

November 9, 2020

BAUDAX BIO[®]

Baudax Bio Reports Third Quarter 2020 Financial Results

ANJESO[®] Launch Underway; Over 50 Institutions have Added ANJESO to Their Formularies with Users Giving Highly Positive Feedback and Average Monthly Orders Increasing over 125% Since Launch

Secured and Implemented Permanent J-Code for ANJESO from CMS October 1, Along with Two Major Group Purchasing Agreements with Vizient and Premier

Management to Host Investor Conference Call and Webcast Today at 9:00 a.m. ET

MALVERN, Pa., Nov. 09, 2020 (GLOBE NEWSWIRE) -- Baudax Bio, Inc. (NASDAQ:BXRX), a pharmaceutical company focused on therapeutics for acute care settings, today reported financial results for the three and nine months ended September 30, 2020.

“The third quarter of 2020 was marked by several important achievements, including continued progress with the commercial launch of ANJESO, the securing of group purchasing agreements with two leading healthcare improvement companies, Vizient and Premier, and the receipt and implementation, on October 1, 2020, of our permanent J-code from the Centers for Medicare and Medicaid Services (CMS), facilitating reimbursement in the hospital outpatient, ambulatory surgery center and physician office settings of care,” said Gerri Henwood, President and Chief Executive Officer of Baudax Bio. “We are pleased with the highly positive feedback we have been receiving from the vast majority of users about ANJESO, together with average monthly orders per account more than doubling. The commercial rollout progress continues, but remains impacted by the ongoing COVID-19 pandemic and as we have said, we continue to believe the launch revenue ramp will likely take more time than originally anticipated.”

“ANJESO has made progress with GPO organizations, formularies, and with meaningful use of the product in acute care centers where formulary approval and EHR, or electronic health record, incorporation has been obtained. The vast majority of users report a high level of satisfaction that ANJESO delivers at or beyond their expectations in terms of pain relief and duration of action. All of these factors give us reasons to believe that this product can continue to deepen usage, grow and ultimately fulfill its promise as a product. The combination of an ongoing pandemic, which has significantly impacted hospitals and other acute care settings, along with the natural adoption curve seen historically with hospital products, has caused us to adjust our plan during this early launch period.”

“Our adjusted plan is to focus on territories with high promise and with early indicators of adoption and usage with a reduced but very focused team during this pandemic of uncertain duration. This approach reduces the total company by approximately 40 professionals and includes additional cost reductions in other areas (manufacturing, out of pocket spend, etc.) which we believe will better position the company to sustain our efforts. We would like to convey our gratitude to the employees who are leaving and who have contributed to the

accomplishments of the Company of ultimate approval and launch of ANJESO, as well as forging a path for continued growth of the product.”

“Looking ahead to the remainder of 2020 and beyond, we are actively working with the surgical and anesthesia community to drive hospital formulary adoption and the incorporation of ANJESO into standard pain management protocols, and look forward to reporting on our continued growth” concluded Ms. Henwood.

Third Quarter 2020 and Recent Business Highlights

ANJESO

- **ANJESO Launch and Commercial Rollout.** In June 2020, ANJESO, Baudax’s lead asset indicated for the management of moderate to severe pain, alone or in combination with other non-NSAID analgesics, became broadly available through wholesalers in the U.S. The commercial rollout is progressing well and as of late October 2020, over 50 institutions have added ANJESO to their formulary and average monthly orders per account has increased over 125% since launch. The ANJESO re-order rate is approximately 50% with a deepening usage pattern. Additionally, sales from hospitals are growing with 60% of October unit sales coming from hospitals. The number of hospitals ordering has tripled since launch and the number of orders from hospitals has quadrupled. In just over 5 months on the market, ANJESO has been utilized across a wide variety of surgical and non-surgical procedures and is now beginning to be incorporated into surgical protocols and electronic health record (EHR) order sets, with demand increasing monthly. Baudax’s ongoing commercial efforts continue to be impacted by COVID-19 pandemic related obstacles, and as a result, the Company believes the launch revenue ramp for ANJESO will likely take more time than originally anticipated.
- **Secured Two Major Group Purchasing Agreements with Vizient and Premier.** During the third quarter, Baudax secured agreements with two major group purchasing organizations, Vizient, Inc. and Premier, Inc. The Vizient agreement offers savings to Vizient’s diverse membership, which includes more than 50% of the nation’s acute care systems, including 95% of the nation’s academic medical centers, and more than 20% of the nation’s ambulatory care market. The Premier agreement provides access to an alliance of approximately 4,100 hospitals and more than 200,000 other providers and organizations. Collectively, these agreements significantly expand the commercial reach of ANJESO.
- **Receipt of J-Code from CMS.** In early August 2020, CMS established a new permanent J-code for ANJESO, facilitating reimbursement in the hospital outpatient, ambulatory surgery center and physician office settings of care. Importantly, the code, J1738 (Injection, meloxicam, 1 mg), took effect on October 1, 2020 and replaced the previously issued C-code (C9059) and during October could improve the “time to payment/reimbursement” for our outpatient setting users (ASCs, Hospital outpatient facilities, etc.)
- **Presented New Phase IIIb ANJESO Data at American Society of Colon and Rectal Surgeons (ASCRS) Meeting.** In July 2020, Baudax presented a virtual poster

highlighting new Phase IIIb ANJESO data from a double-blind placebo-controlled trial, as part of the ASCRS 2020 Annual Scientific Meeting. The published data supports the use of ANJESO administered preoperatively to patients undergoing colorectal surgery. The key findings from this study include statistically significant reductions in opioid use, as well as time to bowel function recovery and hospital discharge, resulting in cost savings for ANJESO-treated patients.

Corporate and Financial

- **Reorganized and Streamlined Workforce to Focus Commercial Efforts Further and Reduce Expenses during the pandemic.** Due to the impacts of COVID-19 and the resultant slower than expected commercial ramp of ANJESO, effective November 9, 2020, Baudax implemented a reduction of its workforce by approximately 40 employees. Baudax expects that the reorganization will result in annualized savings of an estimated \$10.6 million in personnel and other related costs. There were also significant cost reductions made for 2021 manufacturing and launch related activities. The Company estimates that the reorganization will be substantially completed in November 2020 and that it will incur approximately \$1.5 million of charges for severance and other costs, primarily during the fourth quarter of 2020.
- **Completed Strategic Transaction to Exchange Warrants.** Effective October 19, 2020, the Company entered into exchange agreements with holders of its short dated (13 months) Series B Warrants and long dated (5 year) Series A Warrants. As a result of the warrant exchange transaction, and subsequent warrant exercises thereafter, holders exercised or exchanged approximately 12.6 million warrants resulting in the issuance of approximately 7.9 million shares of the Company's common stock in the aggregate to date related to this transaction. This Warrant restructuring transaction was done to remove certain financial impediments and overhang for the 4-year plus life of the Series A Warrants, while reducing dilution for its existing shareholders. Holders of approximately 90% of the Company's warrants participated in the exchange.
- **Appointed Dr. Arnold Baskies and Andrew Drechsler to Board of Directors.** In August 2020, the Company announced the appointment of Arnold Baskies, M.D., and Andrew Drechsler to its board of directors. Dr. Baskies' experience in the surgical setting and Mr. Drechsler's background in finance, most recently as the Chief Financial Officer for Provention Bio and previously of Insmed Incorporated, will prove beneficial as the Company strengthens their efforts to communicate the benefits of ANJESO as an advantageous option for the management of moderate to severe pain.

COVID-19 Impact

The Company's efforts to commercialize ANJESO have been impacted and may continue to be impacted by the COVID-19 pandemic. Hospitals have reduced elective surgeries and many have not yet returned to their prior number of surgeries even where the pandemic has, for a time, abated. In addition, COVID-19 has, in many cases, impacted revenues for hospitals, reduced staffing, diverted resources from other normal activities to patients suffering from COVID-19 and limited hospital access for nonpatients, including the Company's sales professionals, which the Company believes is impacting its marketing and commercialization efforts. The Company believes that the reduction in elective surgeries

during the COVID-19 pandemic has and may continue to result in decreased demand for ANJESO.

The Company anticipates that many hospitals and health care providers will continue to suffer negative financial consequences due to an increase in unexpected costs, personal protective equipment and ventilators, along with a dramatic reduction in revenue due to fewer elective procedures being performed, which may result in a decreased demand for ANJESO. While access restrictions have eased in some locations, cycling spikes of COVID-19 cases in certain states or regions may further impact the Company's sales force as access to hospitals may be restricted and elective surgeries may be limited in those areas. In addition, the absence of hospital formulary meetings where new drugs can be adopted has impacted our efforts to commercialize ANJESO. Many hospital formularies recently resumed meetings after a 6-month absence. Despite the existence of a backlog of agents scheduled to be reviewed, the Company believes it will make progress getting ANJESO added to additional hospital formularies in the near term. Due to the rapidly evolving environment, continued uncertainties from the impact of the COVID-19 global pandemic, and recent regional outbreaks that are impacting the recovery, the Company cannot estimate the full extent to which the Company's commercialization of ANJESO and financial results may be adversely impacted.

Third Quarter 2020 Financial Results

As of September 30, 2020, Baudax had cash and cash equivalents of \$24.6 million.

Net product revenue for the three months ended September 30, 2020 was \$0.1 million, related to sales of ANJESO in the U.S. While in the title model of distribution, product revenue represents shipments to our third-party logistics (3PL) provider. As the second quarter of 2020 included stocking orders to our 3PL, the third quarter revenue is not a reflection of units sold to the end-customers. The number of vials sold to end-customers (e.g., hospitals, ambulatory surgical centers) has increased almost three-fold in the third quarter of 2020 versus the second quarter of 2020. There was no product revenue recognized during the three months ended September 30, 2019.

Cost of sales for the three months ended September 30, 2020 was \$0.5 million and consisted of product costs, royalty expense and certain fixed costs associated with the manufacturing of ANJESO including supply chain and quality costs. Certain product costs of ANJESO units recognized as revenue during the three months ended September 30, 2020 were incurred prior to the FDA approval of ANJESO in February 2020, and therefore are not included in cost of sales during the period. Baudax expects over time its cost of sales will increase as it builds new inventory not expensed during the pre-approval period and depletes its initial inventory levels. No cost of sales was recorded for the three months ended September 30, 2019.

Research and development expenses for the three months ended September 30, 2020 were \$1.5 million, compared to \$1.8 million for the three months ended September 30, 2019. The decrease of \$0.3 million resulted from a decrease in personnel and overhead expenses of \$0.5 million as Baudax allocated or recategorized certain expenses related to supply chain, regulatory, quality and medical affairs associated with support of the commercial launch of ANJESO and a decrease in pre-commercialization manufacturing and clinical costs for ANJESO of \$0.4 million.

Selling, general and administrative expenses for the three months ended September 30, 2020 were \$13.8 million, compared to \$4.5 million for the same prior year period. The increase of \$9.3 million was primarily due to increased selling and marketing expenses in connection with the commercial launch of ANJESO. Selling and marketing expenses of \$7.6 million for the three months ended September 30, 2020 increased \$6.8 million due to increased personnel costs of \$4.9 million and increased commercial costs of \$1.9 million. General and administrative expenses of \$6.2 million for the three months ended September 30, 2020 increased \$2.5 million primarily due to increased personnel costs, over half of which was attributed to medical affairs field personnel and regulatory support functions that had previously been recorded within research and development expense in the prior year period.

Baudax reported a net income (including non-cash benefit of \$25.1 million) of \$11.7 million, or \$0.62 per diluted share, for the three months ended September 30, 2020. The non-cash benefit of \$25.1 million was associated with changes in fair value of contingent consideration and changes in warrant valuations offset by non-cash charges for interest expense, depreciation, amortization, and stock-based compensation. This compares to a net loss of \$10.3 million, or \$(1.10) per share, for the comparable period in 2019. For the three months ended September 30, 2020, there was \$11.8 million in cash used in operating activities which included cash used related to the build of inventory for ANJESO and a \$2.5 million milestone payment to Alkermes, plc.

Nine Months Ended September 30, 2020 Financial Results

Net product revenue for the nine months ended September 30, 2020 was \$0.4 million, related to sales of ANJESO in the U.S. There was no product revenue recognized during the nine months ended September 30, 2019.

Cost of sales for the nine months ended September 30, 2020 was \$1.2 million and consisted of product costs, royalty expense and certain fixed costs associated with the manufacturing of ANJESO including supply chain and quality costs. Certain product costs of ANJESO units recognized as revenue during the nine months ended September 30, 2020 were incurred prior to the FDA approval of ANJESO in February 2020, and therefore are not included in cost of sales during the period. Baudax expects over time its cost of sales will increase as it builds new inventory not expensed during the pre-approval period and depletes its initial inventory levels. No cost of sales was recorded for the nine months ended September 30, 2019.

Research and development expenses for the nine months ended September 30, 2020 were \$5.9 million, compared to \$18.6 million for the nine months ended September 30, 2019, a decrease of \$12.7 million. Excluding \$2.8 million of costs associated with the 2019 strategic restructuring initiative recorded in the nine months ended September 30, 2019, Baudax's research and development expenses decreased \$9.9 million primarily resulting from a decrease in pre-commercialization manufacturing and clinical costs for ANJESO of \$6.6 million, a decrease in personnel and overhead expenses of \$1.7 million as we re-allocated costs related to supply chain, regulatory, quality and medical affairs associated with support of the commercial launch of ANJESO and a decrease in other development costs of \$1.6 million.

Selling, general and administrative expenses for the nine months ended September 30,

2020 were \$33.0 million, compared to \$21.8 million for the same prior year period, an increase of \$11.2 million. Excluding \$4.4 million of costs associated with the 2019 strategic restructuring initiative recorded in the nine months ended September 30, 2019, our selling, general and administrative expenses increased \$15.6 million primarily due to increased selling and marketing expenses in connection with the commercial launch of ANJESO. Selling and marketing expenses of \$16.5 million for the nine months ended September 30, 2020 increased \$10.1 million primarily due to increased personnel costs of \$6.6 million and increased commercial costs of \$3.5 million. General and administrative expenses of \$16.5 million for the nine months ended September 30, 2020 increased \$5.5 million primarily due to increased personnel costs of \$4.9 million, over half of which was attributed to medical affairs field personnel and regulatory support functions that had previously been recorded within research and development expense in the prior year period and increased public company costs of approximately \$0.6 million as the prior year costs represent an allocated portion of the costs in the historical combined financial statements of Baudax Bio and Recro Pharma, Inc. (Recro) prior to our separation from Recro.

Baudax reported a net loss (including non-cash charges of \$26.7 million) of \$59.1 million, or \$(3.84) per diluted share, for the nine months ended September 30, 2020. The non-cash charges of \$26.7 million were associated with changes in fair value of contingent consideration, changes in warrant valuations, non-cash interest expense, depreciation, amortization, and stock-based compensation. This compares to a net loss of \$25.2 million, or \$(2.70) per share, for the comparable period in 2019.

Conference Call Information

Baudax will host a conference call today, Monday, November 9, 2020, at 9:00 a.m. Eastern Time, to discuss the third quarter 2020 financial results and recent corporate achievements. To access the conference call, please dial (866) 220-5595 (local) or (615) 622-8062 (international) at least 10 minutes prior to the start time and refer to conference ID 1173387. A live audio webcast of the call will be available under "Events" in the News & Investors section of the Company's website, <https://www.baudaxbio.com/news-and-investors/events>. An archived webcast will be available on the Company's website approximately two hours after the event.

About ANJESO®

ANJESO (meloxicam) injection is a proprietary, long-acting, preferential COX-2 inhibitor that possesses analgesic, anti-inflammatory and antipyretic activities, which are believed to be related to the inhibition of cyclooxygenase type 2 pathway (COX-2) and subsequent reduction in prostaglandin biosynthesis. ANJESO was launched in the U.S. in June 2020 following its approval by the Food and Drug Administration in February 2020. ANJESO is indicated for the management of moderate to severe pain, alone or in combination with other non-NSAID analgesics. Because of the delayed onset of analgesia, ANJESO alone is not recommended for use when rapid onset of analgesia is required. ANJESO is supported by two pivotal Phase III clinical efficacy trials, a large double-blind, placebo-controlled Phase III safety trial and four Phase II clinical efficacy trials, as well as other safety studies. As a non-opioid, Baudax Bio believes ANJESO has the potential to overcome many of the issues associated with commonly prescribed opioid therapeutics, including respiratory depression, constipation, excessive nausea and vomiting, as well as having no addictive potential, while maintaining meaningful analgesic effects for relief of pain. ANJESO was designed using the

NanoCrystal® platform, a technology that enables enhanced bioavailability of poorly water-soluble drug compounds. NanoCrystal® is a registered trademark of Alkermes Pharma Ireland Limited (APIL).

About Baudax Bio

Baudax Bio is a pharmaceutical company focused on therapeutics for acute care settings. The launch of Baudax Bio's first commercial product ANJESO® began in June 2020 following its approval by the U.S. Food and Drug Administration in February 2020. ANJESO is a once daily IV NSAID with preferential Cox-2 activity, which has successfully completed three Phase III clinical trials, including two pivotal efficacy trials, a large double-blind Phase III safety trial and other studies for the management of moderate to severe pain. In addition to ANJESO, Baudax has a pipeline of other pharmaceutical assets including two novel neuromuscular blocking agents (NMBAs) and a proprietary chemical reversal agent specific to these NMBAs which is currently in preclinical studies, and intranasal dexmedetomidine which is being developed for possible uses in pain or sedation. For more information please visit www.baudaxbio.com.

Cautionary Statement Regarding Forward Looking Statements

This press release contains forward-looking statements that involve risks and uncertainties. Such forward-looking statements reflect Baudax Bio's expectations about its future performance and opportunities that involve substantial risks and uncertainties. When used herein, the words "anticipate," "believe," "estimate," "may," "upcoming," "plan," "target," "goal," "intend," and "expect," and similar expressions, as they relate to Baudax Bio or its management, are intended to identify such forward-looking statements. These forward-looking statements are based on information available to Baudax Bio as of the date of publication on this internet site and are subject to a number of risks, uncertainties, and other factors that could cause Baudax Bio's performance to differ materially from those expressed in, or implied by, these forward-looking statements. These forward-looking statements are subject to risks and uncertainties including, among other things, the ongoing economic and social consequences of the COVID-19 pandemic, including any adverse impact on the commercial launch of ANJESO® or disruption in supply chain, Baudax Bio's ability to maintain regulatory approval for ANJESO, Baudax Bio's ability to successfully commercialize ANJESO; the acceptance of ANJESO by the medical community, including physicians, patients, health care providers and hospital formularies; Baudax Bio's ability and that of Baudax Bio's third party manufacturers to successfully scale-up our commercial manufacturing process for ANJESO, Baudax Bio's ability to produce commercial supply in quantities and quality sufficient to satisfy market demand for ANJESO, Baudax Bio's ability to raise future financing for continued product development, payment of milestones and ANJESO commercialization, Baudax Bio's ability to pay its debt and satisfy conditions necessary to access future tranches of debt, Baudax Bio's ability to comply with the financial and other covenants under its credit facility, Baudax Bio's ability to manage costs and execute on our operational and budget plans, the accuracy of Baudax Bio's estimates of the potential market for ANJESO, Baudax Bio's ability to achieve its financial goals; and Baudax Bio's ability to obtain, maintain and successfully enforce adequate patent and other intellectual property protection. These forward-looking statements should be considered together with the risks and uncertainties that may affect our business and future results included in our filings with the Securities and Exchange Commission at www.sec.gov. These

forward-looking statements are based on information currently available to us, and we assume no obligation to update any forward-looking statements except as required by applicable law.

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BAUDAX BIO, INC.
 Consolidated Balance Sheets
 (Unaudited)

(amounts in thousands, except share and per share data)	September 30, 2020	December 31, 2019
	<hr/>	<hr/>
Assets		
Current assets:		
Cash and cash equivalents	\$ 24,608	\$ 17,740
Inventory	1,784	—
Prepaid expenses and other current assets	2,563	2,395
Total current assets	<hr/> 28,955	<hr/> 20,135
Property, plant and equipment, net	4,835	4,821
Intangible assets, net	24,898	26,400
Goodwill	2,127	2,127
Other long-term assets	652	730
Total assets	<hr/> <hr/> \$ 61,467	<hr/> <hr/> \$ 54,213
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,782	\$ 271
Accrued expenses and other current liabilities	7,292	3,850
Current portion of long-term debt, net	171	—
Current portion of contingent consideration	10,677	3,592
	<hr/>	<hr/>

Total current liabilities	19,922	7,713
Long-term debt, net	8,753	—
Warrant liability	10,228	—
Long-term portion of contingent consideration	67,433	62,766
Other long-term liabilities	361	455
Total liabilities	<u>106,697</u>	<u>70,934</u>
Commitments and contingencies		
Shareholders' equity:		
Preferred stock, \$0.01 par value. Authorized, 10,000,000 shares; none issued and outstanding	—	—
Common stock, \$0.01 par value. Authorized, 100,000,000 shares; issued and outstanding, 18,374,604 shares at September 30, 2020 and 9,350,709 shares at December 31, 2019	184	94
Additional paid-in capital	49,864	19,405
Accumulated deficit	(95,278)	(36,220)
Total shareholders' equity (deficit)	<u>(45,230)</u>	<u>(16,721)</u>
Total liabilities and shareholders' equity	<u>\$ 61,467</u>	<u>\$ 54,213</u>

BAUDAX BIO, INC.

Consolidated and Combined Statements of Operations (Unaudited)

(amounts in thousands, except share and per share data)	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2020	2019	2020	2019
Revenue, net	\$ 68	\$ —	\$ 417	\$ —
Operating expenses:				
Cost of sales	540	—	1,190	—
Research and development	1,469	1,845	5,889	18,578
Selling, general and administrative	13,763	4,524	33,026	21,809
Amortization of intangible assets	643	—	1,502	—
Change in warrant valuation	(11,182)	—	2,863	—
Change in contingent consideration valuation	(17,427)	3,909	14,252	(15,241)
Total operating expenses	<u>(12,194)</u>	<u>10,278</u>	<u>58,722</u>	<u>25,146</u>

Operating income (loss)	<u>12,262</u>	<u>(10,278)</u>	<u>(58,305)</u>	<u>(25,146)</u>
Other expense:				
Other expense	<u>(577)</u>	<u>(37)</u>	<u>(753)</u>	<u>(86)</u>
Net income (loss)	<u>\$ 11,685</u>	<u>\$ (10,315)</u>	<u>\$ (59,058)</u>	<u>\$ (25,232)</u>
Per share information:				
Net income (loss) per share of common stock, basic	<u>\$ 0.64</u>	<u>\$ (1.10)</u>	<u>\$ (3.84)</u>	<u>\$ (2.70)</u>
Net income (loss) per share of common stock, dilutive	<u>\$ 0.62</u>	<u>\$ (1.10)</u>	<u>\$ (3.84)</u>	<u>\$ (2.70)</u>
Weighted average common shares outstanding, basic	<u>18,374,604</u>	<u>9,350,709</u>	<u>15,366,861</u>	<u>9,350,709</u>
Weighted average common shares outstanding, diluted	<u>18,768,376</u>	<u>9,350,709</u>	<u>15,366,861</u>	<u>9,350,709</u>

BAUDAX BIO

Source: Baudax Bio, Inc.