August 10, 2020

Baudax Bio Reports Second Quarter 2020 Financial Results

Commenced Commercial Launch of ANJESO® in the U.S.

Awarded J-Code from CMS

Executed Contract with a top National GPO for hospital purchases, Vizient, and one of the top 3 IDNs Nationally

Secured $50 Million Credit Facility

MALVERN, Pa., Aug. 10, 2020 (GLOBE NEWSWIRE) -- Baudax Bio, Inc. (NASDAQ:BXRX), a pharmaceutical company focused on therapeutics for acute care settings, today reported financial results for the three and six months ended June 30, 2020.

“The second quarter of 2020 was most important because of the full commercial launch of ANJESO,” said Gerri Henwood, President and Chief Executive Officer of Baudax Bio. “We believe that with our experienced acute care sales force, receipt of our J-code from the Centers for Medicare and Medicaid Services (CMS) (effective in October 2020), entry into an agreement with the Group Purchasing Organization (GPO) Vizient Inc., and other strategic initiatives underway, we are well positioned to continue to target the acute care space. We look forward to continuing to raise awareness and educate acute care providers about ANJESO as an advantageous option for the management of moderate to severe pain.”

Second Quarter 2020 and Recent Business Highlights

- **Commenced Full Commercial Launch of ANJESO.** In June 2020, the Company commenced the commercial launch of ANJESO, following its approval by the U.S. Food and Drug Administration (FDA) in February 2020. ANJESO is the only approved 24-hour, intravenous COX-2 preferential NSAID that offers once-daily dosing. Baudax has hired, trained, and now deployed 50 acute care sales representatives to match key territories identified in the U.S.

- **Receipt of J-Code from CMS.** In early August 2020, CMS established a new permanent J-code for ANJESO, facilitating reimbursement in the hospital outpatient, ambulatory surgery center and physician office settings of care. The code, J1738 (Injection, meloxicam, 1 mg), will take effect on October 1, 2020 and it is expected to replace the previously issued C-code (C9059).

- **Company Secures Pharmacy Supplier Agreement with Vizient Inc.** In July 2020, Baudax entered into an agreement with the GPO Vizient Inc., the largest member-driven healthcare performance improvement company in the U.S., to offer ANJESO with enhanced savings to Vizient’s diverse membership, which includes more than 50% of the nation’s acute care providers, 95% of the nation’s academic medical

centers, and more than 20% of ambulatory care providers. Vizient represents more than $100 billion in annual purchasing volume.

- **Company signed agreement with top IDN.** In July 2020, the Company signed an agreement with one of the top 3 Integrated Delivery Networks (IDNs) for terms for availability of ANJESO to their member institutions and the company has begun the regional formulary processes associated with this central review and approval.

- **Presented New Phase IIIb ANJESO Data at American Society of Colon and Rectal Surgeons (ASCRS) Meeting.** In July 2020, Baudax presented a virtual poster highlighting new Phase IIIb ANJESO (meloxicam) injection clinical data as part of the ASCRS 2020 Annual Scientific Meeting. The published data supports the use of ANJESO administered preoperatively to patients prior to undergoing colorectal surgery. The key findings from this study include statistically significant reductions in opioid use, as well as time to bowel function recovery and hospital discharge, resulting in cost savings for ANJESO-treated patients.

- **Secured $50 Million Credit Facility.** In June 2020, the company announced the close of a credit facility of up to $50 million from funds managed by Marathon Asset Management, a global credit solutions partner. Proceeds from the facility will generally be used to support the commercial launch of ANJESO (meloxicam) injection, and for working capital purposes. JMP Securities LLC acted as exclusive financial advisor and sole placement agent to Baudax on this transaction.

COVID-19 Impact

The Company's efforts to commercialize ANJESO have been, and may continue to be, impacted by the COVID-19 pandemic. Hospitals have reduced and diverted staffing, diverted resources to patients suffering from COVID-19 and limited hospital access for nonpatients, including our sales professionals, which the Company believes may impact their marketing and commercialization efforts. The Company believes that the reduction in elective surgeries during the COVID-19 pandemic has and may continue to result in decreased demand for ANJESO. The Company anticipates that many hospitals and health care providers will continue to suffer negative financial consequences due to an increase in unexpected costs, including for additional staff, personal protective equipment and ventilators, along with a reduction in revenue due to fewer elective procedures being performed, which may result in a decreased demand for ANJESO. While access restrictions have eased in some locations, spikes of COVID-19 cases in certain states or regions may further impact the Company's sales force as access to hospitals may be restricted and elective surgeries may be limited in those areas. Due to the rapidly evolving environment, continued uncertainties from the impact of the COVID-19 global pandemic, and recent regional outbreaks that are impacting the recovery, the Company cannot estimate the full extent to which the Company's commercialization of ANJESO and financial results may be adversely impacted.

Second Quarter 2020 Financial Results

As of June 30, 2020, Baudax had cash and cash equivalents of $39.4 million.

For the three months ended June 30, 2020, net product revenue was $350,000, related to sales of ANJESO in the U.S. There was no product revenue recognized during the three

months ended June 30, 2019.

For the three months ended June 30, 2020, cost of sales was $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 three months ended June 30, 2020 were incurred prior to the FDA approval of ANJESO in February 2020, and therefore are not included in cost of sales during the period. We expect cost of sales to increase as we build new inventory not expensed during the pre-approval period, validate a larger manufacturing suite and deplete our initial inventory levels. No cost of sales were recorded for the three months ended June 30, 2019.

For the three months ended June 30, 2020, research and development expenses were $1.4 million, compared to $7.2 million for the three months ended June 30, 2019, a decrease of $5.8 million. Excluding $2.6 million of costs associated with the strategic restructuring initiative recorded in the three months ended June 30, 2019, our research and development expenses decreased $3.2 million primarily resulting from a decrease in pre-commercialization manufacturing and clinical costs for ANJESO of $2.3 million and a decrease in personnel costs and overhead expenses of $0.9 million as we allocated or recategorized certain expenses related to supply chain, regulatory, quality and medical affairs associated with support of the commercial launch of ANJESO.

For the three months ended June 30, 2020, selling, general and administrative expenses were $11.2 million, compared to $7.4 million for the same prior year period, an increase of $3.8 million. Excluding $3.4 million of costs associated with the strategic restructuring initiative recorded in the three months ended June 30, 2019, our selling, general and administrative expenses increased $7.2 million primarily due to selling and marketing expenses in connection with the commercial launch of ANJESO. Selling and marketing expenses of $5.6 million for the three months ended June 30, 2020 increased $5.0 million due to increased personnel costs of $3.1 million and increased commercial costs of $1.9 million. General and administrative expenses of $5.6 million for the three months ended June 30, 2020 increased $2.2 million primarily due to increased personnel costs, including over half of which was attributed to medical affairs and regulatory support functions which had previously been recorded within research and development expense in the prior year period.

For the three months ended June 30, 2020, Baudax reported a net loss (including non-cash charges of $19.8 million) of $30.4 million, or $1.72 per share. The non-cash charges of $19.8 million were associated with stock-based compensation, non-cash interest expense, depreciation, amortization, changes in warrant valuations, and changes in fair value of contingent consideration. This compares to a net loss of $10.6 million, or $1.13 per share, for the comparable period in 2019. For the three months ended June 30, 2020, there was $10.6 million in cash based expenses and an additional $0.7 million use of cash associated with working capital adjustments primarily related to the build of inventory for ANJESO.

Six months ended June 30, 2020 Financial Results

For the six months ended June 30, 2020, net product revenue was $350,000, related to sales of ANJESO in the U.S. There was no product revenue recognized during the six months ended June 30, 2019.

For the six months ended June 30, 2020, cost of sales was $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 six months ended June 30, 2020 were incurred prior to the FDA approval of ANJESO in February 2020, and therefore are not included in cost of sales during the period. We expect cost of sales to increase as we build new inventory not expensed during the pre-approval period, validate a larger manufacturing suite and deplete our initial inventory levels. No cost of sales were recorded for the six months ended June 30, 2019.

For the six months ended June 30, 2020, research and development expenses were $4.4 million, compared to $16.7 million for the six months ended June 30, 2019, a decrease of $12.3 million. Excluding $2.8 million of costs associated with the strategic restructuring initiative recorded in the six months ended June 30, 2019, our research and development expenses decreased $9.5 million primarily resulting from a decrease in pre-commercialization manufacturing and clinical costs for ANJESO of $6.2 million, a decrease in development costs for other pipeline products of $2.1 million and a decrease in personnel and overhead expenses of $1.2 million as we re-allocated costs related to supply chain, regulatory, quality and medical affairs associated with support of the commercial launch of ANJESO.

For the six months ended June 30, 2020, selling, general and administrative expenses were $19.3 million, compared to $17.3 million for the same prior year period, an increase of $2.0 million. Excluding $4.4 million of costs associated with the strategic restructuring initiative recorded in the six months ended June 30, 2019, our selling, general and administrative expenses increased $6.4 million primarily due to increased selling and marketing expenses in connection with the commercial launch of ANJESO. Selling and marketing expenses of $8.9 million for the six months ended June 30, 2020 increased $3.5 million primarily due to increased personnel costs of $1.9 million and increased commercial costs of $1.6 million. General and administrative expenses of $10.4 million for the six months ended June 30, 2020 increased $2.9 million primarily due to increased personnel costs of $2.4 million, including over half of which was attributed to medical affairs and regulatory support functions which had previously been recorded within research and development expense in the prior year period and increased public company costs of approximately $0.5 million as the prior year costs represent an allocated portion of the costs in the historical combined financial statements prior to our separation from Recro Pharma, Inc.

For the six months ended June 30, 2020, Baudax reported a net loss (including non-cash charges of $51.8 million) of $70.7 million, or $5.11 per share. The non-cash charges of $51.8 million were associated with stock-based compensation, non-cash interest expense, depreciation, amortization, changes in warrant valuations, and changes in fair value of contingent consideration. This compares to a net loss of $14.9 million, or $1.60 per share, for the comparable period in 2019.

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 was approved by the U.S. Food and Drug Administration in February 2020 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. The ANJESO product approval was 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 specialty pharmaceutical company focused on therapeutics for acute care settings. The Company's first commercial product, ANJESO®, had its New Drug Application approved by FDA on February 20, 2020 for the management of moderate to severe pain, alone or in combination with other non-NSAID analgesics. ANJESO is a once daily IV NSAID with preferential Cox-2 activity, which has successfully completed three Phase III clinical trials, including two pivotal efficacy trials, a large double-blind Phase III safety trial and other studies for the management of moderate to severe pain. 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 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 forward-looking statements are subject to risks and uncertainties including, among other things, 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 our 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 our 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 our business and future results included in our filings with the Securities and Exchange Commission at www.sec.gov. These forward-looking statements are based on information currently available to us, and we assume 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)

Assets	June 30, 2020	December 31, 2019
Current assets:		
Cash and cash equivalents	$ 39,410	$ 17,740
Accounts receivable	382	—
Inventory	753	—
Prepaid expenses and other current assets	2,122	2,395
Total current assets	$ 42,667	$ 20,135

Property, plant and equipment, net	4,610	4,821
Right of Use asset	542	730
Intangible assets, net	25,541	26,400
Goodwill	2,127	2,127
Total assets	$ 75,487	$ 54,213
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	2,190	271
Accrued expenses & other current liabilities	3,972	3,532
Current portion of long-term debt, net	598	—
Current portion of operating lease liability	258	318
Current portion of contingent consideration	13,135	3,592
Total current liabilities	20,153	7,713
Long-term debt, net	8,097	—
Long-term operating lease liability	329	455
Warrant liability	21,410	—
Long-term portion of contingent consideration	84,902	62,766
Total liabilities	134,891	70,934
Shareholders' equity:		
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, 18,374,604 shares at June 30, 2020 and 9,350,709 shares at December 31, 2019	184	94
Additional paid in-capital	47,375	19,405
Accumulated deficit	(106,963)	(36,220)
Total shareholders' equity	(59,404)	(16,721)
Total liabilities and shareholders' equity	$ 75,487	$ 54,213

BAUDAX BIO, INC.

Consolidated and Combined Statements of Operations

(Unaudited)

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Revenue, net	$ 349	$ —	$ 349	$ —
Operating expenses:				
Cost of sales (excluding amortization of intangible assets)	650	—	650	—
Research and development	1,350	7,180	4,420	16,734

Selling, general and administrative	11,217	7,449	19,263	17,284
Amortization of intangible assets	644	—	859	—
Change in warrant valuation	12,667	—	14,045	—
Change in contingent consideration valuation	4,053	(4,059)	31,679	(19,150)
Total operating expenses	30,581	10,570	70,916	14,868
Operating income / (loss)	(30,232)	(10,570)	(70,567)	(14,868)
Other income (expense):				
Interest income (expense)	(213)	(12)	(176)	(49)
Net loss before income taxes	$ (30,445)	$ (10,582)	$ (70,743)	$ (14,917)
Income tax benefit	—	—	—	—
Net loss	$ (30,445)	$ (10,582)	$ (70,743)	$ (14,917)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (1.72)	$ (1.13)	$ (5.11)	$ (1.60)
Weighted average common shares outstanding, basic and diluted	17,691,700	9,350,709	13,846,464	9,350,709

Source: Baudax Bio, Inc.