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 10, 2020**

Axovant Gene Therapies Ltd.

(Exact name of registrant as specified in its charter)

Bermuda	**001-37418**	**98-1333697**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

Suite 1, 3rd Floor
11-12 St. James's Square
London SW1Y 4LB, United Kingdom
(Address of principal executive offices) (Zip Code)

(Registrant's telephone number, including area code): **+44 203 997 8931**

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 Shares, par value $0.00001 per share	AXGT	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 10, 2020, Axovant Gene Therapies Ltd. (the "***Registrant***") issued a press release announcing its financial results for the three months and fiscal year ended March 31, 2020. 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 No.	Description of Document
99.1	Press Release of Axovant Gene Therapies Ltd., dated June 10, 2020, "Axovant Announces Year-End Financial Results and Expected Key Clinical Milestones in Q4 2020"

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.

AXOVANT GENE THERAPIES LTD.

Dated: June 10, 2020

By: /s/ David Nassif

Name: David Nassif

Title: Principal Financial Officer and Principal Accounting Officer, General Counsel

Exhibit 99.1

Axovant Announces Year-End Financial Results and Expected Key Clinical Milestones in Q4 2020

- *Completed enrollment of cohort 2 of SUNRISE-PD Phase 2 study of AXO-Lenti-PD in Parkinson's disease, with data from this cohort expected in Q4 2020*
- *Completed enrollment of low-dose cohort of Phase 1/2 clinical study of AXO-AAV-GM1 for GM1 gangliosidosis, with data from this cohort expected in Q4 2020*
- *Cash position of $80.8 million as of March 31, 2020 and expected runway into the second calendar quarter of 2021*

NEW YORK and BASEL, Switzerland, June 10, 2020 (GLOBE NEWSWIRE) - Axovant Gene Therapies Ltd (NASDAQ: AXGT), a clinical-stage company developing innovative gene therapies for neurological diseases, today provided financial results and corporate updates for its fiscal year ended March 31, 2020.

"Over the last year, Axovant has progressed toward becoming a leading gene therapy company focused on delivering transformative benefit to patients with neurological diseases, while extending the reach of gene therapies to highly prevalent populations such as Parkinson's disease," said Pavan Cheruvu, M.D., Chief Executive Officer of Axovant. "We are encouraged by early findings across our programs, which now include evidence of durable motor improvement following administration of AXO-Lenti-PD in Parkinson's disease, and the first reported evidence of disease stabilization in infants with Tay-Sachs disease following administration of AXO-AAV-GM2. We have also completed enrollment in the low-dose cohort of our dose escalation study of AXO-AAV-GM1, and are expanding the ongoing registrational program to include patients with Type I (infantile) GM1 gangliosidosis. The dedication and resilience of our employees and scientific collaborators has fueled our progress, and we appreciate the continued trust of patients, families and our shareholders as we continue to advance Axovant's mission."

Key Highlights and Development Updates

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

- Dosing of all four patients in the second dose cohort (1.4 x 10^7 TU) of SUNRISE-PD dose-escalation study was completed in February 2020, with 6-month data from this cohort expected in Q4 2020.
- At 12 months, 22-point mean improvement from baseline on UPDRS Part III "OFF" score observed for the first dose cohort treated with AXO-Lenti-PD, compared with 7-points, 11-points and 15-points of improvement from baseline for each of ProSavin cohorts 1, 2 and 3, respectively.
- Expected completion of the first manufacturing batch of AXO-Lenti-PD using a suspension-based process by year-end 2020.
- Expected enrollment of the first subject in a randomized, controlled trial of AXO-Lenti-PD in 2021.

AXO-AAV-GM1 gene therapy for GM1 gangliosidosis

- Completed enrollment of five late infantile and juvenile onset (Type II) patients in the low-dose cohort of Stage 1 of the registrational study with 6-month data expected in Q4 2020.
- Reported an update from the first child dosed with AXO-AAV-GM1 under an investigator-initiated IND in the fourth quarter of calendar year 2019 indicating safety, tolerability, and evidence of clinical improvement following administration of gene therapy.
- IND amendment cleared to expand Stage 2 of the registrational study protocol to include infantile (Type I) patients, the population most severely affected by the disease, and to evaluate a higher dose level for both Type I and Type II patients.
- Expect to initiate dosing in the high-dose cohort, which will include both Type I and Type II patients, in the second half of 2020.
- Received U.S. Food and Drug Administration (FDA) orphan drug designation for AXO-AAV-GM1 for the treatment of GM1 gangliosidosis.

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

- Reported the first evidence for potential disease modification in Tay-Sachs disease from an expanded access study administering investigational AXO-AAV-GM2 gene therapy in two patients with infantile (Type I) Tay-Sachs disease.
- AXO-AAV-GM2 was successfully administered in both patients and has been generally well-tolerated to date, with no serious adverse events or clinically relevant laboratory abnormalities related to therapy.
- Clearance of a Company-sponsored investigational new drug (IND) application is expected in calendar year 2020.

Corporate Updates

- Announced collaboration with Invitae, a leading medical genetics company, in the Detect Lysosomal Storage Diseases program to facilitate faster diagnoses for children with lysosomal storage disorders including GM1 gangliosidosis and GM2 gangliosidosis, also known as Tay-Sachs/Sandhoff disease.
- Announced in February 2020 the closing of an underwritten public offering resulting in net proceeds of $70.8 million.
- Announced in April 2020 the prepayment in full of $15.7 million outstanding loan from Hercules Capital.

Fiscal Fourth Quarter Financial Summary

For the fiscal fourth quarter ended March 31, 2020, research and development expenses were $10.9 million, an increase of $3.8 million over the prior year quarter. The current period increase was principally due to an increase in costs related to the Company's gene therapy programs, while the prior year period reflected a winddown of the small-molecule programs and the beginning of the increase in spending on the gene therapy programs. Within the current period research and development expense, $0.8 million was attributable to non-cash, share-based compensation expense compared to $1.5 million in the prior-year quarter. The current period decrease in share-based compensation expense is due to reduced headcount.

General and administrative expenses for the fiscal fourth quarter ended March 31, 2020 were $5.1 million, a decrease of $1.0 million compared to the prior-year quarter. The current decrease was principally due to reductions of $0.8 million in personnel costs and $0.3 million in share-based compensation expense related to reduced headcount. Within the current period expense, $1.8 million was attributable to non-cash, share-based compensation expense compared to $2.1 million in the prior-year quarter.

Net loss for the fiscal fourth quarter ended March 31, 2020 was $16.6 million, or $0.54 per share, compared to a net loss of $9.0 million, or $0.45 per share, for the prior-year quarter. Net cash used in operating activities for the fiscal fourth quarter ended March 31, 2020 was $17.9 million.

Fiscal Year Financial Summary

For the fiscal year ended March 31, 2020, research and development expenses were $47.1 million, a decrease of $40.5 million compared to the prior year. Excluding upfront license fees and development and regulatory milestones achieved and due to our partners, Oxford, Benitec and UMMS of $14.0 million in the current year and $46.0 million in the prior year, research and development expenses decreased by $8.5 million. Program-specific costs increased by $12.6 million in the current year for the gene therapy programs currently under development, which were offset by decreases of (i) $9.5 million related to the wind-down of the small molecule programs, (ii) $4.9 million in share-based compensation and personnel-related costs primarily associated with a decrease in headcount, and (iii) $2.4 million in costs allocated under our service agreements with Roivant Sciences, Inc. ("RSI") and Roivant Sciences GmbH ("RSG"), which are wholly owned subsidiaries of our affiliate, Roivant Sciences Ltd., as a result of the decentralization of the services formerly provided to us. Within the current period expense, $2.8 million was attributable to non-cash, share-based compensation expense compared to $4.8 million in the prior-year period.

General and administrative expenses for the fiscal year ended March 31, 2020 were $22.1 million, a decrease of $17.4 million compared to the prior year, primarily due to reductions in (i) share-based compensation expense of $6.6 million and personnel costs of $2.3 million attributable to reduced headcount, (ii) legal fees of $4.5 million, and (iii) costs allocated under our services agreements with RSI and RSG of $2.6 million as a result of the decentralization of the services provided to us. Within the current period, $5.1 million was attributable to non-cash, share-based compensation expense compared to $11.7 million in the prior year period.

Net loss for the year ended March 31, 2020 was $72.6 million, or $2.93 per share, compared to a net loss of $129.1 million or $8.02 per share, in the prior-year period. Net cash used in operating activities was $67.5 million for the fiscal year ended March 31, 2020.

As of March 31, 2020, the Company had $80.8 million of cash and cash equivalents, working capital of $53.4 million, and gross indebtedness of $15.7 million, which was fully prepaid in April 2020. In February 2020, the Company issued and sold 16.6 million common shares and pre-funded warrants to purchase up to 3.3 million common shares in a follow-on public offering resulting in net proceeds to the Company of approximately $70.8 million. In April 2020, the Company prepaid the $16.0 million outstanding balance due under the Loan Agreement with Hercules. The Company expects the cash and cash equivalents to sustain its operations into the second calendar quarter of 2021.

About Axovant Gene Therapies

Axovant Gene Therapies is a clinical-stage gene therapy company focused on developing a pipeline of innovative product candidates for debilitating neurodegenerative diseases. Our current pipeline of gene therapy candidates targets GM1 gangliosidosis, GM2 gangliosidosis (also known as Tay-Sachs disease and Sandhoff disease), and Parkinson's disease. Axovant is focused on accelerating product candidates into and through clinical trials with a team of experts in gene therapy development and through external partnerships with leading gene therapy organizations. For more information, visit www.axovant.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 "may," "might," "will," "would," "should," "expect," "believe," "estimate," and other similar expressions are intended to identify forward-looking statements. For example, all statements Axovant makes regarding costs associated with its operating activities are forward-looking. All forward-looking statements are based on estimates and assumptions by Axovant's management that, although Axovant 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 Axovant 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 scaling up of manufacturing, the expectations for regulatory submissions and approvals; the continued development of its gene therapy product candidates and platforms; Axovant's scientific approach and general development progress; and the availability or commercial potential of Axovant's product candidates. These statements are also subject to a number of material risks and uncertainties that are described in Axovant's most recent Annual Report on Form 10- K filed with the Securities and Exchange Commission on June 10, 2020, 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. Axovant 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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AXOVANT GENE THERAPIES LTD.

Consolidated Statements of Operations

(in thousands, except share and per share amounts)

	Three Months Ended March 31,		Years Ended March 31,	
	2020	2019	2020	2019
	(unaudited)	(unaudited)		
Operating expenses:				
Research and development expenses[1]				
(includes share-based compensation of $766 and $1,459 for the three months ended March 31, 2020 and 2019 and $2,772 and $4,758 for the years ended March 31, 2020 and 2019, respectively)	$ 10,920	$ 7,149	$ 47,110	$ 87,552
General and administrative expenses[2]				
(includes share-based compensation of $1,791 and $2,096 for the three months ended March 31, 2020 and 2019 and $5,123 and $11,671 for the years ended March 31, 2020 and 2019, respectively)	5,133	6,157	22,061	39,466
Total operating expenses	16,053	13,306	69,171	127,018
Interest expense	440	1,722	4,377	7,530
Other income	(127)	(5,891)	(1,358)	(5,616)
Loss before income tax expense	(16,366)	(9,137)	(72,190)	(128,932)
Income tax expense (benefit)	282	(91)	438	133
Net loss	$ (16,648)	$ (9,046)	$ (72,628)	$ (129,065)
Net loss per common share — basic and diluted	$ (0.54)	$ (0.45)	$ (2.93)	$ (8.02)
Weighted average common shares outstanding — basic and diluted	30,939,688	19,962,170	24,812,536	16,100,686

[1] Includes total costs (benefit) allocated from certain wholly owned subsidiaries of our affiliate, Roivant Sciences Ltd., of $0 for the three months ended March 31, 2020 and 2019 and $0 and $(450) for the years ended March 31, 2020 and 2019, respectively.

[2] Includes total costs allocated from certain wholly owned subsidiaries of our affiliate, Roivant Sciences Ltd., of $44 and $126 for the three months ended March 31, 2020 and 2019, respectively, and $147 and $2,898 for the years ended March 31, 2020 and 2019, respectively.

AXOVANT GENE THERAPIES LTD.
Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	March 31, 2020	March 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 80,752	$ 106,999
Prepaid expenses and other current assets	2,971	5,859
Income tax receivable	1,707	1,726
Total current assets	85,430	114,584
Long-term investment	5,871	5,871
Other non-current assets	46	973
Operating lease right-of-use assets	1,532	—
Property and equipment, net	801	1,278
Total assets	$ 93,680	$ 122,706
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 4,412	$ 1,698
Accrued expenses	11,319	20,619
Current portion of operating lease liabilities	889	—
Current portion of long-term debt	15,423	21,182
Total current liabilities	32,043	43,499
Operating lease liabilities, net of current portion	79	—
Long-term debt	—	22,994
Total liabilities	32,122	66,493
Shareholders' equity:		
Common shares, par value $0.00001 per share, 1,000,000,000 shares authorized, 39,526,299 and 22,779,891 issued and outstanding at March 31, 2020 and March 31, 2019, respectively	—	—
Accumulated other comprehensive (loss) income	(55)	911
Additional paid-in capital	820,257	741,318
Accumulated deficit	(758,644)	(686,016)
Total shareholders' equity	61,558	56,213
Total liabilities and shareholders' equity	$ 93,680	$ 122,706