UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **June 9, 2021**

Sio Gene Therapies Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-37418**	**85-3863315**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

130 West 42nd Street
26th Floor
New York, New York 10036
(Address of principal executive offices) (Zip Code)

(Registrant's telephone number, including area code): **+1 877 746 4891**

N/A

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter):

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. ☐

Item 2.02 Results of Operations and Financial Condition.

On June 9, 2021, Sio Gene Therapies Inc. (the "Registrant") issued a press release announcing its financial results for the three months and fiscal year ended March 31, 2021. A copy of this press release is furnished herewith as Exhibit 99.1 to this Current Report and is incorporated herein by reference.

In accordance with General Instruction B.2. of Form 8-K, the information in this Item 2.02, and Exhibit 99.1 hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any of the Registrant's filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any incorporation language in such a filing, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

EXHIBIT INDEX

Exhibit No.	Description of Document
99.1	Press release of Sio Gene Therapies Inc., dated June 9, 2021, "Sio Gene Therapies Announces Fiscal Year 2020 Year-End Financial Results and Expected Fiscal Year 2021 Key Milestones"

SIGNATURE

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 hereunto duly authorized.

SIO GENE THERAPIES INC.

Dated: June 9, 2021

By: /s/ David Nassif

Name: David Nassif

Title: Chief Financial Officer and General Counsel

Exhibit 99.1

Sio Gene Therapies Announces Fiscal Year 2020 Year-End Financial Results and Expected Fiscal Year 2021 Key Milestones

– *Multiple GM1 gangliosidosis program milestones expected in FY2021, including 12-month data updates from the ongoing dose-escalation study and meeting with FDA to align on registrational pathway*

– *Strong cash position with $119 million of cash and cash equivalents as of March 31, 2021, and cash runway expected into Q4 2022*

NEW YORK, NY AND RESEARCH TRIANGLE PARK, NC, June 9, 2021 (GLOBE NEWSWIRE) – Sio Gene Therapies Inc. (NASDAQ: SIOX), a clinical-stage company focused on developing gene therapies to radically transform the lives of patients with neurodegenerative diseases, today provided financial results for its fiscal year ended March 31, 2021.

“At Sio we remain committed to bringing urgently needed treatments to patients with rare pediatric disorders and adult neurodegenerative diseases. We are grateful for the steadfast dedication of patients, caregivers, investigators, and patient advocacy groups who have supported our mission in the midst of a global pandemic, and we are proud of our team’s efforts in advancing the development of Sio’s three clinical-stage product candidates through an extraordinary year,” said Pavan Cheruvu, M.D., Chief Executive Officer of Sio Gene Therapies.

“The positive data recently shared from our Phase 1/2 study of AXO-AAV-GM1, together with our industry-leading position in clinical enrollment and investment in earlier diagnosis, give us renewed momentum as we aim to advance this investigational therapy towards commercialization. In the second half of 2021, we will present 12-month follow-up data on safety, biomarkers, and clinical efficacy from the low-dose cohort of the GM1 gangliosidosis program. We expect these data, as well as a planned regulatory meeting with the FDA expected in the first half of 2022, will help define our registrational pathway in GM1 gangliosidosis. We have confidence in AXO-AAV-GM1 as well as our two other clinical-stage candidates in Tay-Sachs/Sandhoff disease and Parkinson’s disease, and look forward to several major milestones across our three programs during this fiscal year.”

Dr. Cheruvu continued, “In parallel, we are continuing to build our preclinical and analytical development capabilities in our growing laboratory in Research Triangle Park, and are conducting a search and evaluation process for promising genetic medicines that may expand our pipeline with new product candidates in the years ahead. Our strengthened balance sheet leaves us well-positioned to develop first-in-class and best-in-class gene therapy product candidates in our current pipeline, while also investing in exciting new, biology-driven opportunities in areas of significant unmet patient need.”

Key Highlights and Development Updates

AXO-AAV-GM1 gene therapy for GM1 gangliosidosis

- Reductions in CSF GM1 ganglioside were observed in 4 out of 5 children treated with the lowest dose of AXO-AAV-GM1 at 6-months follow up, providing the first clear evidence of a biochemical effect in the CNS following intravenous delivery (data presented at the American Society of Cell and Gene Therapy conference in May 2021)
- Announced six-month follow-up data from 5 patients in the low-dose cohort (1.5×10^{13} vg/kg) of AXO-AAV-GM1, demonstrating that the investigational gene therapy had a favorable safety profile with evidence of clinical disease stability and biomarker improvement
- Based on the favorable safety profile at the low dose, the independent Data Safety Monitoring Committee (DSMC) concurred with progressing to the high-dose cohort (4.5×10^{13} vg/kg). Thus far two patients have received the high dose without complications.
- Upcoming milestones:
  - 12-month topline safety, biomarker, and efficacy data from the low-dose cohort in the second half of 2021
  - 12-month topline data from the first two patients dosed in the high-dose cohort (4.5×10^{13} vg/kg) in Q1 2022
  - Meeting with the U.S. Food and Drug Administration (FDA) to discuss the registrational pathway for AXO-AAV-GM1 in the first half of 2022

AXO-AAV-GM2 gene therapy for Tay-Sachs and Sandhoff disease

- Dosed the first patient in the Phase 1/2 trial investigating AXO-AAV-GM2 in Tay-Sachs and Sandhoff diseases
- Based on the favorable safety profile in the starting dose, the independent Data Safety Monitoring Committee (DSMC) concurred with progressing to the planned enrollment in the low-dose cohort (total dose 1.95×10^{14} vg delivered directly to the CNS). Thus far one patient has received the starting dose and a second patient has received the low dose without complications.
- FDA granted Rare Pediatric Disease Designation for AXO-AAV-GM2
- Upcoming milestones:
    - Continued patient identification, screening, and enrollment in the ongoing dose-escalation study expected throughout FY2021

AXO-Lenti-PD gene therapy for Parkinson's disease

- Reported positive 6-month follow-up data from the second cohort of the SUNRISE-PD Phase 2 trial in October 2020
    - AXO-Lenti-PD was observed to be well-tolerated with no treatment related serious adverse events at 6 months
    - Greater than 2-hour improvement from baseline in both diary "good ON time" and diary OFF time assessments observed across all four patients in Cohort 2
    - 21-point mean improvement in UPDRS Part III "OFF" score in the two patients with evaluable data, representing a 40% improvement from baseline
- Upcoming milestones:
    - Continued development of a scaled-up suspension-based manufacturing process at Oxford Biomedica to enable production of clinical trial material, with certification of at least one batch of clinical trial material by a Qualified Person expected in Q4 2021, following the successful manufacturing of both drug substance and drug product.

Fiscal Fourth Quarter Financial Summary

For the fourth fiscal quarter ended March 31, 2021, research and development expenses were $8.2 million, a decrease of $2.7 million compared to the prior year quarter. The current period decrease was primarily related to reduced AXO-Lenti-PD program clinical expenses as the enrollment of Cohort 2 was completed in the prior year quarter, as well as lower manufacturing expenses due to the delays in the development of a suspension-based manufacturing process at our manufacturing partner, Oxford Biomedica.

General and administrative expenses for the fourth fiscal quarter ended March 31, 2021 were $4.0 million, a decrease of $1.1 million compared to the prior year quarter primarily related to reductions in stock-based compensation expense.

The net loss for the fourth fiscal quarter ended March 31, 2021 was $3.3 million, or $0.05 per share, compared to a net loss of $16.6 million, or $0.54 per share, in the prior year quarter. The net loss for the fourth fiscal quarter ended March 31, 2021 was net of $9.1 million of gains on our long-term investment in Arvelle Therapeutics B.V. ("Arvelle") that was sold in February 2021.

Fiscal Year Financial Summary

For the fiscal year ended March 31, 2021, research and development expenses were $24.9 million, a decrease of $22.2 million compared to the fiscal year ended March 31, 2020. The current period decrease was primarily related to $14.0 million in certain nonrecurring development and regulatory milestones achieved in the prior year for the AXO-Lenti-PD ($13.0 million) and AXO-AAV-GM2 programs. In addition, there were reduced program-specific research and development costs of $7.2 million due to (i) lower AXO-Lenti-PD clinical expenses as the enrollment of Cohort 2 was completed in the prior year, as well as lower manufacturing expenses due to the delays at Oxford, (ii) reduced clinical and manufacturing expenses while awaiting FDA clearance of the IND for the AXO-AAV-GM2 program, and (iii) the discontinuation of the AXO-AAV-OPMD program during the prior year.

General and administrative expenses for the fiscal year ended March 31, 2021 were $17.3 million, a decrease of $4.8 million compared to the fiscal year ended March 31, 2020, primarily related to reductions in (i) stock-based compensation expense of $2.2 million primarily attributable to lower grant date fair values per share for equity awards and lower headcount, and (ii) personnel costs (including severance) of $1.3 million attributable to lower headcount.

The net loss for the fiscal year ended March 31, 2021 was $32.4 million, or $0.62 per share, compared to a net loss of $72.6 million, or $2.93 per share, in the fiscal year ended March 31, 2020. The net loss for the fiscal year ended March 31, 2021 was net of $11.3 million of gains on our long-term investment in Arvelle that was sold in February 2021. For the fiscal year ended March 31, 2021, net cash used in operating activities was $46.6 million and net cash provided by investing activities included $11.6 million of proceeds received from the sale of our long-term investment in Arvelle.

As of March 31, 2021, we had $119.0 million of cash and cash equivalents. We hold no short-term or long-term debt on the balance sheet. We estimate that our current cash and cash equivalents will sustain our operations into Q4 2022, beyond the expected dates of major upcoming milestones for our AXO-AAV-GM1 gene therapy program for the treatment of GM1 gangliosidosis.

About Sio Gene Therapies

Sio Gene Therapies combines cutting-edge science with bold imagination to develop genetic medicines that aim to radically improve the lives of patients. Our current pipeline of clinical-stage candidates includes the first potentially curative AAV-based gene therapies for GM1 gangliosidosis and Tay-Sachs/Sandhoff diseases, which are rare and uniformly fatal pediatric conditions caused by single gene deficiencies. We are also expanding the reach of gene therapy to highly prevalent conditions such as Parkinson’s disease, which affects millions of patients globally. Led by an experienced team of gene therapy development experts, and supported by collaborations with premier academic, industry and patient advocacy organizations, Sio is focused on accelerating its candidates through clinical trials to liberate patients with debilitating diseases through the transformational power of gene therapies. For more information, visit www.siogtx.com.

Forward-Looking Statements

This press release contains forward-looking statements for the purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995 and other federal securities laws. The use of words such as "expect," "estimate," "may" and other similar expressions are intended to identify forward-looking statements. For example, all statements Sio makes regarding costs associated with its operating activities, funding requirements and/or runway to meet its upcoming clinical milestones, and timing and outcome of its upcoming clinical and manufacturing milestones are forward-looking. All forward-looking statements are based on estimates and assumptions by Sio’s management that, although Sio believes to be reasonable, are inherently uncertain. All forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those that Sio expected. Such risks and uncertainties include, among others, the impact of the Covid-19 pandemic on our operations; the actual funds and/or runway required for our clinical and product development activities and anticipated upcoming milestones; actual costs related to our clinical and product development activities and our need to access additional capital resources prior to achieving any upcoming milestones; the initiation and conduct of preclinical studies and clinical trials; the availability of data from clinical trials; the development of a suspension-based manufacturing process for Axo-Lenti-PD; the scaling up of manufacturing, the expectations for regulatory submissions and approvals; the continued development of our gene therapy product candidates and platforms; Sio’s scientific approach and general development progress; and the availability or commercial potential of Sio’s product candidates. These statements are also subject to a number of material risks and uncertainties that are described in Sio’s most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission on June 9, 2021, as updated by its subsequent filings with the Securities and Exchange Commission. Any forward-looking statement speaks only as of the date on which it was made. Sio undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as required by law.

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

	Three Months Ended March 31,		Years Ended March 31	
	2021	**2020**	**2021**	**2020**
	(unaudited)	**(unaudited)**		
Operating expenses:				
Research and development expenses				
(includes stock-based compensation expense of $303 and $766 for the three months ended March 31, 2021 and 2020, respectively, and $1,583 and $2,772 for the years ended March 31, 2021 and 2020, respectively)	$ 8,244	$ 10,920	$ 24,903	$ 47,110
General and administrative expenses				
(includes stock-based compensation expense of $615 and $1,791 for the three months ended March 31, 2021 and 2020, respectively, and $2,909 and $5,123 for the years ended March 31, 2021 and 2020, respectively)	3,965	5,133	17,294	22,061
Total operating expenses	12,209	16,053	42,197	69,171
Other (income) expenses:				
Interest expense	1	440	799	4,377
Other income	(8,971)	(127)	(10,359)	(1,358)
Loss before income tax (benefit) expense	(3,239)	(16,366)	(32,637)	(72,190)
Income tax (benefit) expense	92	282	(212)	438
Net loss	$ (3,331)	$ (16,648)	$ (32,425)	$ (72,628)
Net loss per common share — basic and diluted	$ (0.05)	$ (0.54)	$ (0.62)	$ (2.93)
Weighted-average common shares outstanding — basic and diluted	66,251,597	30,939,688	52,181,398	24,812,536

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

	March 31, 2021	March 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 118,986	$ 80,752
Receivable from sale of long-term investment	4,343	—
Prepaid expenses and other current assets	7,348	2,971
Income tax receivable	1,656	1,707
Total current assets	132,333	85,430
Long-term investment	—	5,871
Other non-current assets	—	46
Long-term restricted cash	1,184	—
Operating lease right-of-use assets	1,152	1,532
Property and equipment, net	478	801
Total assets	$ 135,147	$ 93,680
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 1,341	$ 4,412
Accrued expenses	9,196	11,319
Current portion of operating lease liabilities	311	889
Current portion of long-term debt	—	15,423
Total current liabilities	10,848	32,043
Operating lease liabilities, net of current portion	932	79
Total liabilities	11,780	32,122
Shareholders' equity:		
Common stock, par value $0.00001 per share, 1,000,000,000 shares authorized, 69,377,567 and 39,526,299 issued and outstanding at March 31, 2021 and March 31, 2020, respectively	1	—
Accumulated other comprehensive income (loss)	335	(55)
Additional paid-in capital	914,100	820,257
Accumulated deficit	(791,069)	(758,644)
Total shareholders' equity	123,367	61,558
Total liabilities and shareholders' equity	$ 135,147	$ 93,680