

November 4, 2021

**BAUDAX BIO®**

# Baudax Bio Reports Third Quarter 2021 Financial Results and Business Highlights

*ANJESO® Revenue Up 40% in Q3 2021 over Q2 2021 and Up Over 300% in Q3 2021 over Q3 2020*

*Solid Growth in End User Demand Units, September 2021 Strongest Month Launch-to-Date, Indicating Growing Adoption of ANJESO*

*Neuromuscular Blocking Agent BX1000 Completes Clinical Phase of Dose Escalation Study*

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

MALVERN, Pa., Nov. 04, 2021 (GLOBE NEWSWIRE) -- Baudax Bio, Inc. (NASDAQ:BXRX) (the "Company"), a pharmaceutical company focused on commercializing and developing innovative products for acute care settings, today reported financial results for the three and nine months ended September 30, 2021, and provided key metrics around the ongoing commercial rollout of ANJESO® (meloxicam) injection and updated status of neuromuscular blocking agent (NMBA) BX1000 dose escalation study.

"We are extremely pleased with the continued solid growth we saw during the third quarter in both sales and end-user demand for ANJESO, the significant uptick in sales to new accounts, which grew an estimated 66% quarter-over-quarter and September results that represented our best month to date," said Gerri Henwood, President and CEO of Baudax Bio. "In addition, we are working to advance our pipeline, which includes novel neuromuscular blocking agents and a reversal agent that have the potential to meaningfully reduce time of "onset" of neuromuscular blockade, and "offset" for procedure recovery time, resulting in potentially valuable cost savings to surgical centers. The clinical dosing portion of the dose escalation study has been completed and we look forward to sharing the results in the near future."

## **Third Quarter 2021 and Recent Business Highlights**

### **ANJESO**

- **ANJESO U.S. Commercialization.** ANJESO is indicated for the management of moderate to severe pain, alone or in combination with other non-NSAID analgesics. During the third quarter of 2021, demand for ANJESO demonstrated solid growth and deepening usage patterns, with revenue increasing 40% for the third quarter of 2021 compared to the second quarter of 2021 and increasing over 300% for the third quarter of 2021 compared to the third quarter of 2020.

Despite extensive outbreaks of COVID-19 delta in much of the south and selected other regions, and its impact on elective surgeries in July and August, there was growth in estimated demand units sold to all customers in the third quarter of 2021

compared to the second quarter of 2021 of approximately 16% and vials sold to end-user hospitals and ambulatory surgery centers (ASCs) combined was up 17% in the same period. Vials sold to existing hospitals increased 11% in the third quarter of 2021 compared the second quarter of 2021 and vials sold to existing ASCs increased 66% in the same period. In addition, the month of September 2021 was our single largest month of ANJESO end-user demand units sold launch-to-date for the product.

- **Summer COVID-19 Breakthrough.** COVID-19 related impacts continue to periodically and regionally affect the number of elective surgeries performed, as well as access for field activities. While there were early signs of elective surgeries gradually returning to pre-COVID levels late in the second quarter of 2021, the COVID-19 delta variant had a significant impact on elective surgeries in July and August because of its effects on how hospitals allocated bed space and resources specifically for COVID-19 patients, especially in the Southern U.S. (e.g., Texas, Florida and Alabama, etc.), which comprises approximately 40% of Baudax Bio's target hospitals.

### *Pipeline*

- **BX1000 clinical update and outlook.** Baudax Bio holds exclusive global rights to two NMBA and a proprietary chemical reversal agent specific to both of these NMBA. The Company believes that these agents allow for a very rapid induction of neuromuscular blockade for surgical settings, which especially when used with the proprietary reversal agent, is followed by a rapid reversal of the neuromuscular blockade. BX1000, the Company's intermediate duration NMBA drug candidate, has undergone an earlier Phase 1 trial prior to the Company licensing of the drug. The second study, a dose escalation trial, recently completed its clinical dosing in the trial and is in the data analysis stage, which Baudax Bio believes will be completed in the near future.

### *Corporate and Financial*

- **Amended Articles of Incorporation.** In July 2021, Baudax Bio held a Special Meeting of Shareholders where it secured the required number of shareholder votes to adopt an amendment to its Amended and Restated Articles of Incorporation to increase the number of authorized shares of common stock from 100 million shares to 190 million shares.

### **Third Quarter 2021 Financial Results**

As of September 30, 2021, Baudax Bio had cash, cash equivalents and short-term investments of \$24.9 million.

Net product revenue, recognized according to U.S. GAAP, for the three months ended September 30, 2021 was \$0.3 million, related to sales of ANJESO in the U.S., compared to \$0.1 million for the three months ended September 30, 2020. While utilizing the title model of distribution, product revenue is recognized as shipments are made to the Company's 3PL provider. The increase of \$0.2 million was attributable to securing additional formulary approvals and generating trial and adoption of ANJESO, as well as increased end-user demand leading to increased purchasing by direct customers.

Cost of sales for both the three months ended September 30, 2021 and 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, 2021 and 2020 were expensed prior to the FDA approval of ANJESO in February 2020, and therefore are not included in cost of sales during the related periods. Baudax Bio expects that over time, product costs in cost of sales will increase as sales increase and inventory associated with the units manufactured prior to FDA approval are sold.

Research and development expenses for the three months ended September 30, 2021 were \$0.7 million, compared to \$1.5 million for the three months ended September 30, 2020, a decrease of \$0.8 million. This decrease was primarily a result of a decrease in personnel costs of \$0.5 million as well as a decrease in clinical costs of \$0.5 million.

Selling, general and administrative expenses for the three months ended September 30, 2021 were \$11.1 million, compared to \$13.8 million for the same prior year period, a decrease of \$2.7 million. This decrease was primarily a result of a decrease in personnel costs of \$3.1 million.

Baudax Bio reported a net loss, including a non-cash charge of \$5.7 million, of \$17.0 million, or \$(0.20) per diluted share, for the three months ended September 30, 2021. Adjusted net loss\* for the three months ended September 30, 2021 was \$11.3 million.

### **Nine Months Ended September 30, 2021 Financial Results**

Net product revenue, recognized according to U.S. GAAP, for the nine months ended September 30, 2021 was \$0.7 million, related to sales of ANJESO in the U.S, compared to \$0.4 million for the nine months ended September 30, 2020. While utilizing the title model of distribution, product revenue is recognized as shipments are made to the Company's 3PL provider. The increase of \$0.3 million was attributable to securing additional formulary approvals and generating trial and adoption of ANJESO, as well as increased end-user demand leading to increased purchasing by direct customers.

Cost of sales for the nine months ended September 30, 2021 was \$1.9 million, compared to \$1.2 million for the nine months ended September 30, 2020 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, 2021 and 2020 were expensed prior to the FDA approval of ANJESO in February 2020, and therefore are not included in cost of sales during the related periods. Baudax Bio expects that over time, product costs in cost of sales will increase as sales increase and inventory associated with the units manufactured prior to FDA approval are sold.

Research and development expenses for the nine months ended September 30, 2021 were \$2.6 million, compared to \$5.9 million for the nine months ended September 30, 2020, a decrease of \$3.3 million. Baudax Bio's research and development expenses decreased primarily from a decrease in personnel costs of \$2.6 million and a decrease of \$0.8 million in pre-commercialization manufacturing costs for ANJESO.

Selling, general and administrative expenses for the nine months ended September 30, 2021 were \$33.8 million, compared to \$33.0 million for the same prior year period, an increase of \$0.8 million. The increase was primarily a result of the prior period of 2020 included \$1.5 million in reimbursed general and administrative expenses related to the Transition Services Agreement with Recro Pharma, which ended on December 31, 2020. This increase as well as an increase in public company costs of \$1.2 million were partially offset by a decrease in personnel expenses of \$1.9 million.

Baudax reported a net loss, including a non-cash charge of \$14.9 million, of \$49.2 million, or \$(0.66) per share, for the nine months ended September 30, 2021. Adjusted net loss\* was \$34.3 million.

\*Adjusted net loss is a non-GAAP financial measure (see reconciliation of non-GAAP financial measures in this release).

### **Non-GAAP Financial Measures**

To supplement the Company's financial results determined by U.S. generally accepted accounting principles ("GAAP"), the Company is reporting certain non-GAAP information for its business, including adjusted net loss. Adjusted net loss is net loss as determined under GAAP, excluding the changes in fair values of contingent consideration and warrant valuations, gain on extinguishment of debt, interest, depreciation, amortization, and stock-based compensation. The Company believes this non-GAAP financial measure is helpful in understanding its business as it is useful to investors in allowing for greater transparency of supplemental information used by management. This measure is used by investors, as well as management in assessing the Company's performance. Non-GAAP financial measures should be considered in addition to, but not as a substitute for, reported GAAP results. Further, Non-GAAP financial measures, even if similarly titled, may not be calculated in the same manner by all companies, and therefore should not be compared. Please see the section of this press release titled "Reconciliation of GAAP to Non-GAAP Financial Measures" for a reconciliation of non-GAAP adjusted net loss to its most directly comparable GAAP measure.

### **Conference Call Information**

Baudax Bio will host a conference call today, Thursday, November 4, 2021, at 8:00 a.m. Eastern Time, to discuss the third quarter 2021 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 9972669. 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 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 commercializing and developing innovative products for acute care settings. ANJESO is the first and only 24-hour, intravenous (IV) COX-2 preferential non-steroidal anti-inflammatory (NSAID) for the management of moderate to severe pain. In addition to ANJESO, Baudax Bio has a pipeline of other innovative pharmaceutical assets including two novel neuromuscular blocking agents (NMBAs) and a proprietary chemical reversal agent specific to these NMBAs. For more information, please visit [www.baudaxbio.com](http://www.baudaxbio.com).

### **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 risks and uncertainties include, among other things, risks related to 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 the 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 its 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](http://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.**  
 Consolidated Balance Sheets  
 (Unaudited)

<b>(amounts in thousands, except share and per share data)</b>	<b>September 30, 2021</b>	<b>December 31, 2020</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 14,772	\$ 30,342
Short-term investments	10,150	—
Accounts receivable, net	422	51
Inventory	4,310	2,978
Prepaid expenses and other current assets	1,484	3,346
Total current assets	<u>31,138</u>	<u>36,717</u>
Property, plant and equipment, net	4,933	5,052
Intangible assets, net	22,322	24,254
Goodwill	2,127	2,127
Other long-term assets	979	583
Total assets	<u>\$ 61,499</u>	<u>\$ 68,733</u>

### Liabilities and Shareholders' Deficit

Current liabilities:

Accounts payable	\$	1,819	\$	3,653
Accrued expenses and other current liabilities		4,568		5,326
Current portion of long-term debt, net		1,389		683
Current portion of contingent consideration		6,666		8,467
Total current liabilities		<u>14,442</u>		<u>18,129</u>
Long-term debt, net		6,913		8,469
Long-term portion of contingent consideration		60,059		56,576
Other long-term liabilities		813		358
Total liabilities		<u>82,227</u>		<u>83,532</u>
Commitments and contingencies				
Shareholders' deficit:				
Preferred stock, \$0.01 par value. Authorized, 10,000,000 shares; none issued and outstanding		—		—
Common stock, \$0.01 par value. Authorized, 190,000,000 shares; issued and outstanding, 84,423,342 shares at September 30, 2021 and 48,688,480 shares at December 31, 2020		844		487
Additional paid-in capital		139,951		97,034
Accumulated deficit		<u>(161,523)</u>		<u>(112,320)</u>
Total shareholders' deficit		<u>(20,728)</u>		<u>(14,799)</u>
Total liabilities and shareholders' deficit	\$	61,499	\$	68,733

**BAUDAX BIO, INC.**  
Consolidated Statements of Operations  
(Unaudited)

	<b>For the Three Months Ended September 30,</b>		<b>For the Nine Months Ended September 30,</b>	
	<b>2021</b>	<b>2020</b>	<b>2021</b>	<b>2020</b>
<b>(amounts in thousands, except share and per share data)</b>				
Revenue, net	\$ 281	\$ 68	\$ 680	\$ 417
Operating expenses:				
Cost of sales	462	540	1,869	1,190
Research and development	658	1,469	2,623	5,889
Selling, general and administrative	11,074	13,763	33,770	33,026
Amortization of intangible assets	644	643	1,932	1,502

Change in warrant valuation	(6)	(11,182)	(47)	2,863
Change in contingent consideration valuation	3,829	(17,427)	9,551	14,252
Total operating expenses	<u>16,661</u>	<u>(12,194)</u>	<u>49,698</u>	<u>58,722</u>
Operating (loss) income	(16,380)	12,262	(49,018)	(58,305)
Other expense:				
Other expense, net	(582)	(577)	(185)	(753)
Net (loss) income	<u>\$ (16,962)</u>	<u>\$ 11,685</u>	<u>\$ (49,203)</u>	<u>\$ (59,058)</u>
Per share information:				
Net (loss) income per share of common stock, basic	<u>\$ (0.20)</u>	<u>\$ 0.64</u>	<u>\$ (0.66)</u>	<u>\$ (3.84)</u>
Net (loss) income per share of common stock, diluted	<u>\$ (0.20)</u>	<u>\$ 0.62</u>	<u>\$ (0.66)</u>	<u>\$ (3.84)</u>
Weighted average common shares outstanding, basic	<u>84,400,156</u>	<u>18,374,604</u>	<u>74,008,574</u>	<u>15,366,861</u>
Weighted average common shares outstanding, diluted	84,400,156	18,768,376	74,008,574	15,366,861

### BAUDAX BIO, INC.

#### Reconciliation of GAAP to Non-GAAP Measures (Unaudited)

To supplement the Company's financial results determined by U.S. generally accepted accounting principles ("GAAP"), the Company has disclosed in the tables below the following non-GAAP information about adjusted net loss.

Adjusted net loss is net loss as determined under GAAP, excluding the changes in fair values of contingent consideration and warrant valuations, gain on extinguishment of debt, interest, depreciation, amortization, and stock-based compensation.

The Company believes that non-GAAP financial measures are helpful in understanding its business as it is useful to investors in allowing for greater transparency of supplemental information used by management. Adjusted net loss is used by investors, as well as management in assessing the Company's performance. Non-GAAP financial measures should be considered in addition to, but not as a substitute for, reported GAAP results. Further, Non-GAAP financial measures, even if similarly titled, may not be calculated in the same manner by all companies, and therefore should not be compared.

(amounts in thousands)	For the Three Months Ended		For the Nine Months Ended	
	September 30, 2021	September 30, 2020	September 30, 2021	September 30, 2020

Net loss (GAAP)	\$ (16,962)	\$ 11,685	\$ (49,203)	\$ (59,058)
Stock-based compensation	925	2,489	4,132	7,431
Non-cash interest expense	215	230	673	306
Gain on extinguishment of debt	—	—	(1,553)	—
Depreciation expense	46	104	195	315
Amortization expense	644	643	1,932	1,502
Change in warrant valuation	(6)	(11,182)	(47)	2,863
Change in contingent consideration valuation	3,829	(17,427)	9,551	14,252
Adjusted net loss (non-GAAP)	\$ (11,309)	\$ (13,458)	\$ (34,320)	\$ (32,389)

**BAUDA<sup>®</sup>X BIO**

Source: Baudax Bio, Inc.