

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 15, 2016**

Axovant Sciences Ltd.

(Exact name of registrant as specified in its charter)

Bermuda
(State or other jurisdiction of
incorporation)

001-37418
(Commission File No.)

Not Applicable
(I.R.S. Employer Identification No.)

Clarendon House - 2 Church Street
Hamilton HM 11
Bermuda
(Address of principal executive office)

Not Applicable
(Zip Code)

Registrant's telephone number, including area code: **+1 (441) 824-8100**

(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))

Item 2.02 Results of Operations and Financial Condition.

On August 15, 2016, Axovant Sciences Ltd. (the "**Registrant**") issued a press release announcing its financial results for the three months ended June 30, 2016. 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
99.1	Press Release of Axovant Sciences Ltd., dated August 15, 2016, "Axovant Sciences Announces Expansion of Dementia Pipeline and Reports Financial Results for the First Fiscal Quarter Ended June 30, 2016"

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:
August 15, 2016

By: /s/ Gregory Weinhoff
Name: Gregory Weinhoff
Title: Principal Financial Officer

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release of Axovant Sciences Ltd., dated August 15, 2016, "Axovant Sciences Announces Expansion of Dementia Pipeline and Reports Financial Results for the First Fiscal Quarter Ended June 30, 2016"



Axovant Sciences Announces Expansion of Dementia Pipeline and Reports Financial Results for the First Fiscal Quarter Ended June 30, 2016

- *Announces exclusive license agreement with Qaam Pharmaceuticals and announces plan to develop RVT-103, a combination of glycopyrrolate and donepezil, as a potential treatment for patients with dementia, with potential for an eventual triple combination with intepirdine*
- *Announces plan to launch a phase 2 program to study effects of intepirdine on gait and balance in patients with Alzheimer's disease, dementia with Lewy bodies, and Parkinson's disease dementia*
- *MINDSET study results and potential NDA filing for intepirdine in mild-to-moderate Alzheimer's disease expected in 2017*
- *Key clinical data readouts from three programs in Lewy body dementia expected in 2016 and 2017*
- *Strong balance sheet with \$252.7 million of cash as of June 30, 2016 to support the Company's current development plans*

HAMILTON, Bermuda, Aug. 15, 2016 /PRNewswire/ - Axovant Sciences Ltd. (NYSE: **AXON**), a leading clinical-stage biopharmaceutical company focused on the treatment of dementia, today announced corporate updates and reported financial results for the first fiscal quarter ended June 30, 2016.

“The next year represents an incredibly exciting period for Axovant,” stated Vivek Ramaswamy, Chief Executive Officer of Axovant Sciences. “We continue to execute well on our late-stage clinical programs for patients with Alzheimer's disease and Lewy body dementia. In addition, we announced our exclusive license to a technology that will enable Axovant to develop RVT-103, a combination of glycopyrrolate and donepezil, as a potential treatment for patients with dementia. This technology has the potential to reduce peripheral side effects of cholinesterase inhibitors and to enhance their efficacy through higher doses, and may further lead to a triple combination with intepirdine. This bolt-on transaction adds depth to our late-stage pipeline as we approach commercialization, while preserving our capacity to pursue additional late-stage assets that could further transform Axovant.”

Licensing Transaction with Qaam Pharmaceuticals

Axovant and Qaam Pharmaceuticals (Qaam) have entered into an exclusive license agreement under which Axovant expects to develop and, if successful, commercialize products that combine cholinesterase inhibitors with peripheral muscarinic receptor antagonists including glycopyrrolate, which could mitigate the peripheral side effects of cholinesterase inhibitors. Axovant will initially develop RVT-103, a combination of glycopyrrolate and donepezil. In addition, Axovant expects to develop RVT-104, a combination of glycopyrrolate and high-dose rivastigmine. Axovant believes that the intellectual property portfolio licensed from Qaam as part of this transaction provides a strong exclusivity position in this area.

“This program continues to build on our efforts to deliver comprehensive solutions to patients diagnosed with dementia,” said Axovant Chief Development Officer Dr. Lawrence Friedhoff, who led the development of Aricept (donepezil) for the treatment of Alzheimer’s disease through its approval in 1996. “We believe this product candidate can limit the peripheral side effects of cholinesterase inhibitors which frequently represent an obstacle for patients to adopt or remain on therapy.”

“We believe our lead product candidate intepirdine could deliver sustained cognitive and functional benefits when combined with cholinesterase inhibitors, the current standard of care in Alzheimer’s disease, while RVT-103 has the potential to mitigate known side effects associated with that standard of care,” said Mark Altmeyer, President and Chief Commercial Officer of Axovant Sciences.

“These complementary approaches—of delivering additional cognitive and functional benefits with intepirdine, while also mitigating the side effects of cholinesterase inhibitors with RVT-103— could transform the future standard of care for millions of patients currently diagnosed with Alzheimer’s disease.”

Axovant plans to initiate clinical studies for RVT-103 shortly, with initial results expected in 2017. Depending on results, Axovant may pursue registration programs in the United States. In addition, Axovant intends to evaluate opportunities for higher doses of cholinesterase inhibitors to deliver additional efficacy, potentially in combination with intepirdine.

Axovant believes Qaam’s technology may be superior to other competitive approaches combining an anticholinergic agent with a cholinesterase inhibitor in an attempt to reduce the peripheral side effects associated with cholinesterase inhibitors. Glycopyrrolate is believed to have minimal-to-no penetration into the central nervous system (CNS), and therefore may avoid CNS side effects associated with other anticholinergic agents, including worsening of cognition and an increase in the incidence of falls.

Financial terms of the transaction were not disclosed. Axovant does not expect the program to have a material effect on its use of cash in the fiscal year ending March 31, 2017.

Phase 2 Study of Gait and Balance in Patients with Dementia

Axovant expects to initiate in calendar year 2016 a phase 2 study to evaluate the effects of intepirdine on gait and balance in patients with Alzheimer's disease, dementia with Lewy bodies and Parkinson's disease dementia. In this study, Axovant intends to further investigate the observation of a reduced rate of falls seen in patients treated with intepirdine in the prior 684-patient study of intepirdine on a background of stable donepezil therapy.

“We look forward to this important study,” stated Dr. Nico Bohnen, Professor of Radiology and Neurology at the University of Michigan and the Director of the Movement Disorders Clinic at the Ann Arbor VA. “There is a growing body of scientific research suggesting that cholinergic deficits are a driver of falls in elderly patients diagnosed with dementia and that increasing cholinergic transmission may have benefit for patients.”

Additional Corporate Highlights since March 31, 2016

- **Intepirdine Open-Label Extension study:** Patients completing the double-blind, placebo-controlled, Phase 3 MINDSET study started to enroll in a 12-month open-label study designed to provide further safety and tolerability information. Secondary analyses will assess changes to patient scores on the Dependence Scale. Various background therapies, including cholinesterase inhibitors and memantine will be allowed during the open-label study.
 - **Intepirdine and rosuvastatin drug-drug interaction study:** No drug-drug interactions were observed between intepirdine and rosuvastatin in a group of healthy, elderly subjects.
 - **2016 Alzheimer's Association International Conference:** The company presented the following four posters to highlight aspects of its current clinical programs and development-stage assets:
 - “A Large, Randomized, Double-Blind, Placebo-Controlled Study Evaluating Intepirdine (RVT-101), a Neurotransmitter-Targeted Therapy, in Subjects with Mild-to-Moderate Alzheimer’s Disease on Donepezil Treatment: Phase 3 MINDSET Study Design”
 - “*In Vivo* Alterations in Brain Glucose Utilization with Intepirdine (RVT-101), a 5-HT₆ Receptor Antagonist for the Treatment of Alzheimer’s Disease”
 - “Effect of Food on the Pharmacokinetics of Intepirdine (RVT-101) in Healthy Adult Subjects”
 - “An Evaluation of the Safety of Nelotanserin in Human Subjects, a Potent and Highly Selective 5-HT_{2A} Inverse Agonist that is Being Developed as a Treatment for Visual Hallucinations and REM Behavior Disorder in Lewy Body Dementia”
-

Pipeline Programs

Axovant is developing intepirdine, nelotanserin, RVT-103, and other combinations of cholinesterase inhibitors with glycopyrrolate as potential treatments for patients with Alzheimer's disease and Lewy body dementia. The company expects top-line results from its ongoing and planned clinical studies as follows:

- Results from the Phase 3 study of intepirdine in subjects with mild-to-moderate Alzheimer's disease on a stable background of donepezil therapy, the MINDSET Study, as well as a potential NDA filing in 2017
- Results from the Phase 2b study of intepirdine in subjects with dementia with Lewy bodies, the HEADWAY-DLB study, in 2017
- Preliminary results from the Phase 2 study evaluating nelotanserin for treatment of visual hallucinations in subjects with Lewy body dementia in the second half of 2016
- Results from the Phase 2 study evaluating nelotanserin for treatment of REM Behavior Disorder in subjects with dementia with Lewy bodies in 2017
- Results from the Phase 2 study of the effects of intepirdine on gait and balance in subjects with Alzheimer's disease, dementia with Lewy bodies, and Parkinson's disease dementia in 2017
- Initial results from the RVT-103 program in 2017

First Quarter Financial Summary

For the first fiscal quarter ended June 30, 2016, research and development expenses were \$25.3 million, of which \$5.0 million was attributable to non-cash, share-based compensation expense. General and administrative expenses for the first quarter were \$12.6 million, of which \$6.6 million was attributable to non-cash, share-based compensation expense. Net loss for the quarter ended June 30, 2016 was \$38.1 million, or \$(0.38) per share.

Axovant held cash of \$252.7 million at June 30, 2016, and net cash used in operating activities was \$18.6 million for the three months ended June 30, 2016.

About Axovant

Axovant Sciences Ltd. is a leading clinical-stage biopharmaceutical company focused on acquiring, developing and commercializing novel therapeutics for the treatment of dementia. Axovant intends to develop a pipeline of product candidates to comprehensively address the cognitive, functional and behavioral aspects of dementia and related neurological disorders. Our vision is to become the leading company focused on the treatment of dementia by addressing all forms and aspects of this condition.

About MINDSET

MINDSET is a Phase 3 international, multi-center, double-blind, placebo-controlled clinical study designed to evaluate the safety, tolerability and efficacy of intepirdine in patients with mild-to-moderate Alzheimer's disease. The 24-week trial will compare 35 mg, once-daily oral doses of intepirdine to placebo in approximately 1,150 patients with mild-to-moderate Alzheimer's disease on a stable background of donepezil therapy. The primary efficacy evaluations are the Alzheimer's Disease Assessment Scale - cognitive subscale (ADAS-cog) and the Alzheimer's Disease Cooperative Study - Activities of Daily Living scale (ADCS-ADL), each of which have been used as endpoints to obtain regulatory approval of currently-marketed Alzheimer's disease treatments in the United States and Europe.

The MINDSET trial is being conducted pursuant to a Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA).

The MINDSET trial is designed to confirm the results of a 684-patient Phase 2b international, multi-center, double-blind placebo-controlled study in which patients on a stable background of donepezil therapy receiving 35 mg of intepirdine were observed to have statistically significant improvements in their ADAS-cog and ADCS-ADL scores as compared to patients receiving donepezil alone.

For more information, please visit www.alzheimersglobalstudy.com, email mindset@axovant.com or call 646-495-8197.

About HEADWAY-DLB

HEADWAY-DLB is a Phase 2b international, multi-center, double-blind, placebo-controlled clinical study designed to evaluate the safety, tolerability and efficacy of intepirdine in patients with dementia with Lewy bodies. The 24-week trial will evaluate once-daily oral doses of 70 mg intepirdine, 35 mg intepirdine, and placebo in subjects with probable dementia with Lewy bodies. The primary efficacy evaluations are Clinician's Interview-Based Impression of Change Plus Caregiver Input (CIBIC-Plus) and a computerized cognitive battery.

For more information, please visit www.lewybodystudy.com or e-mail headwaydlb@axovant.com or call 646-677-5778.

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 dementia with Lewy bodies, the Phase 2 study of nelotanserin in patients with DLB or PDD suffering from visual hallucinations, the Phase 2 study of nelotanserin in patients with DLB suffering from RBD, the Phase 2 study of the effects of intepirdine on a background of cholinesterase inhibitor therapy on gait and balance in dementia patients, the clinical studies of RVT-103 and the licensed technology related to a combination of cholinesterase inhibitors and peripheral muscarinic receptor antagonists, 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 and nelotanserin; 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 or nelotanserin 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-Q to be filed with the Securities and Exchange Commission on or about August 15, 2016, 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 and Comprehensive Loss
(in thousands, except share and per share amounts)
(unaudited)

	<u>Three Months Ended</u> <u>June 30, 2016</u>	<u>Three Months Ended</u> <u>June 30, 2015</u>
Operating expenses:		
Research and development expenses (includes \$4,964 and \$6,901 of share-based compensation expense for the three months ended June 30, 2016 and 2015, respectively)	\$ 25,276	\$ 9,486
General and administrative expenses (includes \$6,597 and \$12,276 of share-based compensation expense for the three months ended June 30, 2016 and 2015, respectively)	12,631	15,393
Total operating expenses	<u>37,907</u>	<u>24,879</u>
Loss before provision for income tax	(37,907)	(24,879)
Income tax expense	<u>148</u>	<u>74</u>
Net loss and comprehensive loss	<u>\$ (38,055)</u>	<u>\$ (24,953)</u>
Net loss per common share — basic and diluted	<u>\$ (0.38)</u>	<u>\$ (0.31)</u>
Weighted average common shares outstanding — basic and diluted	<u>99,150,000</u>	<u>80,307,692</u>

AXOVANT SCIENCES LTD.
Condensed Consolidated Balance Sheets
(in thousands)
(unaudited)

	<u>June 30, 2016</u>	<u>March 31, 2016</u>
Assets		
Current assets:		
Cash	\$ 252,657	\$ 276,251
Prepaid expenses and other current assets	3,300	4,865
Income tax receivable	796	970
Total current assets	<u>256,753</u>	<u>282,086</u>
Property, plant and equipment, net	106	89
Deferred tax assets	323	323
Total assets	<u>\$ 257,182</u>	<u>\$ 282,498</u>
Liabilities and Shareholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	\$ 2,843	\$ 622
Due to Roivant Sciences Ltd. and Roivant Sciences, Inc.	2,218	1,814
Accrued expenses	11,872	8,319
Contingent payment liability	—	5,000
Total current liabilities	<u>16,933</u>	<u>15,755</u>
Total liabilities	<u>16,933</u>	<u>15,755</u>
Total shareholders' equity (deficit)	<u>240,249</u>	<u>266,743</u>
Total liabilities and shareholders' equity (deficit)	<u>\$ 257,182</u>	<u>\$ 282,498</u>

Source: Axovant Sciences Ltd.

Contact:

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