# **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): August 7, 2017

# **Axovant Sciences Ltd.**

(Exact name of registrant as specified in its charter)

Bermuda 001-37418 98-1333697 (State or other jurisdiction of (Commission File No.) (I.R.S. Employer Identification No.)

Suite 1, 3rd Floor 11-12 St. James's Square London SW1Y 4LB, United Kingdom

incorporation)

Not Applicable

(Address of principal executive office)

(Zip Code)

Registrant's telephone number, including area code: +44 203 318 9708

## 20-22 Bedford Row London, United Kingdom WC1R 4JS

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation 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)) 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.

X

## Item 2.02 Results of Operations and Financial Condition.

On August 7, 2017, Axovant Sciences Ltd. (the "*Registrant*") issued a press release announcing its financial results for the three months ended June 30, 2017. 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 Finan	cial Statements and Exhibits.
(d) Exhibits.	
Exhibit No.	Description
99.1	Press Release of Axovant Sciences Ltd., dated August 7, 2017, "Axovant Announces Fiscal First Quarter Financial Results and Corporate Updates"

## **SIGNATURES**

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

## Axovant Sciences Ltd.

Date: By: /s/ Gregory Weinhoff

August 7, 2017 Name: Gregory Weinhoff

Title: Principal Financial Officer



## Axovant Announces Fiscal First Quarter Financial Results and Corporate Updates

**BASEL, Switzerland, Aug. 7, 2017** /PRNewswire/ - Axovant Sciences (NYSE: **AXON**) today announced financial results for the three months ended June 30, 2017 as well as general business updates.

## **Key Highlights**

- Strong balance sheet with \$297.9 million of cash as of June 30, 2017 supports Company's current development plans
- Completed enrollment in HEADWAY-DLB (dementia with Lewy bodies) clinical study of intepirdine
- Presented new preclinical data which suggests that intepirdine may have neuroprotective properties against vascular injury and neuronal metabolic dysfunction
- Announced U.S. Food and Drug Administration (FDA) granted Fast Track designation to nelotanserin for the treatment of visual hallucinations disorder in DLB
- Anticipate last patient visit in August in the MINDSET Phase 3 clinical study of intepirdine

"This is a very exciting time for Axovant as we expect top-line results from five late-stage clinical studies over the next several months," said David Hung, M.D., chief executive officer of Axovant. "If successful, we believe that three of these studies — MINDSET, HEADWAY-DLB and the REM Behavior Disorder study — could potentially serve as pivotal studies and may, if approved, lead to new treatment options for people impacted by Alzheimer's disease and Lewy body dementia."

## First Quarter Financial Summary

For the first fiscal quarter ended June 30, 2017, research and development expenses were \$43.7 million, of which \$6.3 million was attributable to non-cash, share-based compensation expense. General and administrative expenses for the first fiscal quarter ended June 30, 2017 were \$21.5 million, of which \$9.3 million was attributable to non-cash, share-based compensation expense. Net loss for the quarter ended June 30, 2017 was \$69.3 million, or \$0.65 per share.

Axovant held cash of \$297.9 million at June 30, 2017. Net cash used in operating activities was \$47.9 million for the three months ended June 30, 2017.

## **Development Update**

Intepirdine, nelotanserin, RVT-103 and RVT-104 are being developed as potential treatments for patients with Alzheimer's disease and Lewy body dementia (LBD). The Company expects top-line results from the following late-stage clinical studies:

- MINDSET: Phase 3 study of intepirdine in subjects with mild-to-moderate Alzheimer's disease on a stable background of
  donepezil therapy. Expected timing: last patient visit in August followed by results in late September 2017.
- HEADWAY-DLB: Phase 2b study of intepirdine in subjects with dementia with Lewy bodies (DLB). Expected timing: fourth quarter 2017.
- Phase 2 study of the effects of intepirdine on gait and balance in subjects with Alzheimer's disease, DLB and Parkinson's disease dementia (PDD). Expected timing: fourth quarter 2017.
- Phase 2 study evaluating nelotanserin for treatment of subjects with LBD who experience frequent visual hallucinations.
   Expected timing: fourth quarter 2017.
- Phase 2 study evaluating nelotanserin for treatment of REM Behavior Disorder in subjects with LBD. Expected timing: first quarter 2018.

Additionally, events relating to the Company's investigational products were announced in June 2017 as follows:

- Recruitment for the Phase 2b HEADWAY-DLB study completed in June with 269 subjects randomized.
- FDA granted Fast Track designation to nelotanserin for the treatment of visual hallucinations disorder in DLB.
- Results of a proof of concept study with RVT-103 were disclosed. The Company expects to meet with the FDA to discuss
  additional studies that could support registration of RVT-103 and initiated a proof of concept study for RVT-104.

In July, the Company presented new data relating to its intepirdine, nelotanserin and RVT-103 programs at the 2017 Alzheimer's Association International Conference (AAIC) in London, and announced new preclinical data that suggests that intepirdine may have neuroprotective properties against vascular injury and neuronal metabolic dysfunction.

In the animal model used in this study, intepirdine demonstrated neuroprotective effects under hypoxic and hypoglycemic conditions in an in vitro assay of mixed cortical neuron (MCN) cultures at clinically relevant concentrations. Specifically, when pre-treated with intepirdine for 24 hours, a decrease in lactate dehydrogenase (LDH) release, a surrogate marker of cell death, was observed in MCN cultures exposed to oxygen and glucose deprivation (p<0.05 at multiple intepirdine concentrations).

#### **About Axovant Sciences**

Axovant is a clinical-stage biopharmaceutical company focused on developing and commercializing innovative medicines to broadly address multiple forms of dementia and related neurological disorders. Axovant is developing a pipeline of late- and early-stage product candidates that focuses on the cognitive, functional and behavioral aspects of debilitating conditions such as Alzheimer's disease, Lewy body dementia and other neurological disorders. For more information, visit <a href="https://www.axovant.com">www.axovant.com</a>.

## **Forward-Looking Statements**

This press release contains forward-looking statements, including statements regarding Axovant's expectations about timing of the results for the Phase 3 MINDSET study of intepirdine in patients with Alzheimer's disease, the Phase 2b HEADWAY-DLB study of intepirdine in patients with DLB, the Phase 2 gait and balance study in patients with Alzheimer's disease, DLB and PDD, the Phase 2 study of nelotanserin in patients with LBD suffering from visual hallucinations, the Phase 2 study of nelotanserin in patients with LBD suffering from RBD, the proof of concept and related studies of RVT-103 and RVT-104 in patients with Alzheimer's disease and DLB, and other elements of its clinical development and regulatory strategy. Forward-looking statements can be identified by the words "believe," "anticipate," "continue," "estimate," "project," "expect," "plan," "potential," "intends," "will," "would," "could," "should" or the negative or plural of these words or other similar expressions that are predictions or indicate future events, trends or prospects. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially and reported results should not be considered as an indication of future performance. These risks and uncertainties include, but are not limited to: risks associated with the success, cost and timing of our product development activities and clinical trials; the approval and commercialization of our product candidates intepirdine, nelotanserin, RVT-103 and RVT-104; and increased regulatory requirements. These statements are subject to the risk that clinical trial data are subject to differing interpretations, and regulatory agencies, medical and scientific experts and others may not share Axovant's views of the clinical study data. There can be no assurance that the clinical programs for intepirdine, nelotanserin, RVT-103 or RVT-104 will be successful in demonstrating safety and/or efficacy, that we will not encounter problems or delays in clinical development, or that any of our product candidates will ever receive regulatory approval or be successfully commercialized. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to Axovant's business in general, see the "Risk Factors" section of our quarterly report on Form 10-O to be filed with the Securities and Exchange Commission on or about August 7, 2017, and other filings that Axovant makes with the SEC from time to time. These forward-looking statements are based on information available to Axovant as of the date of this press release and speak only as of the date of this release. Axovant disclaims any obligation to update these forward-looking statements, except as may be required by law.

AXOVANT SCIENCES LTD.
Condensed Consolidated Statements of Operations
(Unaudited, in thousands, except share and per share amounts)

	 Three Months Ended June 30, 2017		Three Months Ended June 30, 2016	
Operating expenses:				
Research and development expenses				
(includes share-based compensation expense of \$6,256 and \$4,964 for the three months ended June 30, 2017 and 2016, respectively)	\$ 43,712	\$	25,276	
General and administrative expenses				
(includes share-based compensation expense of \$9,344 and \$6,597 for the three months ended June 30, 2017 and 2016, respectively)	21,518		12,631	
Total operating expenses	 65,230		37,907	
Interest expense	1,874		_	
Other income	 (357)		_	
Loss before provision for income taxes	(66,747)		(37,907	
Income tax expense	2,519		148	
income tax expense	 2,319		140	
Net loss	\$ (69,266)	\$	(38,055	
Net loss per common share — basic and diluted	\$ (0.65)	\$	(0.38	
Weighted average common shares outstanding — basic and diluted	106,400,912		99,150,000	

# AXOVANT SCIENCES LTD. Condensed Consolidated Balance Sheets

(Unaudited, in thousands)

		June 30, 2017		March 31, 2017	
Assets					
Current assets:					
Cash	\$	297,858	\$	212,573	
Prepaid expenses and other current assets		7,627		6,457	
Income tax receivable		1,224		658	
Total current assets		306,709		219,688	
Property and equipment, net		2,294		142	
Deferred tax assets		_		2,709	
Total assets	\$	309,003	\$	222,539	
Liabilities and Shareholders' Equity					
Current liabilities:					
Accounts payable	\$	8,547	\$	8,551	
Due to Roivant Sciences Ltd. and Roivant Sciences, Inc.		4,466		2,919	
Accrued expenses		38,041		34,796	
Total current liabilities		51,054		46,266	
Long term debt		51,752		51,436	
Total liabilities		102,806		97,702	
Total shareholders' equity		206,197		124,837	
Total liabilities and shareholders' equity	\$	309,003	\$	222,539	

# **Contact:**

# Investors

Jonathan Neely jonathan.neely@axovant.com

# Media

Samina Bari samina.bari@axovant.com

###