Axsome Therapeutics Reports First Quarter 2023 Financial Results and Corporate Update

May 8, 2023

Auvelity® 1Q 2023 net product sales of $15.7 million

Total 1Q 2023 net product sales of $28.6 million

Total 1Q 2023 revenue of $94.6 million, including Sunosi® ex-U.S. license agreement upfront payment

Company to host conference call today at 8:00 AM Eastern

NEW YORK, May 08, 2023 (GLOBE NEWSWIRE) -- Axsome Therapeutics, Inc. (NASDAQ: AXSM), a biopharmaceutical company developing and delivering novel therapies for the management of central nervous system (CNS) disorders, today reported financial results for the first quarter ended March 31, 2023.

"The first quarter of 2023 was another important milestone for Axsome as it marked the first full quarter of launch for Auvelity. Based on the performance in the quarter, we are pleased that our marketed products are making a difference in the lives of a growing number of patients with major depressive disorder for Auvelity, and with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea for Sunosi," said Herriot Tabuteau, MD, Chief Executive Officer of Axsome. "At the same time, our broad late-stage pipeline continues to advance with important near and intermediate term clinical and regulatory milestones including pivotal trial initiations, read-outs, and NDA filings. Our strong commercial, research, and financial profile positions us to continue to develop and deliver differentiated treatments for the millions of patients living with difficult-to-treat CNS disorders."

First Quarter 2023 Financial Highlights

- Total revenue for the first quarter of 2023 was $94.6 million, consisting of net product sales of $28.6 million, license revenue of $65.7 million, and royalty revenue of $0.3 million. The license revenue represents the upfront payment from Pharmanovia for Sunosi commercialization rights in Europe and certain countries in the Middle East and North Africa region, and the royalty revenue associated with sales of Sunosi in the out-licensed territories. There was no revenue for the 2022 comparable period reflecting the timing of the Auvelity launch and the Sunosi acquisition.
- Auvelity net product sales were $15.7 million for the first quarter of 2023.
- Sunosi net product sales were $12.9 million for the first quarter of 2023, including $1.7 million in international net sales booked by Axsome. An additional $0.3 million in royalty revenue associated with Sunosi sales in the out-licensed territories was recognized. Reported Sunosi net sales in the first quarter were negatively impacted by an estimated one-time $3.3 million reduction in inventory due to a change in distribution from a title to a traditional 3PL model in the U.S, as anticipated.
- Total cost of revenue was $7.6 million for the first quarter of 2023, consisting of cost of goods sold of $2.6 million and a one-time $5 million license revenue sharing expense related to the Pharmanovia agreement.
- Research and development (R&D) expenses were $17.8 million for the first quarter of 2023, compared to $12.6 million for the comparable period in 2022. The increase was primarily related to higher personnel costs associated with ongoing clinical trials, post-marketing commitments for Auvelity and Sunosi and non-cash stock-based compensation expense.
- Selling, general, and administrative (SG&A) expenses were $74.2 million for the first quarter of 2023, compared to $25.7 million for the comparable period in 2022. The increase was primarily related to commercial activities for Auvelity and Sunosi and higher non-cash stock-based compensation expense.
- Net loss for the first quarter of 2023 was $11.2 million or $(0.26) per share, compared to a net loss of $39.6 million, or $(1.03) per share, for the comparable period in 2022. The net loss in the first quarter of 2023 reflects the upfront license revenue received from Pharmanovia and includes $12.9 million of non-cash stock-based compensation expense compared to $7.6 million for the comparable period in 2022.
- Cash and cash equivalents totaled $246.5 million at March 31, 2023, compared to $200.8 million at December 31, 2022.

- In January 2023, Axsome amended its term loan facility agreement with Hercules Capital increasing the size of the facility to $350 million, reducing the interest rate, and extending the maturity and interest-only period, while accessing a new $55 million tranche. There is currently $200 million available on the term loan facility.

- Shares of common stock outstanding were 43,548,466 at March 31, 2023.

Financial Guidance

- Axsome believes that its current cash, along with the remaining committed capital from the $350 million term loan facility, is sufficient to fund anticipated operations into cash flow positivity, based on the current operating plan.

Commercial Highlights

Auvelity

- The first quarter of 2023 was the first full quarter of sales for Auvelity, which was launched in October 2022. Approximately 31,000 prescriptions were reported for Auvelity in the first quarter of 2023, representing a 298% sequential increase versus the fourth quarter of 2022.

- Payer coverage for Auvelity across all channels is currently approximately 65% of all covered lives. The proportion of lives covered in the commercial and government (Medicare and Medicaid) channels are approximately 40% and approximately 100%, respectively.

- Axsome's comprehensive patient and provider support services for Auvelity continue to perform as planned. The Auvelity on My Side program is designed to help clinicians and patients easily access Auvelity and the program includes: the Auvelity Savings Card to reduce out-of-pocket expenses for qualifying patients, telehealth services, HCP samples, and prior authorization assistance.

Sunosi

- First quarter 2023 U.S. Sunosi total prescriptions increased by 13% versus the first quarter of 2022, and by 4% versus the fourth quarter of 2022.

- Sunosi maintains broad payer coverage in the commercial channel with 96% of lives covered. Currently 83% of total lives across all channels are covered.

- Axsome's patient and provider support services for Sunosi, including the Sunosi Savings Card, continue to perform as planned.

- In February 2023, Axsome licensed the marketing rights for Sunosi in Europe and certain countries in the Middle East and North Africa to Pharmanovia. In consideration, Axsome received an upfront payment of $66M, with potential milestones up to $101M. Axsome will receive a royalty percentage in the mid-twenties on net sales in the licensed territory. Pharmanovia will assume responsibility for all local clinical and regulatory activities and requirements including studies in pediatric patients with narcolepsy.

Development Pipeline

Axsome is advancing a portfolio of differentiated, patent-protected, CNS product candidates with five in active clinical development. Recent and anticipated progress for key pipeline programs is summarized below.

AXS-05

AXS-05 (dextromethorphan-bupropion) is Axsome's novel, oral, investigational NMDA receptor antagonist with multimodal activity being developed for Alzheimer's disease (AD) agitation and smoking cessation. AXS-05 has been granted U.S. Food and Drug Administration (FDA) Breakthrough Therapy designation for AD agitation.

- **Alzheimer's Disease Agitation:** The Company is conducting the ADVANCE-2 study, a Phase 3, placebo-controlled, parallel group trial to assess the efficacy and safety of AXS-05 for the treatment of AD agitation. Patients completing ADVANCE-2 may enter a long-term open label safety extension trial. Based on current enrollment trends, the Company continues to anticipate completion of ADVANCE-2 in the first half of 2024.

- **Smoking Cessation:** Axsome plans to proceed to a pivotal Phase 2/3 trial in this indication. The Company anticipates initiation of this study in the fourth quarter of 2023.

AXS-07

AXS-07 (MoSEIC™ meloxicam-rizatriptan) is Axsome's novel, oral, rapidly absorbed, multi-mechanistic, investigational medicine for the acute

treatment of migraine.

- **Migraine:** Manufacturing activities related to the planned resubmission of the New Drug Application (NDA) for AXS-07 for the acute treatment of migraine are ongoing. The Company continues to anticipate resubmission of the NDA in the second half of 2023. No additional clinical efficacy or safety trials have been requested by the FDA for a resubmission of the NDA. The Company expects the NDA resubmission to be designated as Class 2 which would be subject to a six-month review.

AXS-12

AXS-12 (reboxetine) is Axsome's novel, oral, potent, investigational highly selective norepinephrine reuptake inhibitor for the treatment of narcolepsy. AXS-12 has been granted FDA Orphan Drug designation for the treatment of narcolepsy.

- **Narcolepsy:** Axsome is conducting the SYMPHONY study, a Phase 3 randomized, multicenter, double-blind, placebo-controlled, parallel-group trial of AXS-12 in the treatment of narcolepsy. Enrollment in the trial is progressing and topline results continue to be anticipated in the second quarter of 2023.

AXS-14

AXS-14 (esreboxetine) is Axsome's novel, oral, potent, investigational highly selective norepinephrine reuptake inhibitor for the management of fibromyalgia. Esreboxetine, the SS-enantiomer of reboxetine, is more potent and selective than racemic reboxetine.

- **Fibromyalgia:** Manufacturing and other activities related to the planned submission of an NDA for AXS-14 for the management of fibromyalgia are ongoing. The Company expects to submit the NDA in 2023. AXS-14 has previously met the primary endpoints and demonstrated positive and statistically significant results in a Phase 3 and in a Phase 2 trial for the management of fibromyalgia.

Solriamfetol

Solriamfetol is Axsome's dual-acting dopamine and norepinephrine reuptake inhibitor in development for the treatment of attention deficit hyperactivity disorder (ADHD).

- **ADHD:** The Company is on track to initiate a Phase 3 multi-center, randomized, double-blind, placebo-controlled trial to evaluate the efficacy and safety of solriamfetol in adults with ADHD in the second quarter of 2023.

Anticipated Milestones

- **Regulatory and Commercial:**
  - AXS-07 for migraine, NDA resubmission (2H 2023)
  - AXS-14 for fibromyalgia, NDA submission (4Q 2023)
- **Clinical Trial Readouts:**
  - Phase 3 SYMPHONY trial of AXS-12 in narcolepsy, topline data (2Q 2023)
  - Phase 3 ADVANCE-2 trial of AXS-05 for Alzheimer's disease agitation (1H 2024)
- **Clinical Trial Initiations:**
  - Phase 3 trial of solriamfetol for ADHD in adults (2Q 2023)
  - Pivotal Phase 2/3 trial of AXS-05 for smoking cessation (4Q 2023)

Conference Call Information

Axsome will host a conference call and webcast today at 8:00 AM Eastern to discuss first quarter 2023 financial results as well as to provide a corporate update. To participate in the live conference call, please dial (877) 405-1239 (toll-free domestic). The live webcast can be accessed on the "Webcasts & Presentations" page of the "Investors" section of the Company's website at axsome.com. A replay of the webcast will be available for approximately 30 days following the live event.

About Axsome Therapeutics, Inc.

Axsome Therapeutics, Inc. is a biopharmaceutical company developing and delivering novel therapies for central nervous system (CNS) conditions that have limited treatment options. Through development of therapeutic options with novel mechanisms of action, we are transforming the approach to treating CNS conditions. At Axsome, we are committed to developing products that meaningfully improve the lives of patients and provide new therapeutic options for physicians. For more information, please visit the Company's website at axsome.com. The Company may occasionally disseminate material, nonpublic information on the company website.

Forward Looking Statements

Certain matters discussed in this press release are "forward-looking statements". We may, in some cases, use terms such as "predicts," "believes," "potential," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. In particular, the Company's statements regarding trends and potential future results are examples of such forward-looking statements. The forward-looking statements include risks and uncertainties, including, but not limited to, the continued commercial success of our Sunosi® and Auvelity® products and the success of our efforts to obtain any additional indication(s) with respect to solriamfetol and/or AXS-05; the success, timing and cost of our ongoing clinical trials and anticipated clinical trials for our current product candidates, including statements regarding the timing of initiation, pace of enrollment and completion of the trials (including our ability to fully fund our disclosed clinical trials, which assumes no material changes to our currently projected expenses), futility analyses and receipt of interim results, which are not necessarily indicative of the final results of our ongoing clinical trials, and the number or type of studies or nature of results necessary to support the filing of a new drug application ("NDA") for any of our current product candidates; our ability to fund additional clinical trials to continue the advancement of our product candidates; the timing of and our ability to obtain and maintain U.S. Food and Drug Administration ("FDA") or other regulatory authority approval of, or other action with respect to, our product candidates; whether issues identified by FDA in the complete response letter may impact the potential approvability of the Company's NDA for AXS-07 for the acute treatment of migraine in adults with or without aura, pursuant to our special protocol assessment for the MOMENTUM clinical trial; the Company's ability to successfully defend its intellectual property or obtain the necessary licenses at a cost acceptable to the Company, if at all; the successful implementation of the Company's research and development programs and collaborations; the success of the Company's license agreements; the acceptance by the market of the Company's products and product candidates, if approved; the Company's anticipated capital requirements, including the amount of capital required for the continued commercialization of Sunosi and Auvelity and for the Company's commercial launch of its other product candidates, and the potential impact on the Company's anticipated cash runway; unforeseen circumstances or other disruptions to normal business operations arising from or related to COVID-19; and other factors, including general economic conditions and regulatory developments, not within the Company's control. The factors discussed herein could cause actual results and developments to be materially different from those expressed in or implied by such statements. The forward-looking statements are made only as of the date of this press release and the Company undertakes no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstance.

Axsome Therapeutics, Inc.
Selected Consolidated Financial Data

Axsome Therapeutics, Inc.
Consolidated Balance Sheets
(In thousands, except for share and par value amounts)

	March 31, 2023	December 31, 2022
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 246,515	$ 200,842
Accounts receivables, net	44,793	37,699
Inventories, net	7,940	4,320
Prepaid and other current assets	5,201	2,781
Total current assets	304,449	245,642
Equipment, net	703	722
Right-of-use asset - operating lease	106	420
Goodwill	10,310	10,310
Intangible asset, net	58,089	59,661
Non-current inventory and other assets	15,522	14,721
Total assets	$ 389,179	$ 331,476
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 35,770	$ 38,605
Accrued expenses and other current liabilities	58,774	51,631
Operating lease liability, current portion	108	425
Contingent consideration, current	6,000	5,900
Total current liabilities	100,652	96,561
Contingent consideration, non-current	29,100	31,100
Loan payable, long-term	147,615	94,259
Total liabilities	277,367	221,920
Stockholders' equity:		
Preferred stock, $0.0001 par value per share (10,000,000 shares authorized, none issued and outstanding at March 31, 2023 and December 31, 2022, respectively)	—	—
Common stock, $0.0001 par value per share (150,000,000 shares authorized, 43,548,466 and 43,498,617 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively)	4	4
Additional paid-in capital	719,359	705,885
Accumulated deficit	(607,551)	(596,333)

Total stockholders' equity	111,812	109,556
Total liabilities and stockholders' equity	$ 389,179	$ 331,476

Axsome Therapeutics, Inc.
Consolidated Statements of Operations (Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2023	**2022**
Revenues:		
Product sales, net	$ 28,569	$ —
License revenue	65,735	—
Royalty revenue	272	—
Total Revenues	94,576	—
Operating expenses:		
Cost of revenue (excluding amortization and depreciation)	7,556	—
Research and development	17,793	12,585
Selling, general and administrative	74,191	25,704
Gain in fair value of contingent consideration	(162)	—
Intangible asset amortization	1,572	—
Total operating expenses	100,950	38,289
Loss from operations	(6,374)	(38,289)
Interest expense, net	(2,264)	(1,343)
Income before provision for income taxes	(8,638)	(39,632)
Provision for income taxes	(2,580)	—
Net loss	$ (11,218)	$ (39,632)
Net loss per common share, basic and diluted	$ (0.26)	$ (1.03)
Weighted average common shares outstanding, basic and diluted	43,523,631	38,323,167

Axsome Contacts:
Investors:
Mark Jacobson
Chief Operating Officer
Axsome Therapeutics, Inc.
One World Trade Center, 22nd Floor
New York, NY 10007
Tel: 212-332-3243
Email: mjacobson@axsome.com
www.axsome.com

Media:
Darren Opland
Director, Corporate Communications
Axsome Therapeutics, Inc.
One World Trade Center, 22nd Floor
New York, NY 10007
Tel: 929-837-1065
Email: dopland@axsome.com
www.axsome.com

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