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BAUDAX BIO[®]

Baudax Bio Reports First Quarter 2022 Financial Results and Business Highlights

ANJESO[®] Net Product Revenue Up 113% Compared to Same Period in Prior Year; Sixth Consecutive Quarter of Demand Growth

First Cohort Dosed in Pediatric ANJESO Surgical Study

Management to Host Investor Conference Call and Webcast Tomorrow at 8:30 a.m. ET

MALVERN, Pa., May 04, 2022 (GLOBE NEWSWIRE) -- Baudax Bio, Inc. (NASDAQ:BXRX) (the "Company"), a pharmaceutical company focused on innovative products for acute care settings, today reported financial results for the three months ended March 31, 2022, provided key metrics around the ongoing commercial rollout of ANJESO (meloxicam) injection, updated status of neuromuscular blocking (NMB) agent development program, and provided an overview of other corporate and financial developments.

"ANJESO continued to grow during the first quarter, despite the COVID-19 headwinds experienced by the marketplace, and March was our single largest sales month since launch," said Gerri Henwood, President and CEO of Baudax Bio. "We are actively working to expand the ANJESO label in additional patient populations. To that end, we commenced a Phase IV clinical trial evaluating ANJESO in multiple age groups of pediatric patients, with the dosing of one of the age cohorts. We look forward to the advancement of our novel neuromuscular blocking agents during the first half of 2022, including BX1000 progressing into the next clinical study in surgical patients, and the commencement of a dose-escalation study evaluating BX2000 in healthy volunteers. For BX3000, we are completing certain preclinical work and anticipate advancing into the clinic in late 2022 or early 2023."

First Quarter 2022 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. For the first quarter 2022, ANJESO achieved net product revenue of \$0.4 million, reflecting growth of 113% compared to the same period in the prior year and growth of 5% compared to the fourth quarter 2021. For the sixth consecutive quarter, demand for ANJESO increased with deepening usage patterns. Quarterly vials sold to end-users increased by 141% in the first quarter 2022 compared to the same period in the prior year and increased 20% compared to the fourth quarter of 2021. The month of March 2022 was the single largest month of ANJESO units sold launch-to-date for the product.
- **Adjusting ANJESO field coverage.** Given current market conditions, despite the promising trajectory for ANJESO sales, during the first quarter of 2022 Baudax Bio

implemented a reduction in force that significantly cut its commercial spend for field personnel and other related expenses. This restructuring is expected to reduce the Company's burn rate by approximately 65% going forward. Baudax Bio continues to focus on key accounts, contracts, and working with existing ordering accounts as well as continuing to pursue targeted new ones. Baudax Bio is evaluating possible partnering options for the ANJESO portfolio.

- **Impacts from Omicron Variant of COVID-19.** The Omicron variant of COVID-19 continued to impact the number of elective surgeries performed, along with access for field activities, especially during January and February, and in certain geographies. However, elective surgeries began gradually normalizing in March. Cancellations of elective surgeries were primarily due to demand for COVID-19 patient bed space as well as reduced availability of staff for ambulatory surgical centers and hospitals, especially in the Southern U.S. (e.g., Texas, Florida and Alabama), which currently accounts for over one third of Baudax Bio's ANJESO business.
- **Initiated Phase IV Clinical Trial in Pediatric Patients.** The multicenter, open-label clinical trial will study the safety and pharmacokinetics of ANJESO in multiple age groups of children who undergo elective surgery in either an inpatient or outpatient setting. The study has enrolled one of the cohort groups of surgical patients during the first quarter of 2022 and is expected to enroll approximately 90 patients across three age groups (12 to <17, 7 to <12 and 2 to <7 years old) over time.
- **Seventh Orange Book Listable Patent Issued.** Baudax Bio recently announced the issuance of a new U.S. Patent, which covers ANJESO and other injectable, nanoparticulate meloxicam compositions and methods of administering such compositions by intravenous, intramuscular or subcutaneous injection. The ANJESO '478 patent has an expiry date of May 2030 and joins a total of six other patents listed in the Orange Book, amongst others owned or licensed by Baudax Bio that currently provide exclusivity to the ANJESO franchise.

NMBs

- **BX1000 (IV Intermediate-action).** Baudax Bio completed a dose-escalation study evaluating BX1000 in 58 healthy volunteers in 2021. The results of the study showed that 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 expecting to begin enrollment for a Phase II BX1000 study in surgical patients that is expected to commence in the summer of 2022, which it believes enrollment will be completed in 2022.
- **BX2000 (IV Ultra-short action).** Baudax Bio has completed and submitted additional nonclinical testing of BX2000 as requested by the FDA. Baudax Bio has clearance to proceed with the planned dose escalation study in healthy volunteers and believes it is on track to progress through the majority of dosing cohorts in 2022.
- **BX3000 (Reversal agent).** Additional work to enhance formulation of the BX3000 reversal agent is underway and Baudax Bio believes that this data, along with certain

non-clinical data, which will be submitted to FDA later this year, will allow for initiation of the clinical program in healthy volunteers in late 2022 or early 2023.

Corporate and Financial

- **Secured \$10 Million in Financing.** Baudax Bio successfully completed an underwritten public offering and issued 3,508,772 shares of common stock, together with warrants to purchase up to an aggregate of 3,508,772 shares of common stock. Each share of common stock was sold together with one warrant to purchase one share of common stock at a combined public offering price of \$2.85 per share. Gross proceeds from the offering were approximately \$10 million, before deducting underwriting discounts, commissions and other offering expenses.
- **Wayne B. Weisman Appointed Chairman of the Board.** Mr. Weisman has been a director of Baudax Bio since 2019, and brings extensive experience in venture capital investing. He currently serves as founder and managing partner of SCP Vitalife Partners where he has been a member of the investment committee and has led SCP's efforts in the life sciences.

First Quarter 2022 Financial Results

As of March 31, 2022, Baudax Bio had cash and cash equivalents of \$11.5 million.

Net product revenue related to sales of ANJESO in the U.S., recognized according to U.S. GAAP, for the three months ended March 31, 2022 was \$0.4 million. This compares to \$0.2 million for the three months ended March 31, 2021, an increase of \$0.2 million. 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 was attributable to securing additional formulary approvals, which allowed for more usage of ANJESO that can lead to early adoption of the product. Throughout the commercial launch, 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 March 31, 2022 was \$0.6 million, compared to \$0.8 million for the three months ended March 31, 2021, a decrease of \$0.2 million, and consisted of product costs, royalty expense and certain fixed costs associated with the manufacturing of ANJESO, including supply chain and quality costs. The decrease of \$0.2 million was primarily a result of the reduction of inventory scrap expense recorded in the current year compared to the prior year. Certain product costs of ANJESO units recognized as revenue during the three months ended March 31, 2022 and 2021 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 March 31, 2022 were \$1.3 million compared to \$1.1 million for the three months ended March 31, 2021. Research and development expenses increased \$0.2 million, which was primarily due to an increase in clinical trials costs associated with our ANJESO pediatric program of \$0.2 million.

Selling, general and administrative expenses for the three months ended March 31, 2022 were \$14.2 million, of which \$7.3 million was attributable to selling expense and \$6.9 million was attributable to general and administrative expense. This compares to \$12.1 million for the same prior year period, of which \$5.1 million was attributable to selling expense and \$7.0 million was attributable to general and administrative expense. General and administrative expenses remained flat over the comparable periods while selling expenses increased \$2.2 million, which was primarily a result of accrued severance costs associated with the reduction in force in the first quarter of 2022 of \$1.7 million.

Baudax Bio reported net loss of \$12.8 million, including a non-cash benefit of \$2.4 million, or \$(3.17) per share, for the three months ended March 31, 2022. Adjusted net loss* was \$(15.2) million.

*** 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 tomorrow, Thursday, May 5, 2022, at 8:30 a.m. Eastern Time, to discuss the first quarter 2022 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 1078117. 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 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.

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. 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 (Unaudited)

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

Assets	March 31, 2022	December 31, 2021
Current assets:		
Cash and cash equivalents	\$ 11,527	\$ 15,891
Accounts receivable, net	608	542
Inventory	5,212	5,002
Prepaid expenses and other current assets	2,369	2,059
Total current assets	\$ 19,716	\$ 23,494
Property, plant and equipment, net	4,992	5,015
Intangible assets, net	21,034	21,678
Goodwill	2,127	2,127
Other long-term assets	944	963
Total assets	\$ 48,813	\$ 53,277
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	3,284	1,468
Accrued expenses and other current liabilities	6,837	5,540
Current portion of long-term debt, net	3,056	2,222
Current portion of contingent consideration	7,220	6,416
Total current liabilities	20,397	15,646
Long-term debt, net	5,705	6,309

Long-term portion of contingent consideration	12,339	17,446
Other long-term liabilities	629	650
Total liabilities	<u>39,070</u>	<u>40,051</u>
Shareholders' equity:		
Preferred stock, \$0.01 par value. Authorized, 10,000,000 shares; issued and outstanding, 0 shares at March 31, 2022 and 8,289 shares at December 31, 2021	—	—
Common stock, \$0.01 par value. Authorized, 190,000,000 shares; issued and outstanding, 6,412,979 shares at March 31, 2022 and 2,807,239 shares at December 31, 2021	64	28
Additional paid in-capital	154,577	145,287
Accumulated deficit	<u>(144,898)</u>	<u>(132,089)</u>
Total shareholders' equity	<u>9,743</u>	<u>13,226</u>
Total liabilities and shareholders' equity	\$ <u>48,813</u>	\$ <u>53,277</u>

BAUDAX BIO, INC. AND SUBSIDIARIES

Consolidated Statements of Operations and Comprehensive Loss (Unaudited)

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

	Three Months Ended	
	March 31,	
	2022	2021
Revenue, net	\$ 422	\$ 198
Operating expenses:		
Cost of sales (excluding amortization of intangible assets)	648	821
Research and development	1,293	1,108
Selling, general and administrative	14,190	12,088
Amortization of intangible assets	644	644
Change in warrant valuation	(5)	18
Change in contingent consideration valuation	(3,803)	1,841
Total operating expenses	<u>12,967</u>	<u>16,520</u>
Operating loss	(12,545)	(16,322)
Other expense:		
Other expense, net	(264)	(590)
Net loss	\$ (12,809)	\$ (16,912)

Per share information:

Net loss per share of common stock, basic and diluted \$ (3.17) \$ (9.46)

Weighted average common shares outstanding, basic and diluted 4,038,434 1,788,118

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)

	For the Three Months Ended March 31,	
	2022	2021
Net loss (GAAP)	\$ (12,809)	\$ (16,912)
Stock-based compensation	521	2,304
Non-cash interest expense	226	229
Depreciation expense	43	86
Amortization expense	644	644
Change in warrant valuation	(5)	18
Change in contingent consideration valuation	(3,803)	1,841
Adjusted net loss (non-GAAP)	(15,183)	(11,790)

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Source: Baudax Bio, Inc.