February 13, 2020

BAUDAX BIO®

Baudax Bio Reports 2019 Annual Financial Results

FDA Grants Appeal for IV Meloxicam New Drug Application

PDUFA Goal Date of February 20, 2020

MALVERN, Pa., Feb. 13, 2020 (GLOBE NEWSWIRE) -- Baudax Bio, Inc. (NASDAQ:BXRX), a pharmaceutical company focused on therapeutics for acute care settings, today reported its financial results for the year ended December 31, 2019.

"We have been working with the U.S. Food and Drug Administration (FDA) during their review of the intravenous (IV) meloxicam New Drug Application (NDA), and we are currently awaiting the upcoming PDUFA goal date of February 20, 2020," said Gerri Henwood, President and Chief Executive Officer of Baudax Bio. "In parallel, we are making the necessary commercial preparations for our planned product launch."

Recent Highlights

- **Baudax Bio™ Launched as a New Pharmaceutical Company Advancing Promising, Acute Care Therapies.** In November 2019, Baudax launched as an independent, publicly traded pharmaceutical company focused on advancing a non-opioid analgesic and other products for the hospital and other acute care settings. Baudax launched with $19 million in funding from Recro Pharma, Inc., its former parent company, and holds the rights to a pipeline of pharmaceutical assets, including IV meloxicam, two neuromuscular blocking agents and a reversal agent, and dexmedetomidine dosage forms.

- **FDA Assigns PDUFA Date for IV Meloxicam.** In January 2020, Baudax announced that the FDA has set a PDUFA goal date of February 20, 2020 for its decision on the refiled NDA for IV meloxicam.

- **FDA Granted Appeal for IV Meloxicam New Drug Application.** In October 2019, Recro announced that it had received a written decision from the FDA granting its appeal seeking approval for IV meloxicam, and proposing resubmission of the NDA with prescribing information to be worked out with the reviewing Division. The Company resubmitted the NDA to the FDA in late December 2019 that included proposed labeling and other information as requested by the FDA.

Financial Results for the Year Ended December 31, 2019

As of December 31, 2019, Baudax had cash and cash equivalents of $17.7 million.

For the year ended December 31, 2019, research and development expenses were $20.1 million compared to $35.6 million for the year ended December 31, 2018. Excluding $2.8 million of costs associated with the strategic restructuring initiative associated with the March

2019 CRL and recorded in the year ended December 31, 2019, the decrease of $18.3 million was primarily due to a decrease in pre-commercialization manufacturing and clinical costs for IV meloxicam, a decrease in development costs for other pipeline products, and a decrease in personnel costs.

For the year ended December 31, 2019, general and administrative expenses were $27.0 million compared to $29.5 million for the year ended December 31, 2018. Excluding $4.4 million of costs associated with the strategic restructuring initiative associated with the March 2019 CRL and recorded in the year ended December 31, 2019, the decrease of $6.9 million was due to decreases in commercial team personnel and pre-commercial consulting costs incurred for the anticipated launch of IV meloxicam following the receipt of the second CRL in March of 2019. These decreases in costs were partially offset by increases in costs associated with the cost of the separation from Recro Pharma.

For the year ended December 31, 2019, Baudax reported a net loss of $32.6 million, or $3.48 per share, compared to a net loss of $73.7 million, or $7.88 per share, for the comparable period in 2018.

About Baudax Bio, Inc.

Baudax Bio is a pharmaceutical company focused on therapeutics for acute care settings. The Company's lead product candidate is a proprietary intravenous (IV) form of meloxicam, a non-opioid, once a day injectible product which is a preferential COX-2 inhibitor. IV meloxicam has successfully completed two pivotal Phase III clinical efficacy trials, a large double-blind placebo-controlled Phase III safety trial, four Phase II clinical efficacy trials, as well as other safety studies. As a non-opioid, IV meloxicam 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. For more information please visit www.baudaxbio.com.

Cautionary Statement Regarding Forward Looking Statements

This press release contains forward-looking statements that involve risks and uncertainties. Such forward-looking statements reflect Baudax Bio's expectations about its future performance and opportunities that involve substantial risks and uncertainties. When used herein, the words "anticipate," "believe," "estimate," "may," "upcoming," "plan," "target," "goal", "intend" and "expect" and similar expressions, as they relate to Baudax Bio or its management, are intended to identify such forward-looking statements. These forward-looking statements are based on information available to Baudax Bio as of the date of this press release 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. Baudax Bio assumes no obligation to update any such forward-looking statements. Factors that could cause Baudax Bio's actual performance to materially differ from those expressed in the forward-looking statements set forth in this press release include, without limitation: the Company's ability to execute its strategy for further development and commercialization of IV meloxicam, the Company's ability to execute its strategic initiatives, the Company's ability to adequately resolve the outstanding labeling issues with the FDA for IV meloxicam, and ,the time frame associated with any such resolution as well as the timeframe of any FDA action related to the IV

meloxicam NDA; the Company's ability to raise future financing for continued product development and IV meloxicam commercialization; with regard to the Company's clinical trial results, whether there may be changes in the interpretation by the FDA of the data of the Company's clinical trials and the length, cost and uncertain results and timing of our ongoing clinical trials; with regard to the potential commercial opportunity of IV meloxicam, whether any FDA approval of IV meloxicam will include labeling restrictions and the potential that IV meloxicam does not receive regulatory approval or does not receive reimbursement by third party payors, that IV meloxicam is not accepted by the medical community, including physicians, patients, health care providers and hospital formularies or that a commercial market for IV meloxicam does not develop; the Company's ability to manage costs and execute on its operational and budget plans; the Company's ability to achieve its financial goals; the Company's ability to obtain, maintain and successfully enforce adequate patent and other intellectual property protection; the Company's lack of operating history as a standalone business; risks relating to the separation from Recro, including, among others, failure to achieve the anticipated benefits from the separation, reliance on Recro and other third parties to provide certain services post-separation, and the Company's ability to satisfy liabilities and potential indemnification obligations in connection with the separation. The forward-looking statements in this press release 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.

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BAUDAX BIO, INC. AND SUBSIDIARIES
Consolidated and Combined Balance Sheets

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

Assets	**December 31, 2019**	**December 31, 2018**
Current assets:		
Cash and cash equivalents	$ 17,740	$ —
Prepaid expenses and other current assets	2,395	2,514
Total current assets	20,135	2,514
Property, plant and equipment, net	4,821	3,982
Right of use asset	730	—
Intangible assets	26,400	26,400
Goodwill	2,127	2,127
Total assets	$ 54,213	$ 35,023
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 271	$ 2,653
Accrued expenses and other current liabilities	3,532	9,773
Current operating lease liability	318	—
Current portion of contingent consideration	3,592	10,354
Total current liabilities	7,713	22,780
Long-term operating lease liability	455	—
Other long-term liabilities	—	32
Long-term portion of contingent consideration	62,766	80,558
Total liabilities	70,934	103,370
Shareholders' equity:		
Preferred stock, $0.01 par value. Authorized, 10,000,000 shares; none issued and outstanding as of December 31, 2019	—	—
Parent company net investment	—	(68,347)
Common stock, $0.01 par value. Authorized, 100,000,000 shares; issued and outstanding, 9,350,709 shares at December 31, 2019	94	—
Additional paid in-capital	19,405	—
Accumulated deficit	(36,220)	—
Total shareholders' equity	(16,721)	(68,347)
Total liabilities and shareholders' equity	$ 54,213	$ 35,023

BAUDAX BIO, INC. AND SUBSIDIARIES

Consolidated and Combined Statements of Operations

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

	Twelve Months Ended December 31,	
	2019	2018
Operating expenses:		
Research and development	$ 20,061	$ 35,583
General and administrative	27,012	29,453
Change in contingent consideration valuation	(14,554)	8,499
Total operating expenses	32,519	73,535
Operating loss	(32,519)	(73,535)
Other income (expense):		
Other income (expense)	(38)	(132)
Net loss	$ (32,557)	$ (73,667)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (3.48)	$ (7.88)
Weighted average common shares outstanding, basic and diluted	9,350,709	9,350,709

Source: Baudax Bio, Inc.