# 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): **January 9, 2017**

# Axovant Sciences Ltd.

(Exact name of registrant as specified in its charter)

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

| **Clarendon House - 2 Church Street**<br>**Hamilton HM 11**<br>**Bermuda** | **Not Applicable** |
|---|---|
| (Address of principal executive office) | (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 January 9, 2017, Axovant Sciences Ltd. ("***Axovant"***) issued a press release providing its estimated cash balance as of December 31, 2016. This amount is preliminary, unaudited and subject to change upon completion of Axovant's review of its financial statements as of and for the quarterly period ended December 31, 2016. Additional information and disclosures would be required for a more complete understanding of Axovant's financial position and results of operations as of December 31, 2016. A copy of the press release is attached 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 January 9, 2017, "Axovant Sciences Announces Pipeline Program Updates and Presentation at 35th Annual J.P. Morgan Conference" |

**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: January 9, 2017

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 January 9, 2017, "Axovant Sciences Announces Pipeline Program Updates and Presentation at 35th Annual J.P. Morgan Conference" |

**Exhibit 99.1**

**Axovant Sciences Announces Pipeline Program Updates and Presentation at 35th Annual J.P. Morgan Conference**

- ***Recruitment in MINDSET study completed***
- ***Intepirdine TQT study completed with no adverse findings***
- ***Strong cash balance of $200 million at December 31, 2016***
- ***Presentation and Live Webcast at J.P. Morgan Conference on Tuesday, January 10th at 12pm PT (3pm ET)***

BASEL, Switzerland, Jan. 9, 2017 /PRNewswire/ — Axovant Sciences (NYSE: **AXON**), a leading clinical-stage biopharmaceutical company focused on the treatment of dementia, today announced updates that highlight recent advancement within its clinical programs.

**Pipeline Program Updates**

- **MINDSET trial recruitment:** Axovant announced completion of recruitment in the Phase 3 MINDSET study of intepirdine in patients with mild-to-moderate Alzheimer's disease. The MINDSET trial is being conducted pursuant to a Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA).
- **Intepirdine Thorough QT (TQT) study:** The results of the TQT study exclude significant QT interval prolongation following a supratherapeutic dose of intepirdine.
- **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.
- **RVT-103 proof of concept study:** Axovant recently completed the first portion of a proof of concept study. In the first portion of the study, subjects were randomized to treatment with a single dose of donepezil and either placebo or a peripheral muscarinic receptor antagonist. The company remains blinded to these results. The second portion of this study has begun and will explore multiday dosing of donepezil and either placebo or a peripheral muscarinic receptor antagonist. The primary endpoint of this study is safety.

**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 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, the HEADWAY-DLB study, in the fourth quarter of 2017.
- **Nelotanserin Phase 2 Visual Hallucinations Study:** Preliminary results from the first cohort of 10 patients with Lewy Body dementia in February 2017. The company expects to present additional data from all 20 patients in the study in the first half of 2017.
- **Nelotanserin Phase 2 REM Behavior Disorder Study:** Results from the Phase 2 study evaluating nelotanserin for treatment of REM Behavior Disorder in patients with dementia with Lewy bodies 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, dementia with Lewy bodies, and Parkinson's disease dementia in 2017.
- **RVT-103 Proof of Concept Study:** Results from the RVT-103 program in the first half of 2017.

"2016 represented yet another year of major disappointments for late-stage clinical trials in dementia," said Vivek Ramaswamy, Chief Executive Officer of Axovant Sciences. "In 2017, Axovant expects results from five different phase 2 and phase 3 programs for Alzheimer's disease and Lewy body dementia, including results from the Phase 3 MINDSET study. On behalf of the millions of patients in need of new therapeutic options, we hope that 2017 represents a bright year for major advances in the treatment of dementia."

**Cash Balance as of December 31, 2016**

Axovant estimates that its cash balance was approximately $200.4 million as of December 31, 2016.

**J.P. Morgan Conference Presentation and Webcast**

Axovant Sciences will be presenting at the 35th Annual J.P. Morgan Healthcare Conference on January 10 at 12:00 p.m. PST.

A simultaneous webcast will be available in the Investors section of Axovant's website at www.axovant.com. A replay will be available for 30 days following the conference.

**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.

**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.

**Forward-Looking Statements**

This press release contains forward-looking statements, including statements regarding Axovant's clinical development and regulatory strategy, including for intepirdine, nelotanserin, RVT-103 and RVT-104. Forward-looking statements can be identified by the words "believe," "anticipate," "continue", "estimate", "project," "expect," "plan," "potential," "intend," "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, including 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. The products discussed are investigational and not approved and there can be no assurance that the clinical programs, including those for intepirdine, nelotanserin, RVT-103 and 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-Q filed with the Securities and Exchange Commission on November 7, 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.

**Source:** Axovant Sciences

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