

**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): **February 14, 2017**

**Axovant Sciences Ltd.**  
(Exact name of registrant as specified in its charter)

<b>Bermuda</b> (State or other jurisdiction of incorporation)	<b>001-37418</b> (Commission File No.)	<b>98-1333697</b> (I.R.S. Employer Identification No.)
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<b>Clarendon House - 2 Church Street</b> <b>Hamilton HM 11</b> <b>Bermuda</b> (Address of principal executive office)	<b>Not Applicable</b> (Zip Code)
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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 February 14, 2017, Axovant Sciences Ltd. (the "**Registrant**") issued a press release announcing its financial results for the three and nine months ended December 31, 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.

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**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

<b>Exhibit No.</b>	<b>Description</b>
99.1	Press Release of Axovant Sciences Ltd., dated February 14, 2017, "Axovant Sciences Announces Dementia Pipeline Updates and Reports Financial Results for the Third Fiscal Quarter and Nine Months Ended December 31, 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:	By:	<u>/s/ Gregory Weinhoff</u>
<u>February 14, 2017</u>	Name:	Gregory Weinhoff
	Title:	Principal Financial Officer

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description</b>
99.1	Press Release of Axovant Sciences Ltd., dated February 14, 2017, "Axovant Sciences Announces Dementia Pipeline Updates and Reports Financial Results for the Third Fiscal Quarter and Nine Months Ended December 31, 2016"



**Axovant Sciences Announces Dementia Pipeline Updates and Reports Financial Results for the Third Fiscal Quarter and Nine Months Ended December 31, 2016**

BASEL, Switzerland, Feb. 14, 2017 /PRNewswire/ - Axovant Sciences (NYSE: **AXON**), a leading clinical-stage biopharmaceutical company focused on the treatment of dementia, today announced corporate updates and reported financial results for the third fiscal quarter ended December 31, 2016.

“We look forward to a transformational year ahead for Axovant,” stated Vivek Ramaswamy, Chief Executive Officer of Axovant Sciences. “Our clinical programs are on-track to produce results from multiple late-stage clinical studies in 2017, and we continue to prepare for the potential commercial launches of those drugs if we receive marketing approval. In addition, we recently completed a financing that provides additional flexibility to advance or expand our pipeline.”

**MINDSET Trial Recruitment:**

In January 2017, Axovant announced completion of recruitment for the Phase 3 MINDSET study of its investigational drug intepirdine in patients with mild-to-moderate Alzheimer’s disease. Topline results are expected in the third quarter of 2017.

**Venture Debt Financing:**

In February 2017, Axovant announced that it entered into a \$55.0 million debt financing agreement with Hercules Capital, Inc., a leader in customized debt financing for companies in life sciences and technology-related markets. The full amount of the \$55.0 million loan was funded at closing.

The loan will mature on March 1, 2021. Payments under the loan are interest only for a period of 18 months, followed by equal monthly installments of principal and interest thereafter. The interest-only period may be extended to 24 months, contingent upon Axovant achieving certain clinical development milestones.

In connection with the debt financing, Axovant issued Hercules a warrant to purchase up to 274,086 of its common shares at an exercise price of \$12.04 per share.

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**Nelotanserin Preliminary Results:**

In February 2017, Axovant reported preliminary results from the planned interim analysis of the first 11 patients to complete its Phase 2 study of nelotanserin in Lewy body dementia patients.

In these patients, Axovant observed statistically significant improvements in the pre-specified primary endpoint of Unified Parkinson's Disease Rating Scale (UPDRS) Parts II + III for nelotanserin versus placebo. There were no drug-related serious adverse events, and there were no adverse events that led to discontinuation of the study drug. In the interim analysis, secondary endpoints did not demonstrate statistically significant differences for nelotanserin relative to placebo.

Based on these preliminary results, Axovant plans to expand patient recruitment to confirm the treatment benefits observed in the interim results from this ongoing study. Axovant expects the full study to complete in mid-2017.

**Additional Corporate Highlights since September 30, 2016:**

- **Intepirdine Thorough QT (TQT) Study:** A TQT study of intepirdine was completed with no adverse findings.
  - **Intepirdine and itraconazole drug-drug interaction study:** No clinically relevant drug-drug interactions were observed between intepirdine and itraconazole, a potent inhibitor of metabolic enzymes, in a group of healthy subjects.
  - **Intepirdine Function and Independence Data Presentations:** Axovant presented patient function and independence data analyses from its prior Phase 2b study of investigational drug intepirdine in Alzheimer's disease at the Clinical Trials in Alzheimer's Disease (CTAD) Meeting in December 2016.
    - Oral Presentation: "An Assessment of Dependence Level Progression Using a Conversion Algorithm of ADCS-ADL to Dependence Scale and Data From a Double Blind Placebo Controlled Trial of Intepirdine (RVT-101)"
    - Poster Presentation: "The Efficacy of Intepirdine (RVT-101), a 5-HT<sub>6</sub> Receptor Antagonist, as an Adjunct to Donepezil in Adults with Mild-to-Moderate Alzheimer's Disease: Completer Analysis of a Phase 2b Study"
    - Poster Presentation: "Intepirdine (RVT-101) as an Adjunct to Donepezil in Adults with Mild-to-Moderate Alzheimer's Disease: ADCS-ADL Subscale Analyses"
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### **Pipeline Programs:**

Axovant is developing intepirdine, nelotanserin, RVT-103, and RVT-104 as potential treatments for patients with Alzheimer's disease and Lewy body dementia. The company expects the following top-line results from its ongoing clinical studies in 2017:

- **MINDSET:** Results from the Phase 3 MINDSET study in the third quarter of 2017.
- **HEADWAY-DLB:** Results from the Phase 2b study of intepirdine in patients with dementia with Lewy bodies (DLB), the HEADWAY-DLB study, in the fourth quarter of 2017.
- **Nelotanserin Phase 2 Visual Hallucinations Study:** Axovant expects to complete the expanded study in mid-2017 and plans to present detailed results at a scientific meeting in 2017.
- **Nelotanserin Phase 2 REM Behavior Disorder Study:** Results from the Phase 2 study evaluating nelotanserin for treatment of REM Behavior Disorder (RBD) in patients with DLB in the second half of 2017.
- **Gait and Balance in Patients with Dementia Study:** Results from the Phase 2 study of the effects of intepirdine on gait and balance in patients with Alzheimer's disease, DLB and Parkinson's disease dementia (PDD) in 2017.
- **RVT-103 Proof of Concept Study:** Results from the RVT-103 program in the first half of 2017.

### **Third Quarter 2016 Financial Summary**

For the third fiscal quarter ended December 31, 2016, research and development expenses were \$36.6 million, of which \$4.6 million was attributable to non-cash, share-based compensation expense. General and administrative expenses for the third quarter were \$11.3 million, of which \$3.7 million was attributable to non-cash, share-based compensation expense. Net loss for the quarter ended December 31, 2016 was \$47.8 million, or \$(0.48) per share.

### **Nine Months 2016 Financial Summary**

For the nine months ended December 31, 2016, research and development expenses were \$94.0 million, of which \$14.0 million was attributable to non-cash, share-based compensation expense. General and administrative expenses for the nine months were \$33.4 million, of which \$13.8 million was attributable to non-cash, share-based compensation expense. Net loss for the nine months ended December 31, 2016 was \$128.1 million, or \$(1.29) per share.

Axovant held cash of \$200.4 million at December 31, 2016. Proceeds from the debt financing with Hercules Capital, completed in February 2017, are not included in the cash balance at December 31, 2016. Net cash used in operating activities was \$70.8 million for the nine months ended December 31, 2016.

### **About Axovant Sciences**

Axovant Sciences is a global clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapeutics for the treatment of dementia, including Alzheimer's disease and Lewy body dementia. Our vision is to become the leading company focused on the treatment of dementia by addressing all forms and aspects of this condition.

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**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 has been used as respective 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.

**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 DLB. The 24-week trial will evaluate once-daily oral doses of 70 mg intepirdine, 35 mg intepirdine, and placebo in patients with probable DLB. 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](http://www.lewybodystudy.com), e-mail [headwaydlb@axovant.com](mailto:headwaydlb@axovant.com) or call 646-677-5778.

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## **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 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 patients with Alzheimer's disease, DLB and PDD, 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, nelotanserin and RVT-103; 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. In addition, promising interim results or other preliminary analyses do not in any way ensure that later or final results in a clinical trial or in related or similar clinical trials will replicate those interim results. There can be no assurance that the clinical programs including the programs for intepirdine, nelotanserin or RVT-103 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 February 14, 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.

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

	<b>Three Months Ended December 31,</b>		<b>Nine Months Ended December 31,</b>	
	<b>2016</b>	<b>2015</b>	<b>2016</b>	<b>2015</b>
Operating expenses:				
Research and development expenses				
(includes share-based compensation expense of \$4,592 and \$14,599 for the three months ended December 31, 2016 and 2015 and \$14,029 and \$24,421 for the nine months ended December 31, 2016 and 2015, respectively)	\$ 36,630	\$ 34,324	\$ 93,980	\$ 53,209
General and administrative expenses				
(includes share-based compensation expense of \$3,739 and \$24,457 for the three months ended December 31, 2016 and 2015 and \$13,800 and \$39,537 for the nine months ended December 31, 2016 and 2015, respectively)	11,342	28,230	33,422	49,364
Total operating expenses	<u>47,972</u>	<u>62,554</u>	<u>127,402</u>	<u>102,573</u>
Loss before provision for income tax	(47,972)	(62,554)	(127,402)	(102,573)
Income tax (benefit) expense	(161)	802	716	901
Net loss and comprehensive loss	<u>\$ (47,811)</u>	<u>\$ (63,356)</u>	<u>\$ (128,118)</u>	<u>\$ (103,474)</u>
Net loss per common share — basic and diluted	<u>\$ (0.48)</u>	<u>\$ (0.64)</u>	<u>\$ (1.29)</u>	<u>\$ (1.11)</u>
Weighted average common shares outstanding — basic and diluted	<u>99,161,719</u>	<u>99,150,000</u>	<u>99,157,415</u>	<u>92,914,909</u>

**AXOVANT SCIENCES LTD.**  
**Condensed Consolidated Balance Sheets**  
*(Unaudited, in thousands)*

	<b>December 31, 2016</b>	<b>March 31, 2016</b>
<b>Assets</b>		
Current assets:		
Cash	\$ 200,405	\$ 276,251
Prepaid expenses and other current assets	4,234	4,865
Income tax receivable	938	970
Total current assets	<u>205,577</u>	<u>282,086</u>
Property and equipment, net	159	89
Deferred tax assets	323	323
Total assets	<u>\$ 206,059</u>	<u>\$ 282,498</u>
<b>Liabilities and Shareholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 9,251	\$ 622
Due to Roivant Sciences Ltd. and Roivant Sciences, Inc.	4,947	1,814
Accrued expenses	25,397	8,319
Contingent payment liability	—	5,000
Total current liabilities	<u>39,595</u>	<u>15,755</u>
Total liabilities	<u>39,595</u>	<u>15,755</u>
Total shareholders' equity	<u>166,464</u>	<u>266,743</u>
Total liabilities and shareholders' equity	<u>\$ 206,059</u>	<u>\$ 282,498</u>

**Source:** Axovant Sciences

**Contact:**

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