock-based compensation from prior periods resulting from the workforce reduction.

General and Administrative Expenses

General and administrative expenses were $3.0 million for the three months ended June 30, 2022 and $3.9 million for the three months ended June 30, 2021. The decrease of $0.9 million was primarily due to decreases of $0.6 million in stock-based compensation expense and $0.5 million in personnel-related expenses, both related to the workforce reduction that commenced in April 2022, partially offset by an increase of $0.3 million in professional fees primarily due to legal fees related to potential strategic alternatives.

Other Income, net

Other income, net was $124 thousand and $19 thousand for the three months ended June 30, 2022 and 2021, respectively. Other income for the three months ended June 30, 2022 consisted primarily of interest income, partially offset by foreign exchange losses. Other income, net for the three months ended June 30, 2021 consisted primarily of interest income and foreign exchange gains.

Liquidity and Capital Resources

Sources of Liquidity

Since our initial public offering in June 2015, our operations have been financed primarily through sales of common stock and pre-funded warrants, as well as borrowings under our credit facilities. As of June 30, 2022, we had $54.8 million of cash and cash equivalents available to us.

Capital Requirements

We have not yet achieved profitability and expect to continue to incur operating and net losses, as well as negative cash flows from operations, for the foreseeable future. We have not generated any revenue to date. Until such time, if ever, as we can generate substantial product revenue, and subject to our pursuit of strategic alternatives, we expect to primarily finance our cash needs using our existing cash.

For the three months ended June 30, 2022 and the fiscal year ended March 31, 2022, we incurred net losses of $8.4 million and $71.9 million, respectively. As of June 30, 2022, our cash and cash equivalents totaled $54.8 million and our accumulated deficit was $871.4 million. We expect that our existing cash and cash equivalents of $54.8 million at June 30, 2022 will enable us to fund our current operating plan beyond the twelve-month period following the date that the accompanying unaudited condensed consolidated financial statements and footnotes were issued. In order to meet longer operating requirements, including as we continue to explore and pursue strategic alternatives, we will need additional capital resources. We have based these estimates on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Our principal operating focus is currently on pursuing a range of strategic alternatives. We believe we have sufficient cash resources, net of costs which we estimate to incur in relation to such a transaction, to complete a strategic transaction. If we do not complete a strategic transaction, we may consider dissolving the Company and liquidating the assets. In that case, we believe that our cash resources are sufficient to satisfy estimated liabilities and costs of such a process. However, the achievement of a strategic transaction and the associated costs and timing thereof is uncertain and the time, cost and reserves which may be required to be held back for future claims is uncertain so our estimates may prove incorrect.

Our future funding requirements, both near and long-term, will depend on many factors, including, but not limited to, the timing and outcome of our exploration of, and execution upon any, potential strategic alternatives, the cost of obtaining necessary intellectual property and defending potential intellectual property disputes, realization of the anticipated benefits of our headcount reduction, and the costs of operating as a public company.

We expect to primarily finance our cash needs using our existing cash. We do not currently have any committed external source of funds. We continually assess multiple options to obtain additional funding to support our operations, including proceeds from offerings of our equity securities or debt financings. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Sources of a sufficient amount of financing may not be available to us on favorable terms, if at all, and our ability to raise additional capital has been, and may continue to be, adversely impacted by, among other things, potentially worsening global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. In addition, extreme price and volume fluctuations in the stock market in general, and the Nasdaq Global Select Market, in particular, have resulted in volatile and sometimes decreased stock prices for many companies, including us. Broad market and industry factors, including worsening economic conditions and other adverse effects or developments relating to the evolving effects of the COVID-19 pandemic, may negatively affect the market price of our common stock, regardless of our actual operating performance, and impact our ability to raise sufficient additional capital on acceptable terms, if at all.

At-the-Market Equity Offering Program

We have engaged SVB Securities LLC as our agent to sell shares of our common stock from time to time through an at-the-market equity offering program. SVB Securities LLC is entitled to compensation for its services in an amount equal to 3% of the gross proceeds of any of our shares of common stock sold. During the three months ended June 30, 2022, we did not sell any shares of common stock under this program. During the three months ended June 30, 2021, we sold approximately 0.2 million shares of our common stock for total proceeds of approximately $0.5 million, net of brokerage fees, under this program. As of June 30, 2022, we sold a total of approximately $30.4 million shares of our common stock for aggregate proceeds of approximately $92.0 million, net of brokerage fees, under and since the inception of this program.

Cash Flows

The following table sets forth a summary of our cash flows for each of the periods shown (in thousands):

	Three Months Ended June 30,	
	2022	2021
Net cash used in operating activities	$ (8,681)	$ (12,652)
Net cash (used in) provided by investing activities	(277)	4,163
Net cash provided by financing activities	—	479

Operating Activities

Cash flows from operating activities consist of net loss adjusted for non-cash items, including depreciation and stock-based compensation expenses, as well as the effect of changes in working capital and other activities.

For the three months ended June 30, 2022, net cash used in operating activities was $8.7 million and was primarily attributable to a net loss of $8.4 million, which includes costs incurred for research and development activities, including CRO fees, manufacturing, regulatory and other clinical trial costs, as well as our general and administrative expenses, in addition to net decreases in accrued expenses and accounts payable of $3.9 million, which were partially offset by a net decrease in prepaid expenses and other current assets of $2.4 million and a decrease in income tax receivable of $1.3 million.

For the three months ended June 30, 2021, net cash used in operating activities was $12.7 million and was primarily attributable to a net loss of $11.9 million, which includes costs incurred for research and development activities, including CRO fees, manufacturing, regulatory and other clinical trial costs, as well as our general and administrative expenses, in addition to net decreases in accrued expenses and accounts payable of $3.2 million, which were partially offset by $1.3 million of non-cash stock-based compensation expense and a net decrease in prepaid expenses and other current assets of $1.1 million.

Investing Activities

Cash used in investing activities was $0.3 million for the three months ended June 30, 2022, consisting of purchases of fixed assets. Cash provided by investing activities was $4.2 million for the three months ended June 30, 2021, consisting primarily of $4.3 million of cash proceeds from the sale of our long-term investment in Arvelle, partially offset by purchases of fixed assets.

Financing Activities

For the three months ended June 30, 2022, net cash provided by financing activities was zero. For the three months ended June 30, 2021, net cash provided by financing activities was approximately $0.5 million and consisted of net proceeds from the issuance and sale of our shares of common stock under our share sales agreement with SVB Securities LLC.

Contractual Obligations

Our contractual obligations did not materially change during the three months ended June 30, 2022 as compared to those disclosed in our Annual Report on Form 10-K for the year ended March 31, 2022.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our unaudited condensed consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"). The preparation of these unaudited condensed consolidated financial statements and accompanying notes requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities as of the dates of the balance sheets and the reported amounts of expenses during the reporting periods. In accordance with U.S. GAAP, we evaluate our estimates and judgments on an ongoing basis. Significant estimates include research and development accruals. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We define our critical accounting policies as those under U.S. GAAP that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles.

Our significant accounting policies are more fully described in Note 2, "Summary of Significant Accounting Policies," to our unaudited condensed consolidated financial statements in this Quarterly Report on Form 10-Q and in Note 2, "Summary of Significant Accounting Policies," to our audited consolidated financial statements in our Annual Report on Form 10-K. Not all of these significant accounting policies, however, require that we make estimates and assumptions that we believe are "critical accounting estimates." We believe that our estimates relating to research and development accruals have the greatest potential impact on our consolidated financial statements and consider these to be our critical accounting policies and estimates and are "critical accounting estimates." There have been no material changes to our critical accounting policies and significant judgments and estimates as compared to the critical accounting policies and significant judgments and estimates described in our Annual Report.

Recent Accounting Pronouncements

For a discussion of recent accounting pronouncements, see "Note 2(F)—Recent Accounting Pronouncements" in the accompanying notes to the unaudited condensed consolidated financial statements included in "Item 1—Financial Statements" of this Quarterly Report on Form 10-Q for additional information.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Market risk is the potential loss arising from adverse changes in market rates and market prices such as interest rates, foreign currency exchange rates, and changes in the market value of equity instruments. As of June 30, 2022, we had total cash and cash equivalents and restricted cash of $56.0 million, with cash consisting of non-interest-bearing deposits denominated in the U.S. dollar, Swiss franc and Euro, and cash equivalents consisting of interest-bearing money market fund deposits denominated in the U.S. dollar, which are invested in debt securities issued or guaranteed by the U.S. government and repurchase agreements fully collateralized by U.S. Treasury and U.S. government securities. We have policies requiring us to invest in high-quality issuers, limit our exposure to any individual issuer, and ensure adequate liquidity. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our cash equivalent investments are in the form of money market funds and marketable securities and are invested in U.S. Treasury obligations. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our portfolio.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Under the supervision of our principal executive and principal financial officer, we evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2022, the end of the period covered by this Quarterly Report on Form 10-Q. The term "disclosure controls and procedures" (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), means controls and other procedures of a company that are designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms.

Disclosure controls and procedures include, without limitation, controls and procedures designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow for timely decisions regarding required disclosure. Based on this evaluation, our principal executive and principal financial officer concluded that our disclosure controls and procedures were effective as of June 30, 2022, at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(d) and 15d-15(d) under the Exchange Act) that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Our management, including our principal executive and principal financial officer, does not expect that our disclosure controls and procedures or our internal controls will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within Sio Gene Therapies Inc. have been detected.

PART II: OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may become involved in legal proceedings relating to claims arising from the ordinary course of business. We are not currently a party to any material legal proceedings, and we are not aware of any pending or threatened legal proceeding against us that we believe could have an adverse effect on our business, operating results or financial condition.

Item 1A. Risk Factors

You should carefully consider the following risk factors, in addition to the other information contained in this Quarterly Report on Form 10-Q, including the section of this report titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our unaudited condensed consolidated financial statements and related notes. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties of which we are unaware, or that we currently believe are not material, may also become important factors that adversely affect our business. If any of the events described in the following risk factors and the risks described elsewhere in this report occurs, our business, operating results and financial condition could be seriously harmed, and the trading price of our common stock could decline. This Quarterly Report on Form 10-Q also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this report.

Risks Related to our Strategic Alternative Process

We may not be successful in identifying and implementing any strategic business combination or other transaction and any strategic transactions that we may consummate in the future could have negative consequences.

We continue to evaluate all potential strategic options for the Company, including a merger, reverse merger, sale, wind-down, liquidation and dissolution or other strategic transaction. However, there can be no assurance that we will be able to successfully consummate any particular strategic transaction. The process of continuing to evaluate these strategic options may be very costly, time-consuming and complex and we have incurred, and may in the future incur, significant costs related to this continued evaluation, such as legal and accounting fees and expenses and other related charges. We have also incurred, and may continue to incur, additional unanticipated expenses in connection with this process. A considerable portion of these costs will be incurred regardless of whether any such course of action is implemented or transaction is completed. Any such expenses will decrease the remaining cash available for use in our business and may diminish or delay any future distributions to our stockholders or make our company less attractive to potential strategic counterparties. Any delays in identifying a potential counterparty will cause our cash balance to continue to deplete, which could make us less attractive as a strategic counterparty. The continued review of our strategic options may also create continued uncertainty for our employees and this uncertainty has adversely affected, and may continue to adversely affect, our ability to retain key employees and to hire new talent necessary to maintain our ongoing operations or to execute additional potential strategic options, which could have a material adverse effect on our business. Further, the market capitalization of our company has from time to time fallen below the value of our cash and cash equivalents. Potential counterparties in a strategic transaction involving our company may place minimal or no value on our remaining assets or company attributes.

In addition, any strategic business combination or other transactions that we may consummate in the future could have a variety of negative consequences and we may implement a course of action or consummate a transaction that yields unexpected results that adversely affect our business and decrease the remaining cash available for use in our business or the execution of our strategic plan. Our board of directors remains dedicated to diligently deliberating upon and making informed decisions that the directors believe are in the best interests of the Company and its stockholders. However, there can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, be successfully consummated, lead to increased stockholder value, or achieve the anticipated results. Any failure of such potential transaction to achieve the anticipated results could significantly impair our ability to enter into any future strategic transactions and may significantly diminish or delay any future distributions to our stockholders. In addition, given the recent restructuring of our operations, it may be difficult to evaluate our current business and future prospects on the basis of historical operating performance.

If we are successful in completing a strategic transaction, we may be exposed to other operational and financial risks.

The negotiation and consummation of any strategic transaction may also require more time or greater cash resources than we anticipate and expose us to other operational and financial risks, including:

- increased near-term and long-term expenditures;
- exposure to unknown liabilities;
- higher than expected acquisition or integration costs;
- incurrence of substantial debt or dilutive issuances of equity securities to fund future operations;
- write-downs of assets or goodwill or incurrence of non-recurring, impairment or other charges;
- increased amortization expenses;

- difficulty and cost in combining the operations and personnel of any acquired business with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired business due to changes in management and ownership;
- inability to retain key employees of our company or any acquired business; and
- possibility of future litigation.

Any of the foregoing risks could have a material adverse effect on our business, financial condition and prospects.

If a strategic transaction is not consummated, our Board may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

There can be no assurance that a strategic transaction will be completed. If a strategic transaction is not completed, including if our Board determines that no potential transactions or counterparties would be in the best interests of our stockholders, our Board may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision, as with the passage of time the amount of cash available for distribution will be reduced as we continue to fund our operations. Such timing is uncertain and depends on a variety of factors, some of which are not within our control. In addition, if our Board were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations and the timing of any such resolution is uncertain. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation. If a dissolution and liquidation were pursued, our Board, in consultation with our advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up.

We may become involved in securities class action litigation that could divert management's attention and harm the company's business, and insurance coverage may not be sufficient to cover all costs and damages.

In the past, securities class action litigation has often followed certain significant business transactions, such as the sale of a company or announcement of any other strategic transaction, or the announcement of negative events, such as discontinuations of clinical programs. These events may also result in investigations by the SEC. We may be exposed to such litigation or investigation even if no wrongdoing occurred. Litigation and investigations are usually expensive and divert management's attention and resources, which could adversely affect our business and cash resources and our ability to consummate a potential strategic transaction or the ultimate value our stockholders receive in any such transaction.

Risks Related to Our Business, Financial Position and Capital Requirements

We have a limited operating history and have never generated any product revenues.

We are a clinical-stage company with a limited operating history. Our operations to date have been limited to organizing and staffing our company, raising capital, acquiring product candidates and advancing our product candidates into clinical development. We have not yet demonstrated an ability to successfully complete a registration-enabling pivotal clinical trial, obtain marketing approval, manufacture a clinical-stage or commercial-scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. We have recently terminated our clinical programs and have focused our efforts largely on identifying a strategic transaction or alternative. While we continue to explore certain pre-clinical research and development initiatives, we may never be successful in developing or commercializing any product candidates, including following consummation of any strategic transaction. Consequently, we have no meaningful operations upon which to evaluate our business and predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

We have never been profitable, have not generated any revenue from product sales, and have no products approved for commercial sale.

Even if we consummate a strategic transaction with another clinical-stage development company or determine to pursue development of future product candidates, we do not know when those candidates will generate revenue, if at all. Our ability to generate product revenue will depend on a number of factors, including our ability to:

- successfully commence and complete clinical trials and obtain regulatory approval for the marketing of product candidates;
- establish effective sales, marketing and distribution systems for product candidates;
- add operational, financial and management information systems and personnel, including personnel to support our clinical, manufacturing and planned future commercialization efforts and operations as a public company;
- initiate and continue relationships with third-party suppliers and manufacturers and have clinical and commercial quantities of product candidates manufactured at acceptable cost and quality levels;
- attract and retain an experienced management and advisory team;
- raise additional funds when needed and on terms acceptable to us;
- achieve broad market acceptance of future products in the medical community and with third-party payors and consumers;
- launch commercial sales of future products, whether alone or in collaboration with others;
- compete effectively with other biotechnology companies; and
- obtain, maintain, expand and protect necessary intellectual property rights.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses, or when, or if, we will be able to achieve or maintain profitability. Even if any future product candidates are approved for commercial sale, we anticipate incurring significant costs associated with their commercial launch. If we cannot successfully execute any one of the foregoing, our business may not succeed, and your investment will be adversely affected.

Our business, operations and future prospects could continue to be adversely impacted by the effects of health epidemics, including the recent COVID-19 pandemic.

Our business, operations and future prospects could continue to be adversely impacted by health epidemics wherever we have business operations. For example, the global COVID-19 pandemic and measures introduced by local, state and federal governments to contain the virus and mitigate its public health effects have significantly impacted and may continue to significantly impact our industry and the global economy. These and similar, and perhaps more severe, disruptions in our operations, our industry and the global economy could negatively impact our business, operating results and financial condition.

Our prior clinical trials have been affected by the COVID-19 pandemic in the past, including emerging variant strains of the virus. Clinical trial progression, dosing, patient enrollment and related activities have been delayed due to concerns among patients about participating in clinical trials during a pandemic. Certain of our patients experienced difficulty following certain aspects of clinical trial protocols due to quarantines that impeded patient movement and interrupted healthcare services. For example, patients in our prior clinical trials for AXO-AAV-GM1 and AXO-AAV-GM2 were infants, often with advanced disease, who may not be able to safely participate in clinical trials for these product candidates during the COVID-19 pandemic or if they have not or are not eligible to receive COVID-19 vaccinations. Additionally, certain elderly patients in previous clinical trials were either unable to, or refused to, participate in clinical assessments at our research sites in the United Kingdom due to the COVID-19 pandemic.

While the potential future economic impact caused by, and the duration of, the COVID-19 pandemic is difficult to assess or predict, the COVID-19 pandemic (as well as the invasion of Ukraine by Russia and the related sanctions imposed against Russia) could result in significant and prolonged disruption of global financial markets, which has negatively impacted and may continue to reduce our ability to access capital, limiting the financial resources available to us. These impacts have also been caused by related effects of the COVID-19 pandemic, such as inflationary pressures and stock price volatility, particularly in the biotechnology and drug development sectors. In addition, macroeconomic uncertainty, economic recession or additional market corrections resulting from, among other things, the spread of COVID-19 could materially affect our business and the value of our common stock. These impacts may harm our ability to identify and consummate a strategic transaction on attractive terms or at all. In particular, many potential counterparties in any strategic transaction will require additional external financing to realize the benefits from such transaction, which efforts have been challenged by, and such financings may be difficult to execute as a result of, the foregoing factors.

The ultimate impact and evolving effects of the COVID-19 pandemic or a similar health epidemic are highly uncertain and subject to change. While vaccines have become available in many countries and most economies have reopened, we do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole. New waves of outbreak or variant strains of the virus have emerged and may result in re-closures or other preventative measures. These effects could harm our operations, and we will continue to monitor the COVID-19 situation closely.

Our corporate restructuring and the associated headcount reduction may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business.

In June 2022, we completed an organizational restructuring that significantly reduced our workforce. We may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from the restructuring, our operating results and financial condition would be adversely affected. Due to our limited resources, we may not be able to effectively manage our operations or retain qualified personnel, which may result in weaknesses to our infrastructure and operations, risks that we may be unable to comply with legal and regulatory requirements, risks to our internal controls and disclosure controls, and loss of employees and reduced productivity among remaining employees. The loss of additional personnel may also negatively impact our ability to identify and consummate a strategic transaction.

The restructuring resulted in the loss of institutional knowledge and expertise and the reallocation of and combination of certain roles and responsibilities across the organization, all of which could adversely affect our operations. Further, the restructuring and possible additional cost-containment measures may yield unintended consequences, such as attrition beyond our intended workforce reduction and reduced employee morale. We may be required to rely more heavily on temporary or part-time employees, third party contractors and consultants to assist with managing our operations. These consultants are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. We will have only limited control over the activities of these consultants and can generally expect these individuals to devote only limited time to our activities. Failure of any of these persons to devote sufficient time and resources to our business could harm our business. Employee litigation related to the headcount reduction could be costly and prevent management from fully concentrating on the business.

If our management is unable to successfully manage this transition and restructuring activities, our expenses may be more than expected and we may be unable to implement our business strategy. As a result, our future financial performance, operations, and prospects would be negatively affected.

We expect to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

Investment in pharmaceutical and biological product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or become commercially viable. We have never generated any revenues, and we cannot estimate with precision the extent of our future losses. We do not currently have any products that are available for commercial sale and we may never generate revenue from selling products or achieve profitability. We expect to continue to incur substantial and increasing losses as we identify strategic alternatives and continue exploration of certain pre-clinical research and development initiatives. We are uncertain when or if we will achieve profitability and, if so, whether we will be able to sustain it.

Our ability to produce revenue and achieve profitability is dependent on our ability to identify and consummate a strategic transaction or identify and develop future product candidates, obtain necessary regulatory approvals, and have any such product candidates manufactured and successfully marketed and commercialized. We cannot assure you that we will be profitable even if we successfully commercialize any future product candidates. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Failure to become and remain profitable may adversely affect the market price of our common stock and our ability to raise capital and continue operations.

In order to meet our long-term operating requirements, including following any strategic transaction, we will need, among other things, additional capital resources. We could use our available capital resources sooner than we currently expect. We continually assess multiple options to obtain additional funding to support our operations, including proceeds from offerings of our equity securities or debt, or transactions involving product development, technology licensing or collaboration arrangements, or other sources of capital. Sources of a sufficient amount of financing may not be available to us on favorable terms, if at all, and our ability to raise additional capital has been, and may continue to be, adversely impacted by, among other things, potentially worsening global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. If we or any potential strategic counterparties are unable to raise additional capital in sufficient amounts or on acceptable terms, we may not be able to successfully identify and consummate a strategic transaction or pursue the development of any future product candidate.

Our current or prior employees, independent contractors, principal investigators, consultants, commercial collaborators, manufacturers, service providers and other vendors, or those of our affiliates, may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations.

Our employees and contractors, including any current or prior principal investigators, consultants, commercial collaborators, manufacturers, service providers and other vendors, or those of our affiliates, may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or other unauthorized activities that violate the laws and regulations, including those of the FDA and other similar regulatory bodies that require the reporting of true, complete and accurate information; manufacturing standards; federal, state and foreign healthcare fraud and abuse laws and data privacy; or laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and other business arrangements in the healthcare industry are subject to extensive laws intended to prevent fraud, kickbacks, self-dealing, bribery, corruption, antitrust violations, and other abusive practices. These laws may restrict or prohibit a wide range of business activities, including research, manufacturing, distribution, pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in nonclinical studies or clinical trials or illegal misappropriation of drug product, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee or third-party misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Additionally, we are subject to the risk that a person or government agency could allege such fraud or other misconduct, even if none occurred. Even though we have ceased clinical development activities for our existing programs, if our employees, independent contractors, principal investigators, consultants, commercial collaborators, manufacturers, service providers or other vendors, or those of our affiliates, are alleged or found to be in violation of any such regulatory standards or requirements, or become subject to a corporate integrity agreement or similar agreement and curtailment of our operations, it could have a significant impact on our business and financial results, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, FDA debarment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight, any of which could adversely affect our ability to operate our business and our results of operations.

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

The prior use of our product candidates in clinical trials exposes us to the risk of product liability claims. Product liability claims might be brought against us by clinical trial patients, health care providers, pharmaceutical companies or others otherwise coming into contact with our prior product candidates. On occasion, large monetary judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. If we are not successful in defending ourselves against product liability claims, we could incur liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation and significant negative media attention;
- significant costs to defend related litigation;
- distraction of management’s attention from our primary business;
- difficulty in attracting strategic counterparties or the ability for us to realize anticipated benefits of any strategic transaction;
- substantial monetary awards to patients or other claimants; and

- inability to commercialize any future product candidate.

The product liability insurance we currently carry, and any additional product liability insurance coverage we acquire in the future, may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

We are subject to stringent U.S. and foreign privacy laws, regulations and standards related to data privacy and security. If we fail to comply with such requirements, we may be subject to liabilities that adversely affect our business, operations and financial performance, and/or harm to our reputation.

We are subject to laws and regulations requiring that we take measures to protect the privacy and security of certain information we gather and use in our business. For example, in the U.S., the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") and its implementing regulations impose, among other requirements, certain regulatory and contractual requirements regarding the privacy and security of personal health information. In addition to HIPAA, numerous other federal and state laws, including, without limitation, state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use, and storage of personal information. In addition, in June 2018, California enacted the California Consumer Privacy Act ("CCPA") which took effect on January 1, 2020. The CCPA gives California residents expanded rights to access and require deletion of their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that may increase data breach litigation. Although the CCPA includes exemptions for certain clinical trials data, and HIPAA protected health information, the law may increase our compliance costs and potential liability with respect to other personal information we collect about California residents. The CCPA has prompted a number of proposals for new federal and state privacy legislation that, if passed, could increase our potential liability, increase our compliance costs and adversely affect our business.

We may also be subject to or affected by laws and regulations globally, including regulatory guidance, governing the collection, use, disclosure, security, transfer and storage of personal data, such as information that we collect about patients and healthcare providers in connection with future clinical trials and our other operations in the U.S. and abroad. The global legislative and regulatory landscape for privacy and data protection continues to evolve, and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. This evolution may create uncertainty in our business, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future.

Any failure or perceived failure by us to comply with federal, state, or foreign laws or self-regulatory standards could result in negative publicity, diversion of management time and effort and proceedings against us by governmental entities or others. In many jurisdictions, enforcement actions and consequences for noncompliance are rising. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business.

Our current and future relationships with investigators, health care professionals, consultants, third-party payors, and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations.

These laws may regulate the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our products for which we obtain marketing approval. Such laws include:

- the federal Anti-Kickback Statute 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, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation; 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 civil False Claims Act;

- the federal false claims laws including the civil False Claims Act, which can be enforced through civil whistleblower or qui tam actions, and civil monetary penalties laws, 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, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or knowingly making, or causing to be made, a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; in addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- HIPAA imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false or fraudulent statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information on health plans, health care clearing houses, and certain health care providers, known as covered entities, and their business associates, defined as independent contractors or agents of covered entities that create, receive or obtain protected health information in connection with providing a service for or on behalf of a covered entity as well as their covered subcontractors;

- a number of federal, state and foreign laws, regulations, guidance and standards that impose requirements regarding the protection of health data that are applicable to or affect our operations;

- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by the physicians described above and their immediate family members; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to our business practices, including but not limited to, research, distribution, sales, and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing, as well as state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable healthcare laws. If our operations are found to be in violation of any of these or any other health regulatory laws that may apply to us, we may be subject to significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Even the mere issuance of a subpoena or the fact of an investigation alone, regardless of the merit, may result in negative publicity, a drop in our stock price, and other harm to our business, financial condition and results of operations.

Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

Risks Related to Our Intellectual Property

We may need to license intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property, including patent rights and trade secrets that are important or necessary to the development of any future product candidates. It may be necessary for us to use the patented or proprietary technology of one or more third parties to manufacture or commercialize any future product candidates, in which case we would be required to obtain a license from these third parties on commercially reasonable terms, or our business could be harmed, possibly materially. If any such patents were to be asserted against us, there is no assurance that a court would find in our favor or that, if we choose or are required to seek a license, a license to any such patents would be available to us on acceptable terms or at all.

If we breach any license or collaboration agreements, it could have an adverse effect on our business.

Disputes may arise between us and any of these counterparties regarding rights that are subject to such agreements, including, but not limited to:

- the scope of rights and obligations under an agreement and other interpretation-related issues; and
- the effects of termination.

Any such dispute could have an adverse effect on our business. Any uncured, material breach under such agreements could result in liability for potential damages.

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

Competitors may infringe or otherwise violate our future patents, the patents of licensors or future strategic partners, or our other intellectual property rights. To counter infringement or unauthorized use, we may be required to file legal claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours, any future strategic partner, or any licensor is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of such patents at risk of being invalidated or interpreted narrowly and could put patent applications at risk of not issuing. The initiation of a claim against a third party may also cause the third party to bring counter claims against us such as claims asserting that such patents are invalid or unenforceable.

In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement, or lack of statutory subject matter. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant material information from the USPTO, or made a materially misleading statement, during prosecution. Third parties may also raise similar validity claims before the USPTO in post-grant proceedings such as ex parte reexaminations, inter partes review, or post-grant review, or oppositions or similar proceedings outside the United States, in parallel with litigation or even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. We cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. For the patents and patent applications that we may license, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of any future patent protection on the subject matter of such patents. Such a loss of patent protection could harm our business.

We may not be able to detect or prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Any litigation or other proceedings to enforce our intellectual property rights may fail, and even if successful, may result in substantial costs and distract our management and other employees.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common stock.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing any patents that may be issued as a result of any pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

We may not be able to protect our intellectual property rights throughout the world, which could impair our business.

Filing, prosecuting and defending patents covering our future product candidates throughout the world would be prohibitively expensive. Competitors may use our technologies or the technologies of any future strategic partner in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These products may compete with any future products in jurisdictions where we do not have any issued or licensed patents and any future patent claims, or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of some countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of patents generally in some countries. Proceedings to enforce any patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put any patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful.

Furthermore, our or any future strategic partner's efforts to enforce any intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we may develop or license in the future.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of their former employers or other third parties.

We and any future strategic partner employ individuals who were previously employed at other biotechnology or pharmaceutical companies. Although we seek to protect our ownership of intellectual property rights by ensuring that our agreements with our employees, collaborators, and other third parties with whom we do business include provisions requiring such parties to assign rights in inventions to us, we or any future strategic partner may be subject to claims that we, our partner or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We or any future partner may also be subject to claims that former employers or other third parties have an ownership interest in patents or patent applications filed by us. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition.

In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. 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.

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

Any trademarks we have obtained or may obtain may be infringed or successfully challenged, resulting in harm to our business.

We expect to rely on trademarks as one means to distinguish any of our future product candidates that are approved for marketing from the products of our competitors. Once we select new trademarks and apply to register them, our trademark applications may not be approved. Third parties may oppose or attempt to cancel our trademark applications or trademarks, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks.

If we attempt to enforce our trademarks and assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our or any future strategic partner's intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to achieve or maintain a competitive advantage.

Risks Related to Our Common Stock

We may be treated as a "public shell" company which could have negative consequences, including potential Nasdaq delisting of our common stock.

We may be treated as a "public shell" under the Nasdaq rules and the Securities Act. Although the evaluation of whether a listed company is a public shell company is based on a facts and circumstances determination, a Nasdaq-listed company with no or nominal operations and either no or nominal assets, assets consisting solely of cash and cash equivalents, or assets consisting of any amount of cash and cash equivalents and nominal other assets is generally considered to be a public shell. Listed companies determined to be public shells by Nasdaq may be subject to delisting proceedings or additional and more stringent listing criteria.

If Nasdaq should delist our common stock from trading, a reduction in some or all of the following may occur, each of which could have a material adverse effect on holders of our common stock: the liquidity of our common stock; the market price of our common stock; the number of institutional and general investors that will consider investing in our common stock; the number of investors in general that will consider investing in our common stock; the number of market makers in our common stock; the availability of information concerning the trading prices and volume of our common stock; and the number of broker-dealers willing to execute trades in our common stock. In addition to the foregoing, there are certain consequences under the Securities Act of being a public shell, including the unavailability of Rule 144 thereunder for the resale of restricted securities, the inability to utilize Form S-8 for the registration of employee benefit plan securities; and the inability to utilize Form S-3 under the "baby shelf" rules applicable to companies with a non-affiliate market capitalization of less than $75 million. In addition, the potential determination that we are a shell company or the prospective loss of our listing on Nasdaq could make us less attractive as a partner in any potential strategic transaction.

The price of our common stock currently does not meet the requirements for continued listing on the Nasdaq Global Select Market. If we fail to maintain or regain compliance with the minimum listing requirements, our common stock will be subject to delisting. Our ability to publicly or privately sell equity securities and the liquidity of our common stock could be adversely affected if our common stock is delisted.

The continued listing standards of the Nasdaq Global Select Market require, among other things, that the minimum price of a listed company's stock be at or above $1.00. If the minimum bid price is below $1.00 for a period of more than 30 consecutive trading days, the listed company will fail to be in compliance with Nasdaq's listing rules and, if it does not regain compliance within the grace period, will be subject to delisting. The bid price of our common stock has recently closed below the minimum $1.00 per share requirement and on March 16, 2022 we received a notification of noncompliance from Nasdaq. In accordance with Nasdaq's listing rules, we will be afforded 180 calendar days to regain compliance with the bid price requirement, with a potential for an additional 180 calendar days at Nasdaq's discretion. In order to regain compliance, the bid price of our common stock must close at a price of at least $1.00 per share for a minimum of 10 consecutive trading days.

If we fail to regain compliance with the minimum bid price requirement, or if we fail to meet other continued listing requirements in the future, our common stock will be subject to delisting. Delisting from Nasdaq could adversely affect our ability to consummate a strategic transaction and raise additional financing through the public or private sale of equity securities, and would significantly affect the ability of investors to trade our securities and negatively affect the value and liquidity of our common stock. Delisting could also have other negative results, including the potential loss of confidence by employees and the loss of institutional investor interest.

Unless our common stock continues to be listed on a national securities exchange, it will become subject to the so-called "penny stock" rules that impose restrictive sales practice requirements.

If we are unable to maintain the listing of our common stock on Nasdaq or another national securities exchange, our common stock could become subject to the so-called "penny stock" rules if the shares have a market value of less than $5.00 per share. The SEC has adopted regulations that define a penny stock to include any stock that has a market price of less than $5.00 per share, subject to certain exceptions, including an exception for stock traded on a national securities exchange. The SEC regulations impose restrictive sales practice requirements on broker-dealers who sell penny stocks to persons other than established customers and accredited investors. An accredited investor generally is a person whose individual annual income exceeded $200,000, or whose joint annual income with a spouse exceeded $300,000 during the past two years and who expects their annual income to exceed the applicable level during the current year, or a person with net worth in excess of $1.0 million, not including the value of the investor's principal residence and excluding mortgage debt secured by the investor's principal residence up to the estimated fair market value of the home, except that any mortgage debt incurred by the investor within 60 days prior to the date of the transaction shall not be excluded from the determination of the investor's net worth unless the mortgage debt was incurred to acquire the residence. For transactions covered by this rule, the broker-dealer must make a special suitability determination for the purchaser and must have received the purchaser's written consent to the transaction prior to the sale. This means that if we are unable to maintain the listing of our common stock on a national securities exchange, the ability of stockholders to sell their common stock in the secondary market could be adversely affected. If a transaction involving a penny stock is not exempt from the SEC's rule, a broker-dealer must deliver a disclosure schedule relating to the penny stock market to each investor prior to a transaction. The broker-dealer must also disclose the commissions payable to both the broker-dealer and its registered representative, current quotations for the penny stock, and, if the broker-dealer is the sole market-maker, the broker-dealer must disclose this fact and the broker-dealer's presumed control over the market. Finally, monthly statements must be sent disclosing recent price information for the penny stock held in the customer's account and information on the limited market in penny stocks.

The market price of our common stock has been and is likely to continue to be highly volatile, and you may lose some or all of your investment.

The market price of our common stock has been and is likely to continue to be highly volatile and may be subject to wide fluctuations in response to a variety of factors, including the following:

- our ability to identify and consummate a strategic transaction;
- inability to obtain additional funding and deterioration of financing conditions in our industry;
- our internal restructuring and workforce reduction;
- inability to obtain, protect or maintain necessary intellectual property;
- adverse regulatory decisions or statements;
- changes in the structure of healthcare payment systems;
- failure to meet or exceed the estimates and projections of the investment community;
- changes in the market valuations of similar companies;
- market conditions in the pharmaceutical and biotechnology sectors, and the issuance of new or changed securities analysts' reports or recommendations;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- significant lawsuits, including patent or stockholder litigation, and disputes or other developments relating to our proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;

- additions or departures of key personnel;
- short sales of our common stock;
- sales of shares of our common stock by us or our stockholders in the future;
- negative coverage in the media or analyst reports, whether accurate or not;
- issuance of subpoenas or investigative demands, or the public fact of an investigation by a government agency, whether meritorious or not;
- our ability to maintain the listing of our common stock on Nasdaq;
- trading volume of our common stock;
- general economic, industry and market conditions, including macroeconomic uncertainty and effects of inflation; and
- the other factors described in this "Risk Factors" section.

In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies, including in connection with the ongoing COVID-19 pandemic, which has resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. These fluctuations have often been unrelated or disproportionate to the operating performance of those companies. Broad market and industry factors, including potentially worsening economic conditions and other adverse effects or developments relating to the ongoing COVID-19 pandemic, as well as general economic, political, regulatory and market conditions, may negatively affect the market price of our common stock, regardless of our actual operating performance.

Volatility in our stock price could subject us to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities and/or the discontinuation of development of a product candidate due to adverse clinical circumstances or results. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management’s attention and resources, which could harm our business.

An active trading market for our common stock may not be sustained.

Although our common stock is listed on Nasdaq, we cannot assure you that an active trading market for our common stock will be sustained. In addition, as a result of Roivant Sciences Ltd. ("RSL") owning approximately 25.1% of our shares of common stock outstanding as of August 9, 2022, trading in our common stock may be less liquid than the stock of companies with broader public ownership. If an active market for our common stock is not sustained, you may not be able to sell your stock quickly or at the market price. An inactive market may also impair our ability to raise capital to continue to fund operations by selling shares of our common stock and may impair our ability to acquire other companies or technologies by using our common stock as consideration.

RSL owns a significant percentage of our shares of common stock and is able to exert significant control over matters subject to stockholder approval.

Based on shares of our common stock outstanding as of August 9, 2022, RSL beneficially owns approximately 25.1% of the voting power of our outstanding shares of common stock and has the ability to substantially influence us through this ownership position. RSL’s interests may not always coincide with our corporate interests or the interests of other stockholders, and RSL may act in a manner with which you may not agree or that may not be in the best interests of our other stockholders. In 2020, RSL closed a transaction with Sumitomo Dainippon Pharma Co., Ltd. ("Sumitomo") that includes a grant to Sumitomo of a right of first refusal with respect to our shares of common stock held by RSL, which could result in RSL taking actions that may not coincide with our corporate interests or the interests of other stockholders, and could impact our ability to undertake certain corporate transactions. RSL recently became a publicly-traded corporation. There may be changes to the management or ownership of RSL that could impact RSL’s interests in a way that may not coincide with our corporate interests or the interests of other stockholders. So long as RSL continues to own a significant amount of our equity, RSL will continue to be able to strongly influence our decisions.

Our organizational and ownership structure may create significant conflicts of interests.

Our organizational and ownership structure involves a number of relationships that may give rise to certain conflicts of interest between us and minority holders of our common stock, on the one hand, and RSL and its shareholders, on the other hand. Certain of our directors and employees have equity interests in RSL and, accordingly, their interests may be aligned with RSL's interests, which may not always coincide with our corporate interests or the interests of our other stockholders. Further, our other stockholders may not have visibility into the RSL ownership of any of our directors or officers, which may change at any time through acquisition, disposition, dilution, or otherwise. Any change in our directors' or officers' RSL ownership could impact the interests of those holders.

In addition, we are party to certain related party agreements with RSL and its wholly owned subsidiaries, Roivant Sciences, Inc. ("RSI") and Roivant Sciences GmbH ("RSG"). These entities and their shareholders, including certain of our directors and employees, may have interests which differ from our interests or those of the minority holders of our common stock. For example, we are party to an information sharing and cooperation agreement with RSL pursuant to which RSL has granted us a right of first review on any potential dementia-related product or investment opportunity that RSL may consider pursuing. It is possible that we could fail to pursue a product candidate under this agreement and that product candidate is then successfully developed and commercialized by RSL or one of its other subsidiaries or affiliates. Any material transaction between us and RSL, RSI or RSG is subject to our related party transaction policy, which requires prior approval of such transaction by our Audit Committee. To the extent we fail to appropriately deal with any such conflicts of interests, it could negatively impact our reputation and ability to raise additional funds and the willingness of counterparties to do business with us, all of which could have an adverse effect on our business, financial condition, results of operations and cash flows.

Because we do not anticipate paying any cash dividends on shares of our common stock in the foreseeable future, capital appreciation, if any, would be your sole source of gain.

We have never declared or paid any cash dividends on shares of our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. As a result, capital appreciation, if any, of our common stock would be your sole source of gain on an investment in our common stock for the foreseeable future.

Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management and hinder efforts to acquire a controlling interest in us, and the market price of our common stock may be lower as a result.

There are provisions in our certificate of incorporation and bylaws that may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change of control was considered favorable by you and other stockholders. For example, our board of directors will have the authority to issue up to 10,000,000 shares of preferred stock. The board of directors can fix the price, rights, preferences, privileges, and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change of control transaction. As a result, the market price of our common stock and the voting and other rights of our stockholders may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders.

Our charter documents will also contain other provisions that could have an anti-takeover effect, including:

- stockholders will not be entitled to remove directors other than by a 66 2/3% vote and only for cause;
- stockholders cannot call a special meeting of stockholders;
- stockholders cannot act by written consent in lieu of a meeting; and
- stockholders must give advance notice to nominate directors or submit proposals for consideration at stockholder meetings.

In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions by prohibiting Delaware corporations from engaging in specified business combinations with particular stockholders of those companies. These provisions could discourage potential acquisition proposals and could delay or prevent a change of control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

Our certificate of incorporation and bylaws provide that the Court of Chancery of the State of Delaware or, under certain circumstances, the federal district courts of the United States of America are the exclusive forums for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or agents.

Our certificate of incorporation and bylaws provide that the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) is the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty;
- any action arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation, or our amended and restated bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

These provisions would not apply to suits brought to enforce a duty or liability created by the Securities Exchange Act of 1934, as amended (the "Exchange Act") or any claim for which the federal district courts of the United States of America have exclusive jurisdiction. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims.

Our stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of, and consented to, the provisions of our amended and restated certificate of incorporation described in the preceding sentences.

To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our certificate of incorporation and bylaws further provide that the federal district courts of the United States are the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our certificate of incorporation and bylaws. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find the exclusive-forum provisions in our amended and restated certificate of incorporation to be inapplicable or unenforceable, we may incur additional costs associated with resolving the dispute in other jurisdictions.

Your rights as a stockholder arise under Delaware law as well as our Delaware certificate of incorporation and bylaws.

The rights of our stockholders arise under our certificate of incorporation and bylaws as well as Delaware law. These organizational documents and Delaware law contain provisions for class actions and derivative actions, which may result in becoming involved in costly litigation, which could harm our business. In addition, our bylaws may generally be amended by our board of directors, as permitted under the provisions of Section 203 of the Delaware General Corporation Law ("DGCL"). Additionally, while the provisions of Section 203 of the DGCL regarding business combination provisions currently apply, there can be no assurance that the rights afforded by Section 203 of the DGCL will not be changed or rescinded by the Delaware legislature or courts in the future.

Future sales of shares of our common stock, or the perception that such sales may occur, could depress our stock price, even if our business is doing well.

As of August 9, 2022, 18,577,380 of our outstanding shares of common stock, representing 25.1% of our shares of common stock, were held by RSL. If RSL, or any of our executive officers or directors, were to sell our common stock, or if the market perceived that RSL or any of our executive officers or directors intend to sell our common stock, it could negatively affect our stock price. Such a decrease in our stock price could also in turn impair our ability to raise capital through the sale of additional equity securities.

Further, we have filed registration statements on Form S-8 under the Securities Act to register the common stock that may be issued under our equity incentive plans from time to time. Stock registered under these registration statements is available for sale in the public market subject to vesting arrangements and exercise of options, as well as Rule 144 in the case of our affiliates. Sales of these shares of common stock may negatively impact our stock price.

In addition, we have filed a "shelf" registration statement on Form S-3 under the Securities Act, allowing us, from time to time, to offer up to $750 million of any combination of registered shares of common stock or preferred stock, debt securities and warrants. We have also entered into a sales agreement with SVB Securities LLC to sell shares of common stock from time to time through an at-the-market equity offering program with an aggregate offering price of up to approximately $35.1 million remaining available to be sold as of August 9, 2022. To the extent we issue new shares of common stock as a result of needing additional capital, such stock could constitute a material portion of our then outstanding shares of common stock and cause dilution to our existing stockholders.

If we are unable to maintain proper and effective internal controls over financial reporting and disclosure controls and procedures, investor confidence in our company and, as a result, the value of our common stock, may be adversely affected.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and to protect from fraudulent, illegal or unauthorized transactions. Effective disclosure controls and procedures enable us to make timely and accurate disclosure of financial and non-financial information that we are required to disclose. If we cannot provide effective controls and reliable financial reports and other disclosures, our business and operating results could be harmed. We have in the past discovered, and may in the future discover, areas of our internal controls over financial reporting or disclosure controls and procedures that, even if effective, could be improved. Our recent workforce reduction and any further departures of accounting or finance function employees or consultants may increase the likelihood of future internal controls deficiencies.
We are required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on the effectiveness of our internal control over financial reporting as of the end of each fiscal year. Our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting until our first annual report required to be filed with the SEC following the date we are deemed to be an "accelerated filer," as defined in the Exchange Act.

If material weaknesses or control deficiencies occur or our disclosure controls and procedures are ineffective in the future, we may be unable to report our financial results or make other disclosures accurately on a timely basis, which could cause our reported financial results or other disclosures to be materially misstated and result in the loss of investor confidence and cause the market price of our common stock to decline.

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

We currently qualify as a "smaller reporting company". For so long as we continue to be a smaller reporting company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not smaller reporting companies, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and we also may still qualify as a "non-accelerated filer" which provides for exemption from compliance with the auditor attestation requirements of Section 404.

We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

The intended tax effects of our corporate structure prior to and following the Domestication and our corporate reorganization to align our corporate structure with current and future business activity (the "Reorganization"), and intercompany arrangements prior to the Domestication and Reorganization, depend on the application of the tax laws of various jurisdictions and on how we operate our business.

The Domestication and Reorganization involved the tax authorities and related rules and regulations of multiple international jurisdictions. In connection with the Domestication and Reorganization, we relied on the availability of certain exemptions from tax, and losses and other deductions, in certain such jurisdictions in respect of steps being taken as part of the Domestication and Reorganization, which are complex. If the tax authorities of any such jurisdictions do not agree with such exemptions, losses or deductions, we may be subject to tax charges and liabilities. Following the Domestication and Reorganization, we still have subsidiaries that are domiciled in the U.K., Switzerland and Ireland. Our corporate structure is organized so that we can achieve our business objectives in a tax-efficient manner following the Domestication and Reorganization and control operating expenses. Historically, we have conducted operations prior to the Domestication and Reorganization through subsidiaries in various countries and tax jurisdictions, including the U.K. and Switzerland, in part through intercompany service agreements between RSL and certain of its subsidiaries, our subsidiaries and us. In that case, our corporate structure and intercompany transactions, including the manner in which we developed and used our intellectual property, were organized to achieve our business objectives in a tax-efficient manner and in compliance with applicable transfer pricing rules and regulations. If two or more affiliated companies are located in different countries or tax jurisdictions, the tax laws and regulations of each country generally will require that transfer prices be the same as those between unrelated companies dealing at arms' length and that appropriate documentation be maintained to support the transfer prices. While we believe that we have operated in compliance with applicable transfer pricing laws, our transfer pricing procedures are not binding on applicable tax authorities. If tax authorities in any of these countries were to successfully challenge our transfer prices as not reflecting arms' length transactions in historical periods prior to the Domestication and Reorganization, they could require us to adjust our transfer prices and thereby reallocate our income to reflect these revised transfer prices, which could result in a higher tax liability to us. In addition, if the country from which the income is reallocated does not agree with the reallocation, both countries could tax the same income, potentially resulting in double taxation. If tax authorities were to allocate income to a higher tax jurisdiction, subject our income to double taxation or assess interest and penalties, it would increase our consolidated tax liability, which could adversely affect our financial condition, results of operations and cash flows.

Judgment is required in evaluating our tax positions and determining our provision for income taxes. During the ordinary course of business, there are many transactions and calculations for which the ultimate tax determination is uncertain. For example, our effective tax rates could be adversely affected by changes in foreign currency exchange rates or by changes in the relevant tax, accounting, and other laws, regulations, principles, and interpretations. As we intend to operate in more than one country and taxing jurisdiction, the application of tax laws can be subject to diverging and sometimes conflicting interpretations by tax authorities of these jurisdictions. It is not uncommon for taxing authorities in different countries to have conflicting views, for instance, with respect to, among other things, the manner in which the arm's length standard is applied for transfer pricing purposes, or with respect to the valuation of intellectual property. In addition, tax laws are dynamic and subject to change as new laws are passed and new interpretations of the law are issued or applied. Moreover, certain relevant tax, accounting and other laws have special application with respect to "affiliated," "combined" or similar groups, which included RSL and its subsidiaries prior to March 2020, and which may impact the tax liabilities of the companies. We continue to assess the impact of such changes in tax laws on our business and may determine that changes to our structure, practice or tax positions are necessary in light of such changes and developments in the tax laws of other jurisdictions in which we operate. Such changes may nevertheless be ineffective in avoiding an increase in our consolidated tax liability, which could harm our financial condition, results of operations and cash flows.

Changes in our effective tax rate may reduce our net income in future periods.

Our tax position could be adversely impacted by changes in tax rates, tax laws, tax practice, tax treaties or tax regulations or changes in the interpretation thereof by the tax authorities in Ireland, the United States and other jurisdictions for periods following the Domestication and Reorganization, and also Europe (including the U.K. and Ireland), the United States and other jurisdictions for historical periods prior to the Domestication and Reorganization. Such changes may become more likely as a result of recent economic trends in the jurisdictions in which we operate, particularly if such trends continue. If such a situation was to arise, it could adversely impact our tax position and our effective tax rate. Failure to manage the risks associated with such changes, or misinterpretation of the laws providing such changes, could result in costly audits, interest, penalties and reputational damage, which could adversely affect our business, results of our operations and our financial condition.

Our actual effective tax rate may vary from our expectation and that variance may be material. A number of factors may increase our future effective tax rates, including: (1) the jurisdictions in which profits are determined to be earned and taxed; (2) the resolution of issues arising from any future tax audits with various tax authorities; (3) changes in the valuation of our deferred tax assets and liabilities; (4) increases in expenses not deductible for tax purposes, including transaction costs and impairments of goodwill in connection with acquisitions; (5) changes in the taxation of stock-based compensation; (6) changes in tax laws or the interpretation of such tax laws, and changes in generally accepted accounting principles; and (7) challenges to the transfer pricing policies related to our structure prior to the Domestication and Reorganization.

Changes in tax laws in the United States or foreign jurisdictions could materially increase our tax expense.

We are subject to income taxes in the United States and foreign jurisdictions. Changes to income tax laws and regulations, or the interpretation of such laws, in any of the jurisdictions in which we operate could significantly increase our effective tax rate and ultimately reduce our cash flows from operating activities and otherwise have a material adverse effect on our financial condition. Additionally, various levels of government are increasingly focused on tax reform and other legislative actions to increase tax revenue, and President Biden's campaign proposals included increasing the U.S. corporate income tax rate from 21% to 28%. Further changes in the tax laws of foreign jurisdictions could arise as a result of the base erosion and profit shifting project undertaken by the Organisation for Economic Co-operation and Development, which represents a coalition of member countries and recommended changes to numerous long-standing tax principles. If implemented by taxing authorities, such changes, as well as changes in U.S. federal and state tax laws or in taxing jurisdictions' administrative interpretations, decisions, policies, and positions, could have a material adverse effect on our business, results of operations, or financial condition.

General Risk Factors

Our business and operations would suffer in the event of system failures, security breaches or cyber-attacks.

Our computer systems, as well as those of various third parties on which we rely, or may rely in the future, including our CRO's and other contractors, consultants, and law and accounting firms, may sustain damage from computer viruses, unauthorized access, data breaches, phishing attacks, cybercriminals, natural disasters, terrorism, war and telecommunication and electrical failures. We rely on our third-party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. We have experienced phishing attacks in the past, which have not had a material impact on our operations, however, we may in the future experience material system failures or security breaches that could cause interruptions in our operations or result in a material disruption of our development programs. For example, the loss of nonclinical or clinical trial data from completed, ongoing or planned trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability, suffer reputational damage, and the further development of our product candidates could be delayed.

If securities or industry analysts cease to publish research or reports about our business, or publish negative reports about our business, our stock price and trading volume could decline.

The trading market for our common stock depends, in part, on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. If our financial performance fails to meet analyst estimates or one or more of the analysts who cover us downgrade our common stock or change their opinion of our common stock, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our stock price or trading volume to decline.

We have incurred and will continue to incur substantial costs as a result of operating as a public company, and our management has been and will be required to continue to devote substantial time to compliance with our public company responsibilities and corporate governance practices.

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq and other applicable securities rules and regulations impose various requirements on public companies. Our management and other personnel devote a substantial amount of time to compliance with these requirements. Moreover, changing rules and regulations may increase our legal and financial compliance costs and make some activities more time-consuming and more costly. If, notwithstanding our efforts to comply with new or changing laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us, and our business may be harmed.

Further, failure to comply with these laws, regulations and standards may make it more difficult and more expensive for us to obtain directors' and officers' liability insurance, which could make it more difficult for us to attract and retain qualified members of our Board of Directors or members of senior management.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description of Document	Form	File No.	Exhibit No.	Filing Date
3.1	Certificate of Incorporation.	8-K12G3	000-56226	3.1	11/13/2020
3.2	Bylaws.	8-K12G3	000-56226	3.2	11/13/2020
31.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				
32.1*#	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				
101.INS*	XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				
101.SCH*	XBRL Taxonomy Extension Schema Document.				
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document.				
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document.				
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document.				
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document.				
104*	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibits 101).				

* Filed herewith.

These certifications are being furnished solely to accompany this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are not to be incorporated by reference into any filing of the Registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

SIO GENE THERAPIES INC.

By: /s/ David Nassif

Name: David Nassif

Title: Chief Executive Officer; Chief Financial Officer; Chief Accounting Officer and General Counsel

(Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)

Date: August 11, 2022

Exhibit 31.1

CERTIFICATION

I, David Nassif, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Sio Gene Therapies Inc.;

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

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

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

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

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

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

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

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

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

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

Date: August 11, 2022

By: /s/ David Nassif

David Nassif

Chief Executive Officer; Chief Financial Officer; Chief Accounting Officer and General Counsel

(Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Sio Gene Therapies Inc. (the "Company") for the period ended June 30, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, David Nassif, Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

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

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

Date: August 11, 2022

By: /s/ David Nassif
David Nassif
Chief Executive Officer; Chief Financial Officer; Chief Accounting Officer and General Counsel
(Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the SEC or its staff upon request.

This certification accompanies the Report, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), regardless of any general incorporation language contained in such filing.