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): **September 26, 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.)

Suite 1, 3rd Floor 11-12 St. James's Square London SW1Y 4LB, United Kingdom	**Not Applicable**
(Address of principal executive office)	(Zip Code)

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

(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.

☒

Item 8.01 Other Events.

On September 26, 2017, Axovant Sciences Ltd. (the "***Registrant***") issued a press release announcing the results from its Phase 3 MINDSET clinical trial of its investigational drug intepirdine in patients with mild to moderate Alzheimer's disease who were receiving background donepezil therapy. A copy of this press release is furnished herewith as Exhibit 99.1 to this Current Report and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release of Axovant Sciences Ltd., dated September 26, 2017, "Axovant Announces Negative Topline Results of Intepirdine Phase 3 MINDSET Trial in Alzheimer's Disease"

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:
September 26, 2017

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

Exhibit 99.1

AXOVANT

Axovant Announces Negative Topline Results of Intepirdine Phase 3 MINDSET Trial in Alzheimer's Disease

--Conference call today at 8:00 a.m. EDT--

BASEL, Switzerland, September 26, 2017 - Axovant Sciences (NASDAQ: AXON) today announced that the Phase 3 MINDSET clinical trial of its investigational drug intepirdine in patients with mild to moderate Alzheimer's disease (AD) who were receiving background donepezil therapy did not meet its co-primary efficacy endpoints. At 24 weeks, patients treated with 35 mg of intepirdine did not experience improvement in cognition or in measures of activities of daily living as measured by the Alzheimer's Disease Assessment Scale-Cognitive Subscale (ADAS-Cog) and by the Alzheimer's Disease Cooperative Study-Activities of Daily Living scale (ADCS-ADL), respectively, compared to patients treated with placebo. In the study, intepirdine was generally well tolerated.

After 24 weeks of treatment, change from baseline in cognition was non-significantly improved in the intepirdine arm versus the placebo arm (0.36 ADAS-Cog points; p-value = 0.22). In addition, there was essentially no difference between the intepirdine and placebo arms in change from baseline in activities of daily living (0.09 ADCS-ADL points; p-value = 0.83). Of the endpoints analyzed to date, the only endpoint in which any significant improvement was seen in the intepirdine arm versus the placebo arm was in the first key secondary endpoint, the Clinician Interview-Based Impression of Change plus caregiver interview, or CIBIC+ (0.12 CIBIC+ points; p-value = 0.02). The Company will work with investigators to conclude the MINDSET open-label extension study.

"While we are deeply disappointed by these trial results, we also are saddened for the millions of patients and families impacted by Alzheimer's disease. However, we believe that the fight against Alzheimer's and other important areas of unmet need in neurology is too important to be derailed by this setback," said David Hung, M.D., chief executive officer of Axovant. "We are grateful to the investigators, patients and caregivers who participated in this important trial and supported us in this journey. Moreover, we remain committed to advancing our pipeline, which includes our Phase 2b HEADWAY study of intepirdine, and nelotanserin, our highly selective inverse agonist of the 5-HT_{2A} receptor in Phase 2 development, both of which are being evaluated in patients with dementia with Lewy bodies."

The HEADWAY trial studying intepirdine in patients with dementia with Lewy bodies (DLB) remains on track to report topline results at the end of 2017. This study investigates two doses of intepirdine, 35 mg (the dose used in the MINDSET trial) and 70 mg, a higher dose intended to engage both 5-HT_6 and 5-HT_{2A} receptors. Intepirdine has received Fast Track designation from the U.S. Food and Drug Administration for the treatment of DLB.

About MINDSET

The global, randomized, double-blind, placebo-controlled Phase 3 MINDSET trial evaluated the efficacy, safety and tolerability of intepirdine in patients with mild to moderate AD on donepezil therapy over 24 weeks. The trial compared once-daily oral doses of intepirdine 35 mg to placebo in 1,315 patients ages 50 to 85. The Mini-Mental State Examination (MMSE) score at baseline ranged from 10 to 26. Co-primary efficacy endpoints were ADAS-Cog and the ADCS-ADL.

About Alzheimer's Disease
Alzheimer's disease (AD), the most common form of dementia, is a chronic, progressive neurodegenerative disorder that worsens over time. It is the fifth leading cause of death among people age 65 years and older in the United States.[i] According to the Alzheimer's Association, about 5.5 million people in the U.S. today are affected by AD,[i]and that number could triple by 2050.[i] In addition to the suffering and devastating effect on quality of life experienced by both patients and caregivers, AD costs the U.S. approximately $259 billion annually. [i] No new chemical entities for AD have been approved by the FDA since 2003.[ii]

About Intepirdine
Intepirdine is an oral, once-daily, investigational drug in development for the treatment of mild to moderate AD and dementia with Lewy bodies (DLB). A potent antagonist of the 5-HT_6 receptor, intepirdine promotes the release of acetylcholine in the brain. This neurotransmitter is believed to be critical for alertness, memory, thought and judgment -- the key components of cognition and function that are impaired in patients with dementia. At higher doses, intepirdine also blocks the 5-HT_{2A} receptor, which is believed to play a role in the psychosis, REM sleep behavior disorder and motor dysfunction seen in patients with DLB.

Teleconference/Webcast Details
To participate in the live conference call today, September 26, at 8:00 a.m. EDT, please dial (352) 672-9956 from the U.S. and Canada or +1 (844) 842-5660 internationally, and use the passcode 89218918. The live call is being webcast and can be accessed on the "Events and Presentations" page of the "Investors" section of the Company's website at http://investors.axovant.com. A replay of the webcast will be available for 30 days following the live event.

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 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 www.axovant.com.

Forward-Looking Statements
This press release contains forward-looking statements, including statements regarding Axovant's plans for the development of its pipeline and completion of the MINDSET open-label extension study, as well as the HEADWAY study. 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, increased regulatory requirements, and interim results or other preliminary analyses do not 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 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 (SEC) on 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.

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[i] https://www.alz.org/documents_custom/2017-facts-and-figures.pdf
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[ii] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4095696/