



Axovant Sciences Announces 2015 Fiscal Year-End Financial Results and Corporate Updates

June 6, 2016

- Successful completion of a drug-drug interaction study of intepirdine (formerly RVT-101) with memantine
- 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 \$276.3 million of cash as of March 31, 2016 to support the Company's current development plans

HAMILTON, Bermuda, June 6, 2016 /PRNewswire/ -- Axovant Sciences Ltd. (NYSE: **AXON**), a leading clinical-stage biopharmaceutical company focused on the treatment of dementia, today reported financial results for the fourth fiscal quarter and twelve months ended March 31, 2016.

"Axovant has rapidly established itself as the industry leading company pursuing treatments to address the cognitive, functional and behavioral aspects of multiple forms of dementia by initiating four mid to late-stage clinical studies in Alzheimer's disease and Lewy body dementia," stated Vivek Ramaswamy, Chief Executive Officer of Axovant Sciences. "Axovant is now entering an exciting period with several significant data catalysts expected in 2016 through 2017 for both intepirdine and nelotanserin."

Corporate Highlights since December 31, 2015

- **Intepirdine and memantine drug-drug interaction study:** No drug-drug interactions were observed between intepirdine and memantine in a group of healthy, elderly subjects.
- **Intepirdine HEADWAY-DLB initiation:** In February 2016, Axovant initiated a 24-week double blind, randomized, placebo-controlled 240 patient study of intepirdine as a potential treatment for dementia with Lewy bodies (DLB). If the results of this study, referred to as HEADWAY-DLB, are favorable, the Company believes that those results, in combination with positive results from its ongoing MINDSET study, could serve as the basis for seeking regulatory approval of intepirdine in DLB.
- **Nelotanserin Visual Hallucinations (VH) study initiation:** In January 2016, the Company initiated a double-blind, randomized, placebo-controlled, crossover Phase 2 study of nelotanserin in patients with DLB or Parkinson's disease dementia suffering from visual hallucinations. The study is a pilot program, which the Company expects to inform a subsequent pivotal study design in this indication.
- **Nelotanserin REM Behavior Disorder (RBD) study initiation:** In March 2016, Axovant initiated a 4-week double blind, randomized, placebo-controlled Phase 2 study in patients with DLB suffering from REM behavior disorder. The study will utilize objective measures of efficacy as assessed in a sleep-lab setting.
- **Intepirdine registered as the generic name for RVT-101:** The United States Adopted Names Council and the World Health Organization have adopted intepirdine as the nonproprietary (generic) name for Axovant's lead product candidate RVT-101. Pharmacological and/or chemical relationships inform the selection of a drug's United States Adopted Name (USAN) and International Nonproprietary Name (INN) in order to support communications among health care professionals.

Pipeline Programs

Axovant is developing intepirdine and nelotanserin as potential treatments for patients with Alzheimer's disease and Lewy body dementia. The company expects top-line results from four ongoing 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.
- 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.

Fourth Quarter Financial Summary

For the fourth fiscal quarter ended March 31, 2016, research and development expenses were \$23.4 million, of which \$6.2 million was attributable to non-cash, share-based compensation expense. General and administrative expenses for the fourth quarter were \$7.2 million, of which \$2.2 million was attributable to non-cash, share-based compensation expense. Net loss for the quarter ended March 31, 2016 was \$29.7 million, or \$(0.30) per share.

Twelve Months Financial Summary

For the year ended March 31, 2016, research and development expenses were \$76.6 million, of which \$30.6 million was attributable to non-cash, share-based compensation expense. General and administrative expenses for the year ended March 31, 2016 were \$56.5 million, of which \$41.8

million was attributable to non-cash, share-based compensation expense. Net loss for the year ended March 31, 2016, was \$133.1 million, or \$(1.41) per share.

Axovant held cash of \$276.3 million at March 31, 2016, and net cash used in operating activities was \$53.3 million for the twelve months ended March 31, 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 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 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 2 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.

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 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 annual report on Form 10-K to be filed with the Securities and Exchange Commission on or about June 6, 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.

Consolidated Statements of Operations and Comprehensive Loss

(in thousands, except share and per share data)

Fourth Fiscal Quarter Ended Year Ended Period From
October 31, 2014

	March 31, 2016	(Date Of Inception) March 31, 2016 To March 31, 2015	
Operating expenses:			
Research and development expenses			
(includes \$6,201, \$30,622 and \$3,178 share-based compensation expense for the three months ended March 31, 2016, year ended March 31, 2016, and for period from October 31, 2014 (Date of inception) to March 31, 2015, respectively)	\$ 23,435	\$ 76,644	\$ 14,324
General and administrative expenses			
(includes \$2,227, \$41,764 and \$5,118 share-based compensation expense for the three months ended March 31, 2016, year ended March 31, 2016, and for period from October 31, 2014 (Date of inception) to March 31, 2015, respectively)	7,154	56,518	6,722
Total operating expenses	30,589	133,162	21,046
Loss before provision for income tax	(30,589)	(133,162)	(21,046)
Income tax expense	(918)	(17)	1
Net loss and comprehensive loss	\$ (29,671)	\$ (133,145)	\$ (21,047)
Net loss per common share — basic and diluted	\$ (0.30)	\$ (1.41)	\$ (1.32)
Weighted average common shares outstanding — basic and diluted	99,150,000	94,465,164	15,986,842

AXOVANT SCIENCES LTD.

Consolidated Balance Sheets

(in thousands)

	March 31, 2016	March 31, 2015
Assets		
Current assets:		
Cash	\$ 276,251	\$ —
Prepaid expenses and other current assets	4,865	4

Income tax receivable	970	—
Deferred financing costs	—	1,104
Total current assets	282,086	1,108
Property, plant and equipment, net	89	9
Deferred tax assets	323	—
Total assets	\$ 282,498	\$ 1,117

Liabilities and Shareholders' Equity (Deficit)

Current liabilities:

Accounts payable	\$ 622	\$ 403
Due to Roivant Sciences Ltd. and Roivant Sciences, Inc.	1,814	2,307
Accrued expenses	8,319	1,158
Contingent payment liability	5,000	—
Total current liabilities	15,755	3,868
Contingent payment liability	—	5,000
Total liabilities	15,755	8,868
Total shareholders' equity (deficit)	266,743	(7,751)
Total liabilities and shareholders' equity (deficit)	\$ 282,498	\$ 1,117

SOURCE Axovant Sciences Ltd.

Related Links

<http://www.axovant.com>

Contact:

Jonathan Neely
Head, Investor Relations and Corporate Communications
Axovant Sciences, Inc.
(212) 634-9744