

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): **November 2, 2015**

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.)

14 Par-La-Ville Road
Hamilton HM 08, Bermuda
(Address of principal executive office)

Not Applicable
(Zip Code)

Registrant's telephone number, including area code: **+1 (441) 295-5950**

(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 1.01. Entry into a Material Definitive Agreement.

On October 28, 2015, Axovant Sciences Ltd, (the "Company") exercised its option, pursuant to an Option and Waiver Agreement between the Company and its parent company, Roivant Sciences Ltd. ("Roivant"), dated May 8, 2015 ("Option Agreement"), to acquire from Roivant the global rights to nelotanserin, a novel inverse agonist of the 5HT_{2A} receptor, and related compounds. Upon exercise of the option, the Company has assumed all of Roivant's rights and obligations under a development, marketing and supply agreement between Roivant and Arena Pharmaceuticals GmbH ("Arena"), dated May 8, 2015 (the "Arena Agreement").

Pursuant to the Option Agreement, in connection with this exercise, the Company will reimburse Roivant approximately \$4.8 million, which is 110% of (i) payments previously made by Roivant to Arena, and (ii) costs incurred by Roivant to date in connection with the development and commercialization of nelotanserin under the Arena Agreement.

Under the terms of the Arena Agreement, the Company has the exclusive right and responsibility to conduct the preclinical and clinical development of products containing nelotanserin or related compounds (collectively, the “Products”) at the Company’s expense. The Company also has the exclusive right to distribute, market and commercialize the Products. Arena will be responsible for supplying to the Company, and the Company has an obligation to exclusively purchase from Arena, all of the Company’s requirements of Products at a price equal to the greater of (a) an agreed minimum purchase price or (b) an agreed percentage of the Company’s net sales of such Product. The Company will be responsible for future contingent payments under the Arena Agreement, including an aggregate of up to \$4.0 million upon the achievement of specified development milestones, up to \$37.5 million upon the achievement of specified regulatory milestones and up to \$60.0 million upon the achievement of specified commercial milestones.

The Arena Agreement will remain in effect until terminated: (1) by the parties’ mutual agreement; (2) for any reason by Axovant upon 90 days’ written notice to Arena; (3) by either party upon written notice for the other party’s material breach or insolvency event if such party fails to cure such breach or the insolvency event is not dismissed within the specified cure period.; or (4) by Arena if Axovant or its affiliates participate in a challenge to certain Arena patents.

The foregoing description of the Arena Agreement is only a summary and is qualified in its entirety by reference to the Arena Agreement, which will be filed with the Securities and Exchange Commission as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ending December 31, 2015. The Option Agreement was filed with the Securities and Exchange Commission as Exhibit 10.9 to Amendment No. 1 to the Company’s Registration on Form S-1 (Registration No. 333-204073) on May 22, 2015.

Item 2.02 Results of Operations and Financial Condition.

On November 2, 2015, the Company issued a press release announcing its financial results for three and six months ended September 30, 2015. 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, dated November 2, 2015, “Axovant Announces Expansion of Dementia Drug Development Pipeline and Reports Financial Results for the Second Fiscal Quarter and Six Months Ended September 30, 2015 ”



Axovant Announces Expansion of Dementia Drug Development Pipeline and Reports Financial Results for the Second Fiscal Quarter and Six Months Ended September 30, 2015

- *Acquired global rights to nelotanserin, a potential best-in-class 5HT_{2A} inverse agonist*
- *Two clinical studies with nelotanserin planned to start in early 2016 to address multiple aspects of Lewy body dementia*
- *Expanded RVT-101 development program to include a phase 2b study for the treatment of dementia with Lewy bodies*
- *Expansion of pipeline adds multiple key clinical catalysts*
- *Axovant senior management team to host conference call and presentation today at 4:30 p.m. ET*

HAMILTON, Bermuda, November 2, 2015 /PRNewswire/ - Axovant Sciences Ltd. (NYSE: **AXON**), a leading clinical-stage biopharmaceutical company focused on the treatment of dementia, today announced an expansion of its dementia drug development pipeline with the acquisition of nelotanserin and the addition of three new clinical programs to address cognitive, behavioral and functional aspects of Lewy body dementia, a disease affecting approximately 1.4 million people in the U.S. The Company also provided an update on its ongoing Phase 3 development program for RVT-101 to treat Alzheimer's disease. In addition, the Company reported financial results for the second fiscal quarter and first half of 2015.

"Consistent with our mission, we have expanded our development pipeline in a capital-efficient manner that we believe will enable Axovant to create value for patients and our shareholders," stated Vivek Ramaswamy, Chief Executive Officer of Axovant Sciences, Inc. "The acquisition of global rights to nelotanserin and the addition of a development program for RVT-101 in dementia with Lewy bodies should lead to multiple value-creating catalysts in 2016 and help establish Axovant as the global leader in the treatment of Lewy body dementia."

Dr. James Leverenz, Chair, Scientific Advisory Council of the Lewy Body Dementia Association and Director of the Cleveland Lou Ruvo Center for Brain Health at the Cleveland Clinic, stated, "Pharmaceutical companies have historically neglected Lewy body dementia despite its status as the second leading degenerative cause of dementia, next to Alzheimer's disease. The new development programs for RVT-101 and nelotanserin represent an important and promising step towards addressing this devastating disease, and I look forward to the progress of these exciting innovations in the field."

Acquisition of Global Rights to Nelotanserin

In October 2015, Axovant exercised its option to acquire global rights to nelotanserin from its parent company, Roivant Sciences Ltd. (RSL). RSL had previously acquired the global rights from Arena Pharmaceuticals, GmbH (Arena).

After exercising the option, Axovant paid RSL approximately \$4.8 million, which includes reimbursements for amounts paid to date by RSL to Arena. Under the development, marketing and supply agreement to which Axovant is now a party, Arena is eligible to receive future payments from Axovant of up to an aggregate of \$101.5 million based on the achievement of specified developmental, regulatory and commercial milestone events. Under the agreement, Arena will be the sole and exclusive manufacturer of nelotanserin for both clinical and commercial supply and will provide finished drug product to Axovant from Arena's qualified manufacturing facility in Switzerland for a price equal to 15 percent of Axovant's net sales of nelotanserin.

Axovant intends to initiate two Phase 2 clinical studies with nelotanserin in the first quarter of 2016. The first study will be in patients with either dementia with Lewy bodies (DLB) or Parkinson's disease dementia (PDD) who suffer from visual hallucinations. The second study will be in DLB patients experiencing REM Behavior Disorder (RBD).

Axovant also intends, pending additional data available in 2016, to initiate programs for nelotanserin in Alzheimer's disease psychosis and Parkinson's disease psychosis.

Dominic Behan, Ph.D., D.Sc., Chief Scientific Officer and Co-Founder of Arena, commented, "We are excited to work with Axovant to bring this potentially best-in-class 5HT_{2A} inverse agonist to market. We chose Axovant's team based on their clear leadership in the field of dementia. The impressive development plans that Dr. Larry Friedhoff and his team have created reaffirms our belief that working with Axovant will give nelotanserin the best opportunity to reach dementia patients."

RVT-101 in Dementia with Lewy Bodies Program Initiation

Axovant plans to initiate a 24-week Phase 2b study of RVT-101 as a potential treatment for DLB. The study is expected to start in the first quarter of 2016. If the results of this study are favorable, Axovant believes that the study could serve as the basis for seeking approval of RVT-101 to treat DLB patients.

RVT-101 in Alzheimer's Disease Program Update

As announced previously, in October 2015 Axovant commenced a global, multi-center, double-blind, placebo-controlled confirmatory Phase 3 study of RVT-101 for the treatment of mild-to-moderate Alzheimer's disease called the MINDSET Study.

The MINDSET Study is evaluating the safety, tolerability and efficacy of RVT-101 and seeks to confirm the results of a prior study in which patients treated with RVT-101 were observed to have statistically significant improvements in cognition and function in mild-to-moderate Alzheimer's disease patients. Subjects completing the MINDSET Study will be eligible to enroll in a 12 month open-label extension trial in which other medications for the treatment of Alzheimer's disease, including memantine and other cholinesterase inhibitors may be administered in combination with RVT-101.

Axovant has received a Special Protocol Assessment (SPA) agreement from the FDA for the MINDSET Study. The SPA agreement states that the design and planned analysis of this study adequately address the objectives necessary to support an application for marketing approval.

Second-Quarter 2015 Financial Summary

For the second fiscal quarter ended September 30, 2015, research and development expenses for the period were \$8.3 million, of which \$1.8 million was attributable to non-cash, share-based compensation expense. General and administrative expenses for the period were \$3.8 million, of which \$0.8 million was attributable to non-cash, share-based compensation expense. Net loss for the quarter of 2015 was \$12.1 million, or \$(0.12) per share.

First-Half 2015 Financial Summary

For the first half of 2015, research and development expenses for the period were \$18.9 million, of which \$9.8 million was attributable to non-cash, share-based compensation expense. General and administrative expenses for the period were \$21.1 million, of which \$15.1 million was attributable to non-cash, share-based compensation expense. Net loss for the first half of 2015 was \$40.1 million, or \$(0.45) per share.

Axovant held cash of \$320.2 million at September 30, 2015, and net cash used in operating activities was \$14.7 million for the first-half of 2015.

Conference Call Information

There will be a conference call with management today at 4:30 p.m. Eastern Time to discuss the strategic expansion of the Company's development pipeline as well as second quarter and first half 2015 financial results.

To participate in the call, please dial (866)-807-9684 (U.S. and Canada) or (412)-317-5415 (International) and ask to be connected to the "Axovant Call". Please dial in 10 minutes prior to the scheduled start time.

A replay of the call will be available from one hour after the end of the live call on November 2, 2015 until 11:59 p.m. ET on November 16, 2015 by dialing (877)-344-7529 (U.S.) or (855)-669-9658 (Canada) or (412)-317-0088 (International) and the passcode 10075025.

A simultaneous webcast can be accessed by visiting the Investors section of www.axovant.com and selecting Events and Presentations. In addition, a replay of the webcast will be available until 11:59 p.m. ET on December 2, 2015. The replay can be accessed by clicking on "Events" in the Investor Relations section of the website.

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 components 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 the disease.

About RVT-101

RVT-101 is an orally administered, potent antagonist of the 5HT₆ receptor. Antagonism of the 5HT₆ receptor is a novel mechanism of action that promotes the release of acetylcholine and other neurotransmitters thought to improve cognition and function in patients suffering from Alzheimer's disease and other forms of dementia. RVT-101 has been studied in 13 clinical trials and dosed in over 1,250 human subjects with a favorable safety and tolerability profile.

RVT-101 is an investigational new drug candidate and is not approved for any indication in any markets.

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 RVT-101 in patients with mild-to-moderate Alzheimer's disease. The 24-week trial will compare 35-mg, once-daily oral doses of RVT-101 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 designed to confirm the results of a 684-patient Phase 2 international, multi-center, double-blind placebo-controlled study in which patients on a stable background of donepezil therapy receiving 35 mg of RVT-101 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 Nelotanserin

Nelotanserin is a potentially best-in-class, once-daily orally-administered, highly potent and selective inverse agonist of the 5HT_{2A} receptor, which has been implicated in the pathophysiology of neuropsychiatric disturbances including psychosis and visual hallucinations. Axovant intends to develop nelotanserin to address multiple aspects of Lewy body dementia. Nelotanserin has been studied in seven clinical studies completed to date with nearly 800 human subjects exposed to the drug candidate. Nelotanserin has been well-tolerated in all clinical studies to date.

Nelotanserin is an investigational new drug candidate and is not approved for any indication in any markets.

About Lewy Body Dementia

Lewy body dementia is a progressive neurodegenerative disorder, which is pathologically characterized by the aggregation of alpha synuclein and other proteins in the brain known as Lewy bodies, causing cognitive, functional and behavioral effects. Lewy body dementia includes two similar conditions; dementia with Lewy bodies, or DLB, and Parkinson's disease dementia, or PDD. There are approximately 1.4 million people in the U.S. with Lewy body dementia.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding Axovant's expectations about timing of the Phase 3 registration program for RVT-101, planned clinical studies of nelotanserin, and other elements of its clinical development and regulatory strategy, and payments that may become due to Arena under the parties' development, marketing and supply agreement. Forward-looking statements can be identified by the words "believes," "expects," "plans," "potential," "intends," "will," "should" and 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 RVT-101 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 RVT-101 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 November 2, 2015, 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 data)
(unaudited)

	(Second Fiscal Quarter) Three Months Ended September 30, 2015	Six Months Ended September 30, 2015
Operating expenses:		
Research and development (includes \$1,799 and \$9,822 of share-based compensation expense for three and six months ended, September 30, 2015, respectively)	\$ 8,277	\$ 18,886
General and administrative (includes \$821 and \$15,080 of share-based compensation expense for the three and six months ended, September 30, 2015, respectively)	3,760	21,134
Total operating expenses	<u>12,037</u>	<u>40,020</u>
Loss before provision for income tax	(12,037)	(40,020)
Income tax expense	24	99
Net loss and comprehensive loss	<u>\$ (12,061)</u>	<u>\$ (40,119)</u>
Net loss per common share — basic and diluted	<u>\$ (0.12)</u>	<u>\$ (0.45)</u>
Weighted average common shares outstanding — basic and diluted	<u>99,150,000</u>	<u>89,780,328</u>

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

	<u>September 30, 2015</u>	<u>March 31, 2015</u>
Assets		
Current assets:		
Cash	\$ 320,211	\$ —
Prepaid expenses and other current assets	2,031	4
Deferred tax assets	273	—
Deferred financing costs	—	1,104
Total current assets	<u>322,515</u>	<u>1,108</u>
Property, plant and equipment, net	33	9
Deferred tax assets	115	—
Total assets	<u>\$ 322,663</u>	<u>\$ 1,117</u>
Liabilities and Shareholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	\$ 697	\$ 403
Due to Roivant Sciences Ltd. and Roivant Sciences, Inc.	2,458	2,307
Accrued legal fees	232	832
Accrued expenses	1,707	326
Contingent payment liability	5,000	—
Income tax payable	284	—
Total current liabilities	<u>10,378</u>	<u>3,868</u>
Contingent payment liability	—	5,000
Total liabilities	<u>10,378</u>	<u>8,868</u>
Total shareholders' equity (deficit)	<u>312,285</u>	<u>(7,751)</u>
Total liabilities and shareholders' equity (deficit)	<u>\$ 322,663</u>	<u>\$ 1,117</u>

Source: Axovant Sciences Ltd.

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