

February 16, 2021

BAUDAX BIO[®]

Baudax Bio Reports 2020 Annual Financial Results

Deepening Usage of ANJESO Evidenced by a Reorder Rate of 60% by the End of 2020 and 58% Growth in Vials Sold from the Sequential Quarter

Secured Approximately \$55 Million in Gross Proceeds from Equity Offerings Over the Past Four Months

Management to Host Investor Conference Call and Webcast Today at 8:00 a.m. ET

MALVERN, Pa., Feb. 16, 2021 (GLOBE NEWSWIRE) -- Baudax Bio, Inc. (Nasdaq: BXRX), a pharmaceutical company focused on therapeutics for acute care settings, today reported its financial results for the year ended December 31, 2020.

“As we continue to navigate the ongoing global pandemic, we continue to see a slower rate of commercialization of ANJESO than we would have expected without COVID-19, but feedback from users of ANJESO and our third-party market research is encouraging,” said Gerri Henwood, President and CEO of Baudax Bio. “Interest in the product continues to grow as we raise awareness and educate health care providers on the benefits of ANJESO for the management of moderate to severe pain in the acute care setting. We are happy to have added our fifth additional Orange Book listed patent in November, which has an expiry date of May 2030 and we have seen continued support for the safety and efficacy of ANJESO from peer-reviewed publications.”

“The fourth quarter and full year 2020 was marked by several significant milestones for Baudax Bio. We secured approximately \$24 million of gross proceeds in the fourth quarter of 2020 and \$31 million in the first quarter of 2021 from registered direct offerings and warrant exercises,” concluded Ms. Henwood.

Recent Highlights

ANJESO

- **Update on Vials Sold to End-Customer.** In 2020, over 65 institutions added ANJESO to their formulary. The number of vials sold to end-customers has increased 58% in the fourth quarter of 2020 versus the third quarter of 2020. The number of vials sold to hospitals and ambulatory surgical centers increased over 80% during the same time period. The average quarterly orders per account increased over 60% in the fourth quarter of 2020 versus the third quarter of 2020 and the re-order rate is approximately 55% with a deepening usage pattern.
- **Commercialization Update.** While the Company reduced its commercial headcount in November, it launched a virtual tele-sales team to help increase awareness and broaden usage in a cost-efficient manner. This team, deployed in December, has had early success increasing awareness of ANJESO in hospitals not currently targeted by

our sales team and has expanded modestly in late January 2021. Another approach deployed in late January 2021 enlists individuals with medical device background and previous relationships with orthopedic surgeons to further expand our access and reach in orthopedics.

- **Publication of ANJESO Network Meta-Analysis in Peer-Reviewed Journal BMC Anesthesiology.** In November 2020, the company announced the online publication of a Network Meta-Analysis for ANJESO injection in the peer-reviewed medical journal BMC Anesthesiology. ANJESO was found to be superior in pain reduction for abdominoplasty, bunionectomy and hysterectomy with similar or better safety compared to other approved IV non-opioid analgesics.
- **Receipt of Additional Orange Book Listed Patent for ANJESO.** In November 2020, the company announced the issuance of an additional United States patent on July 14, 2020. The patent covers the use of ANJESO to treat moderate to severe pain and has been listed in the U.S. Food and Drug Administration's (FDA) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations as it relates to ANJESO. This patent is an additional ANJESO patent to be listed in the Orange Book with an expiry date of May 2030 and joins four other patents listed in the Orange Book, amongst others owned or licensed by Baudax that currently provide exclusivity to the ANJESO franchise.

Corporate and Financial

- **Announced a \$17.6 Million Registered Direct Offering.** In February 2021, the company entered into a definitive agreement with institutional and accredited investors for the purchase and sale of an aggregate of 11,000,000 shares of common stock at a purchase price of \$1.60 per share in a registered direct offering priced at-the-market under Nasdaq rules. The gross proceeds from the offering were approximately \$17.6 million, prior to deducting fees and expenses.
- **Announced Exercise of Warrants for Gross Proceeds of \$13.4 Million.** In January 2021, the company entered into an agreement with an accredited healthcare-focused institutional investor to cash exercise its warrants to purchase 10,300,430 shares of common stock having an exercise price of \$1.18. In connection therewith, the company sold the exercising holder new warrants, which are cash exercisable for an aggregate of 10,300,430 shares of common stock at an exercise price of \$1.60 per share. The purchase price of the additional warrants was \$1,287,554, or \$0.125 per warrant. The gross proceeds to the company from the exercise of the warrants and the sale of the additional warrants were \$13.4 million, prior to deducting fees and expenses. The offering was conducted as a registered direct offering priced at-the-market under Nasdaq rules.
- **Closed Two \$12 Million Registered Direct Offerings.** In November and December 2020, the company entered into two definitive agreements with a healthcare-focused institutional investor for the purchase and sale of an aggregate of 10,126,583 and 10,300,430 shares of common stock (or pre-funded warrants in lieu of shares of common stock) and warrants to purchase up to an aggregate of 10,126,583 and 10,300,430 shares of common stock, respectively. Both offerings were registered direct offerings priced at-the-market under Nasdaq rules. The gross proceeds to

Baudax Bio from the offerings were approximately \$24 million, prior to deducting fees and expenses.

Financial Results for the Year Ended December 31, 2020

As of December 31, 2020, Baudax had cash and cash equivalents of \$30.3 million.

Net product revenue for the year ended December 31, 2020 was \$0.5 million related to sales of ANJESO in the U.S. since its launch in June 2020. There was no product revenue recognized for the year ended December 31, 2019.

Cost of sales for the year ended December 31, 2020 was \$1.7 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 for the year ended December 31, 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 Bio expects that over time, its cost of sales will increase as sales increase and as inventory values change to include all direct and indirect costs and expenses post FDA approval. No cost of sales was recorded for the year ended December 31, 2019.

Research and development expenses for the year ended December 31, 2020 were \$9.1 million compared to \$20.1 million for the year ended December 31, 2019. Excluding \$0.9 million and \$2.8 million of costs associated with restructuring initiatives recorded for the years ended December 31, 2020 and 2019, respectively, research and development expenses decreased \$9.1 million. The decrease was primarily due to a decrease in pre-commercial manufacturing and clinical costs of \$5.9 million, a decrease of \$1.3 million as a result of re-allocating costs related to supply chain, regulatory, quality, and medical affairs associated with support of the commercial launch of ANJESO, a decrease of \$1.2 million in preclinical costs and a decrease of \$0.7 million in other general expenses.

Selling, general and administrative expenses for the year ended December 31, 2020 were \$43.3 million, compared to \$27.0 million for the same prior year period, an increase of \$16.3 million. Excluding \$0.8 million and \$4.4 million of costs associated with restructuring initiatives recorded for the years ended December 31, 2020 and 2019, respectively, selling, general and administrative expenses increased \$19.9 million. This increase was primarily due to the commercial launch of ANJESO, specifically, an increase in personnel related costs of \$11.6 million, an increase in marketing and consulting costs of \$6.4 million, and an increase of \$3.9 million attributable to medical affairs and regulatory support. Other general costs increased \$0.9 million. These increases were partially offset by the decrease in costs associated with the separation from Recro of \$2.9 million in 2019.

For the year ended December 31, 2020, Baudax reported a net loss, including non-cash charges of \$31.4 million, of \$76.1 million, or \$3.93 per share, compared to a net loss of \$32.6 million, including non-cash income of \$8.6 million, or \$3.48 per share, for the comparable period in 2019. The non-cash charges of \$31.4 million in 2020 were associated with stock-based compensation, non-cash interest expense, depreciation, amortization, changes in warrant valuations, and changes in fair value of contingent consideration. The non-cash income of \$8.6 million in 2019 was associated with changes in fair value of contingent consideration, stock-based compensation, and depreciation.

Conference Call Information

Baudax will host a conference call today, Tuesday, February 16, 2021, at 8:00 a.m. Eastern Time, to discuss the full year 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 4354098. 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 Bio 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 Baudax Bio’s business and future results included in Baudax Bio’s filings with the Securities and Exchange Commission at www.sec.gov. These forward-looking statements are based on information currently available to Baudax Bio, and Baudax Bio assumes no obligation to update any forward-looking statements except as required by applicable law.

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BAUDAX BIO, INC. AND SUBSIDIARIES

Consolidated Balance Sheets

(amounts in thousands, except share and per share data)

Assets	December 31, 2020	December 31, 2019
Current assets:		
Cash and cash equivalents	\$ 30,342	\$ 17,740
Accounts receivable, net	51	—
Inventory	2,978	—
Prepaid expenses and other current assets	3,346	2,395
Total current assets	\$ 36,717	\$ 20,135
Property, plant and equipment, net	5,052	4,821
Right-of-use asset	583	730
Intangible assets, net	24,254	26,400
Goodwill	2,127	2,127
Total assets	\$ 68,733	\$ 54,213
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	3,653	271
Accrued expenses & other current liabilities	4,993	3,532
Current portion of long-term debt, net	683	—
Current portion of operating lease liability	333	318
Current portion of contingent consideration	8,467	3,592
Total current liabilities	18,129	7,713
Long-term debt, net	8,469	—
Long-term operating lease liability	293	455
Warrant liability	65	—
Long-term portion of contingent consideration	56,576	62,766
Total liabilities	83,532	70,934
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, 48,688,480 shares at December 31, 2020 and 9,350,709 shares at December 31, 2019	487	94
Additional paid in-capital	97,034	19,405

Accumulated deficit	(112,320)	(36,220)
Total shareholders' equity	(14,799)	(16,721)
Total liabilities and shareholders' equity	\$ 68,733	\$ 54,213

BAUDAX BIO, INC. AND SUBSIDIARIES
Consolidated Statements of Operations and Comprehensive Loss

(amounts in thousands, except share and per share data)

	Twelve Months Ended	
	December 31,	
	2020	2019
Revenue, net	\$ 493	\$ —
Operating expenses:		
Cost of sales	1,732	—
Research and development	9,087	20,061
Selling, general and administrative	43,335	27,012
Amortization of intangible assets	2,146	—
Change in warrant valuation	16,734	—
Change in contingent consideration valuation	2,245	(14,554)
Total operating expenses	<u>75,279</u>	<u>32,519</u>
Operating loss	(74,786)	(32,519)
Other income (expense):		
Other income (expense)	45	(38)
Interest expense	(1,359)	—
Net loss	<u>\$ (76,100)</u>	<u>\$ (32,557)</u>
Per share information:		
Net loss per share of common stock, basic and diluted	\$ (3.93)	\$ (3.48)
Weighted average common shares outstanding, basic and diluted	19,355,944	9,350,709

BAUDAX BIO

Source: Baudax Bio, Inc.