Axovant Announces Fiscal First Quarter Financial Results and Corporate Updates

August 7, 2017

BASEL, Switzerland, Aug. 7, 2017 /PRNewswire/ -- Axovant Sciences (NYSE: **AXON**) today announced financial results for the three months ended June 30, 2017 as well as general business updates.

Key Highlights

- Strong balance sheet with $297.9 million of cash as of June 30, 2017 supports Company's current development plans
- Completed enrollment in HEADWAY-DLB (dementia with Lewy bodies) clinical study of intepirdine
- Presented new preclinical data which suggests that intepirdine may have neuroprotective properties against vascular injury and neuronal metabolic dysfunction
- Announced U.S. Food and Drug Administration (FDA) granted Fast Track designation to nelotanserin for the treatment of visual hallucinations disorder in DLB
- Anticipate last patient visit in August in the MINDSET Phase 3 clinical study of intepirdine

"This is a very exciting time for Axovant as we expect top-line results from five late-stage clinical studies over the next several months," said David Hung, M.D., chief executive officer of Axovant. "If successful, we believe that three of these studies — MINDSET, HEADWAY-DLB and the REM Behavior Disorder study — could potentially serve as pivotal studies and may, if approved, lead to new treatment options for people impacted by Alzheimer's disease and Lewy body dementia."

First Quarter Financial Summary

For the first fiscal quarter ended June 30, 2017, research and development expenses were $43.7 million, of which $6.3 million was attributable to non-cash, share-based compensation expense. General and administrative expenses for the first fiscal quarter ended June 30, 2017 were $21.5 million, of which $9.3 million was attributable to non-cash, share-based compensation expense. Net loss for the quarter ended June 30, 2017 was $69.3 million, or $0.65 per share.

Axovant held cash of $297.9 million at June 30, 2017. Net cash used in operating activities was $47.9 million for the three months ended June 30, 2017.

Development Update

Intepirdine, nelotanserin, RVT-103 and RVT-104 are being developed as potential treatments for patients with Alzheimer's disease and Lewy body dementia (LBD). The Company expects top-line results from the following late-stage clinical studies:

- MINDSET: Phase 3 study of intepirdine in subjects with mild-to-moderate Alzheimer's disease on a stable background of donepezil therapy. Expected timing: last patient visit in August followed by results in late September 2017.
- HEADWAY-DLB: Phase 2b study of intepirdine in subjects with dementia with Lewy bodies (DLB). Expected timing: fourth quarter 2017.
- Phase 2 study of the effects of intepirdine on gait and balance in subjects with Alzheimer's disease, DLB and Parkinson's disease dementia (PDD). Expected timing: fourth quarter 2017.
- Phase 2 study evaluating nelotanserin for treatment of subjects with LBD who experience frequent visual hallucinations. Expected timing: fourth quarter 2017.
- Phase 2 study evaluating nelotanserin for treatment of REM Behavior Disorder in subjects with LBD. Expected timing: first quarter 2018.

Additionally, events relating to the Company's investigational products were announced in June 2017 as follows:

- Recruitment for the Phase 2b HEADWAY-DLB study completed in June with 269 subjects randomized.
- FDA granted Fast Track designation to nelotanserin for the treatment of visual hallucinations disorder in DLB.
- Results of a proof of concept study with RVT-103 were disclosed. The Company expects to meet with the FDA to discuss additional studies that could support registration of RVT-103 and initiated a proof of concept study for RVT-104.

In July, the Company presented new data relating to its intepirdine, nelotanserin and RVT-103 programs at the 2017 Alzheimer's Association International Conference (AAIC) in London, and announced new preclinical data that suggests that intepirdine may have neuroprotective properties against vascular injury and neuronal metabolic dysfunction.

In the animal model used in this study, intepirdine demonstrated neuroprotective effects under hypoxic and hypoglycemic conditions in an in vitro assay of mixed cortical neuron (MCN) cultures at clinically relevant concentrations. Specifically, when pre-treated with intepirdine for 24 hours, a decrease in lactate dehydrogenase (LDH) release, a surrogate marker of cell death, was observed in MCN cultures exposed to oxygen and glucose deprivation ($p<0.05$ at multiple intepirdine concentrations).

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 late- and early-stage 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 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 gait and balance study in patients with Alzheimer's disease, DLB and PDD, the Phase 2 study of nelotanserin in patients with LBD suffering from visual hallucinations, the Phase 2 study of nelotanserin in patients with LBD suffering from RBD, the proof of concept and related studies of RVT-103 and RVT-104 in patients with Alzheimer's disease and DLB, 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, 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. There can be no assurance that the clinical programs for intepirdine, nelotanserin, RVT-103 or 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 to be filed with the Securities and Exchange Commission on or about 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.

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

	Three Months Ended June 30, 2017	Three Months Ended June 30, 2016
Operating expenses:		
Research and development expenses		
(includes share-based compensation expense of $6,256 and $4,964 for the three months ended June 30, 2017 and 2016, respectively)	$ 43,712	$ 25,276
General and administrative expenses		
(includes share-based compensation expense of $9,344 and $6,597 for the three months ended June 30, 2017 and 2016, respectively)	21,518	12,631
Total operating expenses	65,230	37,907
Interest expense	1,874	—
Other income	(357)	—
Loss before provision for income taxes	(66,747)	(37,907)
Income tax expense	2,519	148
Net loss	$ (69,266)	$ (38,055)

Net loss per common share — basic and diluted	$ (0.65)	$ (0.38)
Weighted average common shares outstanding — basic and diluted	106,400,912	99,150,000

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

	June 30, 2017	March 31, 2017
Assets		
Current assets:		
Cash	$ 297,858	$ 212,573
Prepaid expenses and other current assets	7,627	6,457
Income tax receivable	1,224	658
Total current assets	306,709	219,688
Property and equipment, net	2,294	142
Deferred tax assets	—	2,709
Total assets	$ 309,003	$ 222,539
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 8,547	$ 8,551
Due to Roivant Sciences Ltd. and Roivant Sciences, Inc.	4,466	2,919
Accrued expenses	38,041	34,796
Total current liabilities	51,054	46,266
Long term debt	51,752	51,436
Total liabilities	102,806	97,702
Total shareholders' equity	206,197	124,837
Total liabilities and shareholders' equity	$ 309,003	$ 222,539