



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

June 13, 2017

BASEL, Switzerland, June 13, 2017 /PRNewswire/ -- Axovant Sciences (NYSE: AXON), today reported financial results for the fourth fiscal quarter and full fiscal year ended March 31, 2017, as well as general business updates.

Key Highlights

- Strong balance sheet with \$212.6 million of cash as of March 31, 2017 supports Company's current development plans; does not include net proceeds of \$134.2 million from the Company's recent follow-on offering
- Patient recruitment complete for HEADWAY-DLB clinical study
- Initiation of RVT-104 proof of concept study planned in second half of 2017 based on reduction of nausea observed in RVT-103 proof of concept study

"With top line results expected from our MINDSET clinical study in late September and from our HEADWAY-DLB clinical study in the fourth quarter, this is a very exciting time for Axovant," stated David T. Hung, M.D., Chief Executive Officer of Axovant Sciences. "We believe our late-stage programs have the potential to lead to much-anticipated treatments to broadly address multiple forms of dementia. In addition, our strong balance sheet will allow us to fund current programs while pursuing opportunities to acquire and develop additional innovative therapies to address a more expansive set of neurological conditions."

Fourth Quarter Financial Summary

For the fourth fiscal quarter ended March 31, 2017, research and development expenses were \$40.8 million, of which \$5.2 million was attributable to non-cash, share-based compensation expense. General and administrative expenses for the fourth quarter were \$12.3 million, of which \$3.4 million was attributable to non-cash, share-based compensation expense. Net loss for the quarter ended March 31, 2017 was \$52.8 million, or \$0.53 per share.

Full Year Financial Summary

For the year ended March 31, 2017, research and development expenses were \$134.8 million, of which \$19.2 million was attributable to non-cash, share-based compensation expense. General and administrative expenses for the year ended March 31, 2017 were \$45.7 million, of which \$17.2 million was attributable to non-cash, share-based compensation expense. Net loss for the year ended March 31, 2017 was \$181.0 million, or \$1.82 per share.

Axovant held cash of \$212.6 million at March 31, 2017. Net proceeds of approximately \$134.2 million from the public offering of common shares completed in April 2017 are not included in the cash balance at March 31, 2017. Net cash used in operating activities was \$112.1 million for the year ended March 31, 2017.

Corporate Update

In April, David T. Hung, M.D. was appointed Chief Executive Officer of Axovant Sciences, Inc. and a member of the board of directors of the Company, and Marion McCourt was appointed President and Chief Operating Officer of Axovant Sciences, Inc. In addition, Kathryn E. Falberg and W. Anthony Vernon were appointed as two new members of the board of directors of the Company. In June, Patrick Machado was appointed to the board of directors of the Company, with an effective date of June 15, 2017.

Also in April, the Company closed its underwritten public offering of 7,753,505 of its common shares at a price to the public of \$18.54 per common share, including 1,011,326 common shares sold pursuant to the underwriters' exercise in full of their option to purchase additional common shares. Gross proceeds to Axovant from the offering were approximately \$143.7 million, before deducting underwriting discounts and commissions and estimated offering expenses.

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 clinical studies in 2017:

- MINDSET: Phase 3 study of intepirdine in subjects with mild-to-moderate Alzheimer's disease on a stable background of donepezil therapy. Expected timing: 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 patients with Alzheimer's disease, DLB and Parkinson's disease dementia (PDD). Expected timing: 2017.
- Phase 2 study evaluating nelotanserin for treatment of LBD patients who experience frequent visual hallucinations. Expected timing: second half 2017.
- Phase 2 study evaluating nelotanserin for treatment of REM Behavior Disorder in patients with LBD. Expected timing: second half 2017.

Intepirdine

Recruitment for the Phase 3 MINDSET study completed in January, with 1,315 subjects randomized. The Company also recently completed recruitment for the Phase 2b HEADWAY-DLB study.

Netotanserin

In February, the Company reported preliminary results from a planned interim analysis of the first 11 subjects to complete the Phase 2 study of netotanserin in patients diagnosed with LBD who experience frequent visual hallucinations. Among these subjects, a statistically significant 8.73 point difference in change from baseline at week 4 of the pre-specified primary endpoint of Unified Parkinson's Disease Rating Scale (UPDRS) Parts II+III (p-value = 0.012) was observed during periods during which subjects received netotanserin, as compared to periods during which those same subjects received placebo. Based on these preliminary results, the Company has increased the recruitment target beyond the original target of 20 subjects in order to further explore the potential treatment benefits observed in the interim results from the ongoing study.

RVT-103

The Company recently completed the RVT-103 proof of concept study, which was designed to characterize the pharmacokinetic profile, safety, and tolerability of 5 mg donepezil plus placebo versus 10 mg of donepezil when given concomitantly with one of three different regimens including either glycopyrrolate or trospium over a 10-day period. The study measured subject nausea in 48 healthy, elderly subjects using a Visual Analog Scale (VAS) at baseline and once every two hours for eight hours after dosing on Days 1, 3, 7, and 10.

On the final day of dosing, when nausea for subjects in the 5 mg donepezil plus placebo arm achieved a peak mean change from baseline on the VAS, subjects in the arms receiving 10 mg donepezil plus either glycopyrrolate or trospium demonstrated a 67 percent to 95 percent reduction in nausea relative to the 5 mg donepezil plus placebo arm.

Based on these results, the Company expects to meet with the U.S. Food and Drug Administration (FDA) to discuss additional studies that could support registration of RVT-103 and expects to initiate a proof of concept study for RVT-104 in the second half of 2017.

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, DLB and PDD, the Phase 2 study of netotanserin in patients with LBD suffering from visual hallucinations, the Phase 2 study of netotanserin 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, netotanserin, 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, netotanserin, 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 annual report on Form 10-K to be filed with the Securities and Exchange Commission on or about June 13, 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.
Consolidated Statements of Operations
(in thousands, except share and per share data)

	<u>Three Months Ended</u> <u>March 31, 2017</u>	<u>Three Months Ended</u> <u>March 31, 2016</u>	<u>Year Ended</u> <u>March 31, 2017</u>	<u>Year Ended</u> <u>March 31, 2016</u>
	(unaudited)	(unaudited)		
Operating expenses:				
Research and development expenses (includes \$5,157 and \$6,201 share-based compensation expense for the three months ended March 31, 2017 and 2016, respectively, and \$19,186 and \$30,622 for the years ended March 31, 2017 and 2016, respectively)	\$ 40,798	\$ 23,435	\$ 134,778	\$ 76,644
General and administrative expenses (includes \$3,384 and \$2,227 share-based compensation expense for the three months ended March 31, 2017 and 2016, respectively, and \$17,184 and \$41,764 for the years ended March 31, 2017 and 2016, respectively)	12,299	7,154	45,721	56,518
Total operating expenses	<u>53,097</u>	<u>30,589</u>	<u>180,499</u>	<u>133,162</u>

Interest expense	1,143	—	1,143	—
Other expense	369	—	369	—
Loss before income tax benefit	(54,609)	(30,589)	(182,011)	(133,162)
Income tax benefit	(1,776)	(918)	(1,060)	(17)
Net loss	<u>\$ (52,833)</u>	<u>\$ (29,671)</u>	<u>\$ (180,951)</u>	<u>\$ (133,145)</u>
Net loss per common share — basic and diluted	<u>\$ (0.53)</u>	<u>\$ (0.30)</u>	<u>\$ (1.82)</u>	<u>\$ (1.41)</u>
Weighted average common shares outstanding — basic and diluted	<u>99,162,623</u>	<u>99,150,000</u>	<u>99,158,699</u>	<u>94,465,164</u>

AXOVANT SCIENCES LTD.
Consolidated Balance Sheets
(in thousands)

	<u>March 31, 2017</u>	<u>March 31, 2016</u>
Assets		
Current assets:		
Cash	\$ 212,573	\$ 276,251
Prepaid expenses and other current assets	6,457	4,865
Income tax receivable	658	970
Total current assets	<u>219,688</u>	<u>282,086</u>
Property and equipment, net	142	89
Deferred tax assets	2,709	323
Total assets	<u>\$ 222,539</u>	<u>\$ 282,498</u>
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	\$ 8,551	\$ 622
Due to Roivant Sciences Ltd. and Roivant Sciences, Inc.	2,919	1,814
Accrued expenses	34,796	8,319
Contingent payment liability	—	5,000
Total current liabilities	<u>46,266</u>	<u>15,755</u>
Long term debt	51,436	—
Total liabilities	<u>97,702</u>	<u>15,755</u>
Total shareholders' equity	<u>124,837</u>	<u>266,743</u>
Total liabilities and shareholders' equity	<u>\$ 222,539</u>	<u>\$ 282,498</u>

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/axovant-sciences-announces-fiscal-year-end-financial-results-and-corporate-updates-300472909.html>

SOURCE Axovant Sciences

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