ADMA Biologics Reports Second Quarter 2016 Results

RAMSEY, N.J., Aug. 12, 2016 (GLOBE NEWSWIRE) -- ADMA Biologics, Inc. (NASDAQ:ADMA), a late-stage biopharmaceutical company that develops, manufactures, and intends to commercialize specialty plasma-based biologics for the proposed treatment of immune deficiencies and prevention of certain infectious diseases, today announced its financial results for the quarter ended June 30, 2016.

“We are working with our third-party vendors and the U.S. Food and Drug Administration to progress towards an approval of our Biologics License Application for our lead product candidate, RI-002, while also continuing to move forward with commercialization and pre-launch activities,” stated Adam Grossman, President and CEO of ADMA Biologics, Inc. “During the second quarter, we generated increased revenues over last year’s second quarter from our plasma collection centers and strengthened our balance sheet through a $14.1 million secondary common stock offering and additional debt financing of $4.0 million.”

Financial Results for the Second Quarter Ended 2016

At June 30, 2016, ADMA had cash, cash equivalents and short-term investments of $23.8 million, as compared to $16.8 million at December 31, 2015.

The consolidated net loss for the second quarter ended June 30, 2016 was $6.0 million, or $(0.50) per share, as compared to a consolidated net loss of $4.7 million, or ($0.44) per share, for the second quarter ended June 30, 2015. We had revenues of $2.3 million for the second quarter ended June 30, 2016 compared to $1.3 million for the second quarter ended June 30, 2015, which represents approximately 77% revenue growth quarter-over-quarter. This growth was primarily driven by revenues generated by our second plasma center, which received U.S. Food and Drug Administration (FDA) approval in the third quarter of 2015. The quarter-over-quarter net loss increased by $1.3 million, which is primarily attributable to an increase in operating expenses of $2.9 million, offset by an increase in revenues of $1.0 million and a decrease in other expense of $0.6 million. The increase in operating expenses is primarily attributable to increased research and development expenses for RI-002, due to higher validation, testing and production costs and regulatory consulting services related to our Biologics License Application submitted to the FDA for RI-002. Operating expenses also increased due to higher plasma center operating expenses related to our second plasma center receiving FDA approval in the third quarter of 2015 and increased general and administrative costs associated with pre-launch commercial planning activities for RI-002’s anticipated launch. The decrease in other expense is related to a loss on extinguishment of debt recorded in the second quarter of 2015. Included in the net loss for the quarter ended June 30, 2016 were non-cash expenses of $0.3 million for stock based compensation and $0.3 million for depreciation and amortization.
About ADMA Biologics, Inc. (ADMA)

ADMA is a late-stage biopharmaceutical company that develops, manufactures and intends to commercialize specialty plasma-based biologics for the proposed treatment of Primary Immune Deficiency Disease (PIDD) and the prevention and treatment of certain infectious diseases. ADMA's mission is to develop and commercialize plasma-derived, human immune globulins targeted to niche patient populations for the treatment and prevention of certain infectious diseases. The target patient populations include immune-compromised individuals who suffer from an underlying immune deficiency disease, or who may be immune-compromised for medical reasons. The Company has received U.S. Patent 9,107,906 relating to certain aspects of its product candidate. For more information, please visit www.admabiologics.com.

Forward-Looking Statements

This press release contains "forward-looking statements" pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include, without limitation, any statement that may predict, forecast, indicate, or imply future results, performance or achievements, and may contain the words "estimate," "intend," "target," "will," "is likely," "would," "may," or, in each case, their negative, or words or expressions of similar meaning. These forward-looking statements include, but are not limited to, statements concerning our ability to develop, manufacture, and commercialize specialty plasma-based biologics for the proposed treatment of immune deficiencies and the prevention of certain infectious diseases, the success of our work with our third party vendors and the U.S. Food and Drug Administration in furtherance of an approval of our Biologics License Application for RI-002 and the ability of such third parties to respond adequately to the issues raised by the FDA, our ability to successfully pursue commercialization and prelaunch activities, and the timeframe within which we may receive approval from the FDA for RI-002, if at all. Forward-looking statements are subject to many risks and uncertainties that could cause our actual results and the timing of certain events to differ materially from any future results expressed or implied by the forward-looking statements, including those risks and uncertainties described in our filings with the U.S. Securities and Exchange Commission, including our most recent reports on Forms 10-K, 10-Q and 8-K, and any amendments thereto. Therefore, current and prospective security holders are cautioned that there also can be no assurance that the forward-looking statements included in this press release will prove to be accurate. In light of the significant uncertainties inherent in the forward-looking statements included herein, the inclusion of such information should not be regarded as a representation or warranty by ADMA or any other person that the objectives and plans of ADMA will be achieved in any specified time frame, if at all. Except to the extent required by applicable laws or rules, ADMA does not undertake any obligation to update any forward-looking statements or to announce revisions to any of the forward-looking statements.

ADMA BIOLOGICS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
Three and Six Months Ended June 30, 2016 and 2015
(Unaudited)

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## 2016 | 2015 | 2016 | 2015
---|---|---|---
**REVENUES:**
Product revenue | $2,236,035 | $1,291,044 | $4,324,213 | $2,775,261
License and other revenue | 35,709 | 18,889 | 71,417 | 37,778
**Total Revenues** | 2,271,744 | 1,309,933 | 4,395,630 | 2,813,039

**OPERATING EXPENSES:**
Cost of product revenue | 1,344,241 | 786,315 | 2,610,662 | 1,695,944
Research and development | 3,399,889 | 1,505,909 | 5,427,601 | 2,907,633
Plasma centers | 1,294,301 | 1,096,878 | 2,574,720 | 2,144,972
General and administrative | 1,724,163 | 1,437,436 | 3,432,033 | 2,783,432
**TOTAL OPERATING EXPENSES** | 7,762,594 | 4,826,538 | 14,045,016 | 9,531,981
**LOSS FROM OPERATIONS** | (5,490,850) | (3,516,605) | (9,649,386) | (6,718,942)

**OTHER INCOME (EXPENSE):**
Interest income | 12,017 | 9,795 | 25,525 | 14,776
Interest expense | (537,998) | (453,411) | (1,005,439) | (929,450)
Other income | 4,496 | - | 4,496 | -
Change in fair value of stock warrants | - | - | - | 67,860
Loss on extinguishment of debt | - | (719,097) | - | (719,097)
**OTHER EXPENSE, NET** | (521,485) | (1,162,713) | (975,418) | (1,565,911)

**NET LOSS** | $6,012,335 | $4,679,318 | $10,624,804 | $8,284,853

**NET LOSS PER COMMON SHARE,**
Basic and Diluted | $(0.50) | $(0.44) | $(0.93) | $(0.81)

**WEIGHTED AVERAGE SHARES**
OUTSTANDING, Basic and Diluted | 12,121,500 | 10,705,573 | 11,407,918 | 10,283,239

**CONDENSED CONSOLIDATED BALANCE SHEET INFORMATION:**
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<th>June 30, 2016 (Unaudited)</th>
<th>*December 31, 2015</th>
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<td>Cash, cash equivalents and short-term investments</td>
<td>$ 23,820,136</td>
<td>$ 16,809,136</td>
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<td>Total Assets</td>
<td>$ 31,741,989</td>
<td>$ 23,714,517</td>
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<td>Accumulated deficit</td>
<td>$ (98,044,471 )</td>
<td>$ (87,419,667 )</td>
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<td>Total Stockholders’ Equity</td>
<td>$ 3,916,136</td>
<td>$ 820,974</td>
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*Condensed from audited financial statements

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Source: ADMA Biologics, Inc.