

March 16, 2022



# Baudax Bio Reports 2021 Fourth Quarter and Annual Financial Results

*ANJESO End User Demand and Revenue Increases Four Quarters In A Row*

*Neuromuscular Blocking Agents Advancing*

MALVERN, Pa., March 16, 2022 (GLOBE NEWSWIRE) -- Baudax Bio, Inc. (NASDAQ:BXR) (the "Company"), a pharmaceutical company focused on commercializing and developing innovative products for acute care settings, today reported financial results for the fourth quarter and year ended December 31, 2021, provided key metrics around the ongoing commercial rollout of ANJESO® (meloxicam) injection, updated status of its neuromuscular blocking agent (NMB) portfolio, and provided other recent updates.

"We're excited about the continued growth we've seen throughout 2021 in both the fourth quarter and annual revenue and end-user demand for ANJESO, despite the challenging backdrop of fewer elective surgeries due to the COVID-19 pandemic," said Gerri Henwood, President and CEO of Baudax Bio. "In addition, we are actively progressing our novel neuromuscular blocking agents, including the advancement of BX1000 into the next clinical study in surgical patients expected in the first half of 2022, submission of requested additional information to FDA for BX2000 this quarter and the initiation of a BX2000 dose-escalation study in healthy volunteers, and planning for the commencement of clinical work for BX3000 in late 2022 or early 2023. Collectively, these assets have the potential to meaningfully reduce both time of 'onset' of neuromuscular blockade and 'offset' for procedure recovery time, resulting in potentially greater certainty and control of desired duration of neuromuscular blockade, which can produce meaningful cost savings and time savings for surgical centers."

## Recent 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. For the fourth consecutive quarter, demand for ANJESO demonstrated solid growth and deepening usage patterns, with quarterly vials sold to end-users increasing by approximately 32% in the fourth quarter of 2021 compared to the third quarter of 2021. The number of vials sold to ambulatory surgical centers (ASCs) increased approximately 45% during the same time period. ANJESO is now approved on over 200 formularies nationwide. The average quarterly orders per account increased over 23% in the fourth quarter of 2021 versus the third quarter of 2021 and the re-order rate grew to nearly 70% with a deepening usage pattern. In addition, the month of December 2021 was our single largest month of ANJESO units sold launch-to-date for the product.

Charts accompanying this announcement are available at <https://www.globenewswire.com/NewsRoom/AttachmentNg/c88ec503-7bb2-4b6f-9d41-d274a108c46c>

<https://www.globenewswire.com/NewsRoom/AttachmentNg/00fcf044-2132-4550-8908-1280dd355dc3>

- **COVID-19 Breakthrough.** COVID-19 related impacts continue to periodically and regionally affect the number of elective surgeries performed, as well as impacting access for field activities in certain geographies. While there were early signs of elective surgeries gradually returning to pre-COVID levels late in the third quarter of 2021, the COVID-19 omicron variant had a significant impact on institutions cancelling elective surgeries in November and December due to COVID-19 demand for patient bed space as well as reduced ASC and hospital staff availability, especially in the Southern U.S. (e.g., Texas, Florida and Alabama), which currently accounts for approximately 40% of Baudax Bio's hospital business.

#### *NMBs*

- **BX1000.** Baudax Bio completed the dose-escalation study that evaluated the product candidate in 58 healthy volunteers. Overall BX1000 was generally well tolerated through the dosing range tested. Muscle paralysis was rapidly achieved along with complete spontaneous recovery. Baudax Bio is preparing the clinical study report for this dose-escalation study and expects to submit it to the U.S. Food and Drug Administration (FDA) in 2022. Additionally, Baudax Bio is preparing for the next BX1000 study in surgical patients that is expected to commence in the first half of 2022.
- **BX2000.** Baudax Bio completed additional nonclinical testing of BX2000 requested by FDA, which was submitted in February of 2022, and in March, FDA notified us that we could proceed with initiation of a dose-escalation study in healthy volunteers in the first half of 2022.
- **BX3000.** Additional work to enhance formulation of BX3000 is underway and Baudax Bio believes that this data, along with certain non-clinical data, will be submitted to FDA and allows for initiation of the clinical program in healthy volunteers in late 2022 or early 2023.

#### *Corporate and Financial*

- **Regains Compliance with NASDAQ Listing Requirements.** In March 2022, Baudax Bio announced that it received a letter from The Nasdaq Stock Market noting the Company has regained compliance with the minimum bid price requirement under Listing Rule 5550(a)(2), which requires the Company to maintain a minimum closing bid price of \$1.00 per share. Nasdaq staff made this determination of compliance after the Company's bid price closed above \$1.00 per share for 10 consecutive business days from February 16, 2022 to March 2, 2022, and has now deemed the matter closed.
- **Implemented Plans to Reduce Expenses.** In March 2022, the Company

implemented plans to reduce expenses including an approximately 80% reduction in the Company's workforce. The reduction in workforce is intended to reduce the Company's operating costs in connection with ANJESO commercialization. The Company expects to substantially complete the reduction plan by the end of the second quarter of 2022. Severance and other related costs are estimated to be approximately \$4.0 million, recognized primarily in the first quarter. In conjunction with the reduction of the Company's workforce, Richard S. Casten, Chief Financial Officer, is leaving, and Jillian Dilmore, CPA and Corporate Controller, will assume interim responsibilities as the Principal Financial Officer. For more details regarding this plan to reduce expenses, please see the Company's form 10-K, which will be filed on March 16, 2022.

- **Announced \$10.0 Million Public Offering.** During the first quarter 2022, Baudax Bio completed an underwritten public offering of 3,508,772 shares of common stock (or common stock equivalents), together with warrants to purchase up to an aggregate of 3,508,772 shares of common stock (the "Offering"). Each share of common stock (or common stock equivalent) was sold together with one warrant to purchase one share of common stock at a combined public offering price of \$2.85 per share of common stock and accompanying warrant, less the underwriting discounts and commissions. The warrants have an exercise price of \$3.25 per share, are exercisable immediately, and will expire five years following the date of issuance. In addition, the underwriter partially exercised its option to purchase an additional 113,896 warrants.
- **Announced 1-for-35 Reverse Stock Split.** During the first quarter 2022, Baudax Bio announced a 1-for-35 reverse stock split of its common shares (the "Reverse Stock Split"). The Reverse Stock Split became effective at 12:01 a.m. Eastern time on February 16, 2022 and the Company's common stock opened for trading on The Nasdaq Capital Market on a post-split basis under the Company's existing trading symbol "BXR". At such time, the Company's common stock also commenced trading under a new CUPSIP number, 07160F206. All issued and outstanding shares of common stock, warrants, common stock options, and unvested restricted stock units and the related per share amounts contained in the financial statements have been retroactively adjusted to reflect this Reverse Stock Split for all periods presented.
- **Announced \$4.2 Million Registered Direct Offering.** In December 2021, Baudax Bio entered into a definitive agreement with certain institutional investors for the issuance and sale of 42,289.3 shares of Series A preferred stock and warrants to purchase up to an aggregate of approximately 362,479 shares of common stock, which resulted in gross proceeds of \$4.2 million in a registered direct offering. The shares of preferred stock have a stated value of \$100 per share and were convertible after the closing date into an aggregate of approximately 483,306 shares of common stock at a conversion price of \$8.75 per share. All shares of preferred stock were converted into common stock by the first quarter of 2022.

### **Financial Results for the Three Months Ended December 31, 2021**

For the three months ended December 31, 2021, Baudax Bio saw continued quarterly growth in units sold to end users of approximately 32% compared to the third quarter of 2021, totaling approximately 5,000 units sold to end users in the fourth quarter.

As of December 31, 2021, Baudax Bio had cash and cash equivalents of \$15.9 million.

Net product revenue related to sales of ANJESO in the U.S., recognized according to U.S. GAAP, for the three months ended December 31, 2021 was \$0.4 million. This compares to \$0.1 million for the three months ended December 31, 2020, which included certain initial stocking of ANJESO to wholesaler distribution centers in the early part of the COVID-19 launch year. While utilizing the title model of distribution, product revenue is recognized as shipments are made to the Company's third-party logistics provider. The increase in net product revenue of \$0.3 million was attributable to securing additional formulary approvals, which allowed for more trial usage of ANJESO that led to early adoption of ANJESO. Ultimately throughout 2021, this adoption led to deepening usage and increased end-user demand as well as increased purchasing through both wholesalers and by direct customers.

Cost of sales for the three months ended December 31, 2021 was \$0.6 million, compared to \$0.5 million for the three months ended December 31, 2020, an increase of \$0.1 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 December 31, 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 have been sold.

Research and development expenses for the three months ended December 31, 2021 were \$0.5 million compared to \$3.2 million for the three months ended December 31, 2020. Research and development expenses decreased \$2.7 million, which was primarily due to a decrease in personnel related costs of \$1.5 million, a decrease in project costs associated with increasing manufacturing capacity at its supplier for ANJESO of \$0.7 million, and a decrease of \$0.5 million in clinical costs.

Selling, general and administrative expenses for the three months ended December 31, 2021 were \$11.5 million, of which \$6.5 million was attributable to selling expense and \$5.0 million was attributable to general and administrative expense. This compares to \$10.3 million for the same prior year period, of which \$6.3 million was attributable to selling expense and \$4.0 million was attributable to general and administrative expense. Selling expenses remained flat over the comparable period while general and administrative expenses increased \$1.0 million, which was primarily a result of the prior period including \$0.4 million in reimbursed general and administrative expenses related to the Transition Services Agreement with Recro, which ended on December 31, 2020, as well as an increase of \$0.3 million in both personnel and public company costs.

Baudax Bio reported net income of \$29.4 million, including a non-cash benefit of \$41.3 million, or \$10.03 per diluted share, for the three months ended December 31, 2021. Adjusted net loss\* was \$11.9 million.

### **Financial Results for the Year Ended December 31, 2021**

Net product revenue related to sales of ANJESO in the U.S., recognized according to U.S. GAAP, for the year ended December 31, 2021 was \$1.1 million. This compares to \$0.5 million for the year ended December 31, 2020, which included certain initial stocking of

ANJESO to wholesaler distribution centers in the early part of the COVID-19 launch year. While utilizing the title model of distribution, product revenue is recognized as shipments are made to the Company's third party logistics provider. The increase of \$0.6 million was attributable to securing additional formulary approvals, which allowed for more trial usage of ANJESO that lead to early adoption of ANJESO. Ultimately throughout 2021, this adoption led to deepening usage and increased end-user demand and increased purchasing through both wholesalers and by direct customers.

Cost of sales for the year ended December 31, 2021 was \$2.4 million, compared to \$1.7 million for the year ended December 31, 2020, an increase of \$0.7 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 during the years ended December 31, 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 have been sold.

Research and development expenses for the year ended December 31, 2021 were \$3.1 million compared to \$9.1 million for the year ended December 31, 2020. Research and development expenses decreased \$6.0 million, which was primarily due to a decrease in personnel related costs of \$4.0 million and a decrease in pre-commercial manufacturing and clinical costs of \$2.0 million.

Selling, general and administrative expenses for the year ended December 31, 2021 were \$45.3 million, of which \$22.4 million was attributable to selling expense and \$22.9 million was attributable to general and administrative expense. This compares to \$43.3 million for the same prior year period, of which \$22.8 million was attributable to selling expense and \$20.5 million was attributable to general and administrative expense. Selling expenses remained flat over the comparable period while general and administrative expenses increased \$2.4 million. The increase was primarily a result of the prior period of 2020 including \$2.0 million in reimbursed general and administrative expenses related to the Transition Services Agreement with Recro Pharma, which ended on December 31, 2020.

Baudax Bio reported a net loss of \$19.8 million, including a non-cash benefit of \$26.4 million, or \$(10.14) per share, for the year ended December 31, 2021. Adjusted net loss\* was \$46.2 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.

### **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 (NMBs) and a proprietary chemical reversal agent specific to these NMBs. 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, including statements relating to the development of each of BX-1000, BX-2000 and BX-3000, 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, Baudax Bio's ability to advance its current product candidate pipeline through pre-clinical studies and clinical trials, Baudax Bio's ability to raise future financing for continued development of its product candidates such as BX-1000, BX-2000 and BX-3000, 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, 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. AND SUBSIDIARIES**

### **Consolidated Balance Sheets**

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

	<b>December 31, 2021</b>	<b>December 31, 2020</b>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 15,891	\$ 30,342
Accounts receivable, net	542	51
Inventory	5,002	2,978

Prepaid expenses and other current assets	2,059	3,346
Total current assets	23,494	36,717
Property, plant and equipment, net	5,015	5,052
Intangible assets, net	21,678	24,254
Goodwill	2,127	2,127
Other long-term assets	963	583
Total assets	\$ 53,277	\$ 68,733
<b>Liabilities and Shareholders' Deficit</b>		
Current liabilities:		
Accounts payable	\$ 1,468	\$ 3,653
Accrued expenses and other current liabilities	5,540	5,326
Current portion of long-term debt, net	2,222	683
Current portion of contingent consideration	6,416	8,467
Total current liabilities	15,646	18,129
Long-term debt, net	6,309	8,469
Long-term portion of contingent consideration	17,446	56,576
Other long-term liabilities	650	358
Total liabilities	40,051	83,532
Shareholders' deficit:		
Preferred stock, \$0.01 par value. Authorized, 10,000,000 shares; issued and outstanding, 8,289 shares at December 31, 2021 and 0 shares at December 31, 2020	—	—
Common stock, \$0.01 par value. Authorized, 190,000,000 shares; issued and outstanding, 2,807,240 shares at December 31, 2021 and 1,391,099 shares at December 31, 2020	983	487
Additional paid in-capital	144,332	97,034
Accumulated deficit	(132,089)	(112,320)
Total shareholders' equity (deficit)	13,226	(14,799)
Total liabilities and shareholders' deficit	\$ 53,277	\$ 68,733

## BAUDAX BIO, INC. AND SUBSIDIARIES

### Consolidated Statements of Operations and Comprehensive Loss

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

**Three Months  
Ended**

**For the Year Ended**



	<u>December 31,</u>		<u>December 31,</u>	
	<u>2021</u>	<u>2020</u>	<u>2021</u>	<u>2020</u>
Revenue, net	\$ 400	\$ 76	\$ 1,080	\$ 493
Operating expenses:				
Cost of sales (excluding amortization of intangible assets)	576	542	2,445	1,732
Research and development	502	3,198	3,125	9,087
Selling, general and administrative	11,540	10,309	45,310	43,335
Amortization of intangible assets	644	644	2,576	2,146
Change in warrant valuation	(11)	13,871	(58)	16,734
Change in contingent consideration valuation	(42,863)	(12,007)	(33,312)	2,245
Total operating expenses	(29,612)	16,557	20,086	75,279
Operating income (loss)	30,012	(16,481)	(19,006)	(74,786)
Other income (expense):				
Other income	1	(561)	1,540	45
Interest expense	(579)	—	(2,303)	(1,359)
Net income (loss)	\$ 29,434	\$ (17,042)	\$ (19,769)	\$ (76,100)
Beneficial conversion feature upon issuance of Series A convertible preferred stock	(2,422)	—	(2,422)	—
Net income (loss) attributable to common shareholders	\$ 27,012	\$ (17,042)	\$ (22,191)	\$ (76,100)
Per share information:				
Net income (loss) per share of common stock, basic	\$ 11.16	\$ (20.93)	\$ (10.14)	\$ (142.87)
Net income (loss) per share of common stock, diluted	\$ 10.03	\$ (20.93)	\$ (10.14)	\$ (142.87)
Weighted average common shares outstanding, basic	2,421,273	814,342	2,189,504	532,639
Weighted average common shares outstanding, diluted	2,693,893	814,342	2,189,504	532,639

**BAUDAX BIO, INC. AND SUBSIDIARIES**  
Reconciliation of GAAP to Non-GAAP Measures

To supplement our financial results determined by U.S. generally accepted accounting principles (“GAAP”), we have 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.

We believe that non-GAAP financial measures are helpful in understanding our 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 our 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)	Three Months Ended December 31,		For the Year Ended December 31,	
	2021	2020	2021	2020
Net income (loss) (GAAP)	\$ 29,434	\$ (17,042)	\$ (19,769)	\$ (76,100)
Stock-based compensation	657	1,910	4,789	9,341
Non-cash interest expense	224	229	897	535
Gain on extinguishment of debt	—	—	(1,553)	—
Depreciation expense	45	93	240	408
Amortization expense	644	644	2,576	2,146
Change in warrant valuation	(11)	13,871	(58)	16,734
Change in contingent consideration valuation	(42,863)	(12,007)	(33,312)	2,245
Adjusted net loss (non-GAAP)	\$ (11,870)	\$ (12,302)	\$ (46,190)	\$ (44,691)

**BAUDaX BIO**

Source: Baudax Bio, Inc.

Units Sold by Quarter



Units Sold by Quarter

Quarterly Customer Sales / Quarterly ASC Sales



Quarterly Customer Sales / Quarterly ASC Sales