

August 5, 2021

BAUDAX BIO[®]

Baudax Bio Reports Second Quarter 2021 Financial Results and Highlights

Total Number of ANJESO[®] Vials Sold to End-Users in the Second Quarter 2021 Match Total Vials Sold for the Full Year 2020

ANJESO[®] Demand Showing Strong Growth Based on Several Key Quarter-Over-Quarter Metrics (Second Quarter of 2021 Compared to First Quarter of 2021);

- *Total Number of Vials Sold to All Customers Up 30%*
- *Vials Sold to Hospitals and ASCs Combined Up 46%*
 - *Vials Sold to Existing Hospitals Up 55%*
- *Vials Sold to New Ambulatory Surgery Centers Up 150%*

Formulary Wins: 82% Success Rate at P&T Committee Meetings

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

MALVERN, Pa., Aug. 05, 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 six months ended June 30, 2021. In addition, Baudax Bio highlighted select corporate achievements, including the ongoing commercial rollout of ANJESO[®] (meloxicam) injection.

Gerri Henwood, President and CEO of Baudax Bio, stated, "We are extremely pleased to see strong growth in end user demand for ANJESO during the second quarter of 2021 based on a number of key metrics for hospital-based drugs, including significant increases in total number of vials sold, end-user sales, sales to existing hospital accounts and sales to new ambulatory surgery centers (ASCs). Most notable was the total number of vials sold for just the second quarter of 2021, which was comparable to the number sold for the full year of 2020. Our teams have worked with our partners in hospital and ASC settings and have been added to over 100 formularies in our challenging first year on the market. We are highly confident in ANJESO's long-term commercial potential and in our ability to further increase utilization of this innovative, non-opioid alternative for the management of moderate to severe pain, and we look forward to continuing to drive adoption in the months and quarters ahead."

Second 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 just the second quarter of 2021, the total number of vials sold to end-users was comparable to the number sold for the entire year of 2020. In addition, demand for

ANJESO demonstrated strong growth and deepening usage patterns based on several key quarter-over-quarter metrics. Specifically, for the second quarter of 2021 as compared to the first quarter of 2021:

- *Total number of vials sold to all customers was up 30%*
 - *End-user vials sold to hospitals and ambulatory surgery centers (ASCs) combined was up 46%*
 - *Vials sold to existing hospitals was up 55%*
 - *Vials sold to NEW ASCs was up 150%*
- **ANJESO added to over 100 formularies in less than one year on the market.**In June 2021, Baudax Bio announced that ANJESO has achieved approvals at over 100 formularies across the U.S. in under one year of commercialization. Baudax Bio continues to receive positive feedback from physicians and see increases in new accounts, units sold, reorder rates, and usage patterns across the surgical setting and has had a success rate of over 80% at Pharmacy and Therapeutics (P&T) committee meetings. ANJESO's presence on formularies is expected to drive usage through regular availability at both hospitals and ambulatory surgery centers covered by these formularies.
 - **Phase IIIb ANJESO data published in Pain Management.**In May 2021, Baudax Bio highlighted the online publication of Phase IIIb study results evaluating preoperative injection of ANJESO prior to colorectal surgery in the journal Pain Management. The findings from the study express that preoperative administration of ANJESO was well tolerated, with over 92% of patients reporting satisfaction with their post-operative pain medication. In addition, opioid use was significantly lower (35%) in the ANJESO treated group ($p=0.03$). Notably, the ANJESO treated group also reported a decreased hospital length of stay by over 1 day (28 hours) compared to placebo.

Corporate and Financial

- **Adjourned Special Meeting of Shareholders.**On July 13, 2021, the Company held a Special Meeting of Shareholders (the "Special Meeting"), which was adjourned solely with respect to voting on Proposal 1, the approval of an amendment to the Company's Amended and Restated Articles of Incorporation to increase the number of authorized shares of common stock from 100 million shares to 190 million shares. The resolution was set forth in the Company's Definitive Proxy Statement filed with the Securities and Exchange Commission on June 14, 2021. Baudax Bio will resume its Special Meeting on August 11, 2021.
- **Completed \$11.9 million registered direct offering.**During the second quarter 2021, Baudax Bio announced that the company entered into an agreement with select institutional investors for the purchase and sale of a total of 14,028,520 shares of common stock and warrants to purchase up to a total of 14,028,520 shares of common stock at a purchase price of \$0.85 per share and accompanying warrants in a registered direct offering. The warrants have an exercise price of \$0.90 per share and will become exercisable following the later of (i) the six-month anniversary of the

closing date of the offering, and (ii) the approval by Baudax Bio shareholders to increase the number of authorized shares of common stock. The gross proceeds to Baudax Bio from the offering were approximately \$11.9 million. In addition, in the event the warrants are exercised in full, Baudax Bio expects to receive approximately \$12.6 million in additional gross proceeds.

Second Quarter 2021 Financial Results

As of June 30, 2021, Baudax Bio had cash, cash equivalents and short-term investments of \$37.6 million.

Net product revenue, recognized according to U.S. GAAP, for the three months ended June 30, 2021 was \$0.2 million, related to sales of ANJESO in the U.S compared to \$0.3 million for the three months ended June 30, 2020. While utilizing the title model of distribution, product revenue represents shipments to the Company's 3PL provider.

Cost of sales for the three months ended June 30, 2021 was \$0.6 million compared to \$0.7 million for the three months ended June 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 three months ended June 30, 2021 and 2020 were incurred 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, its cost of sales will increase as sales increase and as inventory values change to include all direct and indirect costs, manufacturing expenses and other expenses post FDA approval.

Research and development expenses for the three months ended June 30, 2021 were \$0.9 million compared to \$1.4 million for the three months ended June 30, 2020, a decrease of \$0.5 million. This decrease was primarily a result of a decrease in personnel costs of \$0.4 million and a decrease in pre-commercialization manufacturing costs for ANJESO of \$0.1 million.

Selling, general and administrative expenses for the three months ended June 30, 2021 were \$10.6 million, compared to \$11.2 million for the same prior year period, a decrease of \$0.6 million. This decrease was primarily a result of a decrease in personnel costs of \$1.1 million, which was partially offset by an increase of \$0.5 million as the three months ended June 30, 2020 included 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 \$15.3 million, or \$(0.21) per diluted share, for the three months ended June 30, 2021. Adjusted net loss* for the three months ended June 30, 2021 was \$11.2 million, which excludes a net non-cash charge of \$4.1 million associated primarily with the change in the fair value of contingent consideration as well as stock-based compensation, non-cash interest expense, depreciation and amortization partially offset by non-cash benefits from the gain on extinguishment of debt and the change in the fair value of warrants. This compares to a net loss of \$30.4 million, or \$(1.72) per share, for the comparable period in 2020. Adjusted net loss* for the comparable period in 2020 was \$10.6 million, which excludes non-cash charges of \$19.8 million primarily associated with changes in the fair value of contingent consideration and warrant valuation as well as stock-based compensation, non-cash interest expense, depreciation and amortization.

Six Months Ended June 30, 2021 Financial Results

Net product revenue, recognized according to U.S. GAAP, for the six months ended June 30, 2021 was \$0.4 million, related to sales of ANJESO in the U.S compared to \$0.3 million for the six months ended June 30, 2020. While utilizing the title model of distribution, product revenue represents shipments to the Company's 3PL provider.

Cost of sales for the six months ended June 30, 2021 was \$1.4 million compared to \$0.7 million for the six months ended June 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 six months ended June 30, 2021 and 2020 were incurred 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, its cost of sales will increase as sales increase and as inventory values change to include all direct and indirect costs, manufacturing expenses and other expenses post FDA approval.

Research and development expenses for the six months ended June 30, 2021 were \$2.0 million, compared to \$4.4 million for the six months ended June 30, 2020, a decrease of \$2.4 million. Baudax Bio's research and development expenses decreased primarily from a decrease in personnel costs of \$2.1 million and pre-commercialization manufacturing costs for ANJESO of \$0.7 million. This was partially offset by an increase in clinical costs of \$0.4 million.

Selling, general and administrative expenses for the six months ended June 30, 2021 were \$22.7 million, compared to \$19.3 million for the same prior year period, an increase of \$3.4 million. The increase was primarily due to the commercial launch of ANJESO, specifically an increase of \$1.2 million attributable to the reclassification of medical affairs and regulatory support from research and development expense post FDA approval, an increase of \$0.9 million in public company costs and an increase of \$0.6 million in personnel costs. In addition, the first half of 2020 included \$1.0 million in reimbursed general and administrative expenses related to the Transition Services Agreement with Recro Pharma, which ended on December 31, 2020. These increases were slightly offset by a decrease in other general expenses of \$0.3 million.

Baudax reported a net loss \$32.2 million, or \$(0.47) per share, for the six months ended June 30, 2021. Adjusted net loss* was \$23.0 million, which excludes a net non-cash charge of \$9.2 million primarily associated with the change in the fair value of contingent consideration as well as stock-based compensation, non-cash interest expense, depreciation, and amortization partially offset by the non-cash benefit from the gain on extinguishment of debt and the change in the fair value of warrants. This compares to a net loss of \$70.7 million, or \$(5.11) per share, for the comparable period in 2020. Adjusted net loss* for the comparable period in 2020 was \$18.9 million, which excludes a non-cash charge of \$51.8 million primarily associated with changes in fair value of contingent consideration and warrant valuation as well as stock-based compensation, non-cash interest expense, depreciation and amortization.

*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, August 5, 2021, at 8:00 a.m. Eastern Time, to discuss the second 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 5791175. 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 which is currently in preclinical studies. 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 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. 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)

(amounts in thousands, except share and per share data)	June 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 25,412	\$ 30,342
Short-term investments	12,147	—
Accounts receivable, net	219	51
Inventory, net	3,558	2,978
Prepaid expenses and other current assets	1,945	3,346
Total current assets	43,281	36,717
Property, plant and equipment, net	4,979	5,052
Intangible assets, net	22,966	24,254
Goodwill	2,127	2,127
Other long-term assets	455	583
Total assets	\$ 73,808	\$ 68,733
Liabilities and Shareholders' Deficit		
Current liabilities:		
Accounts payable	\$ 2,085	\$ 3,653
Accrued expenses and other current liabilities	5,084	5,326
Current portion of long-term debt, net	555	683
Current portion of contingent consideration	6,098	8,467
Total current liabilities	13,822	18,129
Long-term debt, net	7,518	8,469
Long-term portion of contingent consideration	56,798	56,576
Other long-term liabilities	243	358
Total liabilities	78,381	83,532
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,
100,000,000 shares; issued and
outstanding, 84,273,222 shares at June 30, 2021
and 48,688,480 shares at
December 31, 2020

	843	487
Additional paid-in capital	139,145	97,034
Accumulated deficit	<u>(144,561)</u>	<u>(112,320)</u>
Total shareholders' deficit	<u>(4,573)</u>	<u>(14,799)</u>
Total liabilities and shareholders' deficit	\$ 73,808	\$ 68,733

BAUDAX BIO, INC.

Consolidated and Combined Statements of Operations (Unaudited)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2021	2020	2021	2020
(amounts in thousands, except share and per share data)				
Revenue, net	\$ 201	\$ 349	\$ 399	\$ 349
Operating expenses:				
Cost of sales	586	650	1,407	650
Research and development	857	1,350	1,965	4,420
Selling, general and administrative	10,608	11,217	22,696	19,263
Amortization of intangible assets	644	644	1,288	859
Change in warrant valuation	(59)	12,667	(41)	14,045
Change in contingent consideration valuation	3,881	4,053	5,722	31,679
Total operating expenses	<u>16,517</u>	<u>30,581</u>	<u>33,037</u>	<u>70,916</u>
Operating loss	(16,316)	(30,232)	(32,638)	(70,567)
Other income (expense):				
Other income (expense)	987	(213)	397	(176)
Net loss	<u>\$ (15,329)</u>	<u>\$ (30,445)</u>	<u>\$ (32,241)</u>	<u>\$ (70,743)</u>
Per share information:				
Net loss per share of common stock, basic	<u>\$ (0.20)</u>	<u>\$ (1.72)</u>	<u>\$ (0.47)</u>	<u>\$ (5.11)</u>
Net loss per share of common stock, diluted	<u>\$ (0.21)</u>	<u>\$ (1.72)</u>	<u>\$ (0.47)</u>	<u>\$ (5.11)</u>

Weighted average common shares outstanding, basic	<u>74,778,530</u>	<u>17,691,700</u>	<u>68,715,016</u>	<u>13,846,464</u>
Weighted average common shares outstanding, diluted	74,810,621	17,691,700	68,715,016	13,846,464

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 June 30,		For the Six Months Ended June 30,	
	2021	2020	2021	2020
Net loss (GAAP)	\$ (15,329)	\$ (30,445)	\$ (32,241)	\$ (70,743)
Stock-based compensation	903	2,309	3,207	4,942
Non-cash interest expense	229	76	458	76
Gain on extinguishment of debt	(1,553)	—	(1,553)	—
Depreciation expense	63	106	149	211
Amortization expense	644	644	1,288	859
Change in warrant valuation	(59)	12,667	(41)	14,045
Change in contingent consideration valuation	3,881	4,053	5,722	31,679
Adjusted net loss (non-GAAP)	<u>\$ (11,221)</u>	<u>\$ (10,590)</u>	<u>\$ (23,011)</u>	<u>\$ (18,931)</u>

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Source: Baudax Bio, Inc.