Sio Gene Therapies Announces Financial Results for Third Fiscal Quarter Ended December 31, 2020

February 9, 2021

- Company had $81 million of cash and cash equivalents as of December 31, 2020, and expects to receive additional $16 million in cash in 2021 from sale of Arvelle Therapeutics shares

- Cash runway expected into the second calendar quarter of 2022

NEW YORK and RESEARCH TRIANGLE PARK, N.C., Feb. 09, 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 third fiscal quarter ended December 31, 2020.

"In recent months, Sio Gene Therapies has made important progress in advancing its patient-focused mission: harnessing the power of gene therapy to improve the lives of patients living with debilitating CNS diseases," said Pavan Cheruvu, M.D., Chief Executive Officer of Sio Gene Therapies. "Our AAV-based gene therapies for GM1 gangliosidosis and Tay-Sachs/Sandhoff diseases are the first gene therapy programs to enter clinical trials for each indication, and we have just begun to see evidence of their therapeutic potential. For the AXO-AAV-GM1 program, we presented 6-month follow up data in GM1 gangliosidosis highlighting the potential to preserve functional outcomes, increase enzyme activity, and reduce disease burden for patients and their families. We expect to report 12-month clinical safety and efficacy from the low-dose cohort, as well as biomarker data, in the second half of 2021 while we continue to enroll patients in the high-dose cohort. We have also made significant progress with AXO-AAV-GM2, the first potentially disease-modifying gene therapy for GM2 gangliosidosis, which entered the clinic with dosing of the first infantile (Type 1) patient and will continue enrollment throughout this year."

Dr. Cheruvu continued, "AXO-Lenti-PD represents the most advanced gene therapy in active clinical development for Parkinson's disease, with a highly differentiated profile that aims to improve motor function across a broad spectrum of disease progression. We are working collaboratively with our partner, Oxford Biomedica, on the development of a reliable suspension-based manufacturing process to enable scale-up of production and advancement of the clinical program. Oxford Biomedica has initiated the manufacture of GMP batches using this process and we will continue to provide periodic updates on our progress."

"Our recent rebranding as Sio Gene Therapies, establishment of a Board composed of a majority of independent directors, addition of a leading AAV scientist to our advisory board, expansion of our preclinical research and development capabilities with a new laboratory facility in North Carolina, and extended cash runway, leave us well-positioned to execute across our pipeline. Over the coming year, we intend to continue advancing treatments that have the potential to radically alter the lives of patients while we explore opportunities to augment our existing portfolio of gene therapies."

Fiscal Third Quarter Financial Summary

For the third fiscal quarter ended December 31, 2020, research and development expenses were $6.4 million, a decrease of $1.9 million compared to the prior year quarter due to a $1.0 million nonrecurring development and regulatory milestone to UMMS achieved in the prior year period for the AXO-AAV-GM2 program. In addition, there were reduced AXO-Lenti-PD program costs of $1.0 million due to lower clinical expenses as the enrollment of Cohort 2 was completed in February 2020, as well as lower manufacturing expenses due to delays in the development of a suspension-based manufacturing process by our partner, Oxford Biomedica.

General and administrative expenses for the third fiscal quarter ended December 31, 2020 were $4.2 million, a decrease of $1.2 million compared to the prior year quarter, primarily due to a reduction in stock-based compensation expense attributable to reduced headcount and lower grant date fair values per share for equity awards, as well as reduced outside legal costs.

The net loss for the third fiscal quarter ended December 31, 2020 was $10.5 million, or $0.20 per share, compared to a net loss of $14.0 million, or $0.62 per share, in the prior year quarter.

Nine-Months Financial Summary

For the nine months ended December 31, 2020, research and development expenses were $16.7 million, a decrease of $19.5 million compared to the nine months ended December 31, 2019. The current period decrease was primarily related to $14.0 million in certain nonrecurring development and regulatory milestones achieved in the prior year period for the AXO-Lenti-PD and AXO-AAV-GM2 programs. As well, there were reduced program-specific research and development costs of $3.7 million due to (i) lower AXO-Lenti-PD clinical expenses as the enrollment of Cohort 2 was completed in February 2020, as well as lower manufacturing expenses due to the delays at Oxford and (ii) reduced clinical and manufacturing expenses while awaiting FDA clearance of the IND for the AXO-AAV-GM2 program.

General and administrative expenses for the nine months ended December 31, 2020 were $13.3 million, a decrease of $3.6 million compared to the nine months ended December 31, 2019, primarily related to reductions in (i) personnel costs (including severance) of $1.2 million and stock-based compensation expense of $1.0 million attributable to reduced headcount and lower grant date fair values per share for equity awards, (ii) outside legal costs of $0.7 million, and (iii) pharmaceutical market research expenses of $0.6 million.

The net loss for the nine months ended December 31, 2020 was $29.1 million, or $0.61 per share, compared to a net loss of $56.0 million, or $2.46 per share, in the nine months ended December 31, 2019. Net cash used in operating activities was $36.3 million for the nine months ended December 31, 2020.

As of December 31, 2020, we had $81.0 million of cash and cash equivalents. We hold no short-term or long-term debt on the balance sheet. We expect the cash and cash equivalents to sustain our operations into the second calendar quarter of 2022.

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" and other similar expressions are intended to identify forward-looking statements. For example, all statements Sio makes regarding costs associated with its operating activities 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 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on February 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.

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

	Three Months Ended December 31,		Nine Months Ended December 31	
	2020	2019	2020	2019
Operating expenses:				
Research and development expenses (includes stock-based compensation expense of $259 and $876 for the three months ended December 31, 2020 and 2019 and $1,280 and $2,006 for the nine months ended December 31, 2020 and 2019, respectively)	$ 6,407	$ 8,267	$ 16,659	$ 36,190
General and administrative expenses (includes stock-based compensation expense of $617 and $1,436 for the three months ended December 31, 2020 and 2019 and $2,294 and $3,332 for the nine months ended December 31, 2020 and 2019, respectively)	4,198	5,409	13,329	16,928
Total operating expenses	10,605	13,676	29,988	53,118
Other (income) expenses:				
Interest expense	1	1,066	798	3,937
Other (income) expense	98	(694)	(1,388)	(1,231)
Loss before income tax (benefit) expense	(10,704)	(14,048)	(29,398)	(55,824)
Income tax (benefit) expense	(188)	(9)	(304)	156
Net loss	$ (10,516)	$ (14,039)	$ (29,094)	$ (55,980)
Net loss per common share — basic and diluted	$ (0.20)	$ (0.62)	$ (0.61)	$ (2.46)

Weighted-average common shares outstanding — basic and diluted	52,679,816	22,791,669	47,581,795	22,785,006

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

	December 31, 2020	March 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 81,019	$ 80,752
Short-term investment	8,055	—
Prepaid expenses and other current assets	6,272	2,971
Income tax receivable	1,686	1,707
Total current assets	97,032	85,430
Long-term investment	—	5,871
Other non-current assets	122	46
Operating lease right-of-use assets	1,347	1,532
Property and equipment, net	463	801
Total assets	$ 98,964	$ 93,680
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 987	$ 4,412
Accrued expenses	7,722	11,319
Current portion of operating lease liabilities	240	889
Current portion of long-term debt	—	15,423
Total current liabilities	8,949	32,043
Operating lease liabilities, net of current portion	986	79
Total liabilities	9,935	32,122
Stockholders' equity:		
Common stock, par value $0.00001 per share, 1,000,000,000 shares authorized, 56,602,626 and 39,526,299 issued and outstanding at December 31, 2020 and March 31, 2020, respectively	1	—
Additional paid-in capital	876,423	820,257
Accumulated deficit	(787,738)	(758,644)
Accumulated other comprehensive income (loss)	343	(55)
Total stockholders' equity	89,029	61,558
Total liabilities and stockholders' equity	$ 98,964	$ 93,680

Source: Sio Gene Therapies, Inc.