February 23, 2023

Baudax Bio Reports 2022 Fourth Quarter and Annual Financial Results and Provides Business Update

Company Focuses on Development of Neuromuscular Blocking Agents

Phase II Randomized Trial for BX1000 Initiated, Positive Interim Results Announced; Completion of Study Enrollment Expected Q1 2023, Top Line Results Expected Early Q2 2023

BX2000 Dose Escalation Study Progressing

$5 Million in Financing Secured through Public Offering

MALVERN, Pa., Feb. 23, 2023 (GLOBE NEWSWIRE) -- Baudax Bio, Inc. (Nasdaq:BXRX) (the "Company"), a pharmaceutical company focused on innovative products for hospital and related settings, today reported financial results for the fourth quarter and year ended December 31, 2022, updated the status of the neuromuscular blocking (NMB) agent development program, and provided an overview of other corporate and financial developments.

"During our fourth quarter we refocused our priorities on our NMB portfolio, initiating our Phase II trial for BX1000 and advancing our Phase I dose escalation trial for BX2000," said Gerri Henwood, Baudax Bio's President and Chief Executive Officer. "The encouraging interim data we announced from the BX1000 trial showed all patients treated to date have met the criteria for Good or Excellent intubating conditions at 60 seconds, and that BX1000 has been generally well tolerated. We believe these data speak to the potential of our NMB portfolio to improve patient management and deliver cost efficiencies in procedures where NMB is required. We expect to complete enrollment in the BX1000 trial during the first quarter of 2023, and to announce top line data early in the second quarter of 2023. Concurrently, BX2000, our ultrashort acting NMB, is continuing through its dose escalation study, which we expect to complete by the end of 2023. BX3000, our NMB reversal agent, remains on track, and we expect to complete the nonclinical and manufacturing studies needed to support an IND filing for BX3000, the NMB reversal agent in the summer of 2023. Data from these trials will provide us with insight on the profiles of the two blocking agents, which will contribute to decisions to move forward later in 2023."

"Due to persistent economic challenges facing hospitals, as previously disclosed, we have taken the strategic decision to discontinue commercialization of ANJESO," continued Ms. Henwood. "We continue to believe in ANJESO's advantages over other non-opioid pain therapies, as well as its potential to overcome many of the issues associated with commonly prescribed opioid therapeutics."

Fourth Quarter 2022 and Recent Business Highlights

NMBs

- **BX1000 (IV Intermediate duration of action).** Results for a planned interim analysis of the Phase II trial for BX1000 were announced in January 2023. This randomized, double-blind, active-controlled clinical trial comparing three different doses of BX1000 to a standard dose of rocuronium (rocuronium bromide 0.6 mg/kg IV Bolus) is planned to enroll a total of 80 adult patients undergoing elective surgery utilizing total intravenous anesthesia currently at a single clinical site in the U.S. The primary efficacy endpoint is the proportion of patients meeting criteria for Good or Excellent intubating conditions using a standardized scale. Additionally, the trial is evaluating the safety and tolerability profile of BX1000 and rocuronium in this patient population.

- **BX1000 Interim Data.** The pre-planned interim analysis evaluated the intubating conditions for each randomized patient after administration of study drug in a blinded fashion. In the 20-patient cohort, 5 patients per group received one of the study medications. All 20 patients were observed to have met the criteria for Good or Excellent intubating conditions at 60 seconds. Nineteen of the subjects were successfully intubated following the assessment at 60 seconds, with one remaining subject successfully intubated following the assessment at 90 seconds. Study treatments were generally well tolerated with no occurrence of severe or serious adverse events. This blinded interim analysis did not result in the decision to drop any of the four study groups nor any decision to adjust planned study enrollment numbers.

- **BX2000 (IV Ultra-short duration of action).** Cohort enrollment is ongoing for the Phase I dose escalation study evaluating the safety, tolerability, and pharmacokinetics of BX2000 in intubated healthy volunteers. This study is comprised of likely seven or eight dosing cohorts and each cohort is planned to enroll eight patients. The first and second cohorts have been dosed and enrollment of the third cohort is underway. The Company expects to complete enrollment of the remaining cohorts in the study by the end of 2023.

- **BX3000 (Reversal agent).** Baudax Bio expects to complete nonclinical studies and manufacturing data required to support the IND for BX3000 in the summer of 2023. Early single agent clinical trials of BX3000 will not require intubation and so would be expected to progress quickly once the IND is active, and trials are ready to initiate. The Company believes progress towards a reversal study using BX3000 in patients who have received BX1000 could begin before the end of 2023.

- The Company believes the data from the ongoing clinical trials for BX1000 and BX2000 will contribute to decisions to move forward later in 2023.

ANJESO

- **ANJESO U.S. Commercialization Discontinued.** Despite having distinct benefits as the first and only once-daily, non-opioid IV analgesic, market conditions are not favorable for the introduction and commercialization of a new pain management product in the hospital market. As a result, Baudax Bio has formally discontinued the commercialization of ANJESO and the product is currently on hold due to these business conditions.

Corporate and Financial

- **Closed $5 million public offering** – on December 6, 2022 the Company closed a public offering of an aggregate of 1,042,787 shares of its common stock (or pre-funded warrants in lieu thereof), Series A-3 warrants to purchase up to 1,042,787 shares of common stock and Series A-4 warrants to purchase 1,042,787 shares of common stock, at a combined public offering price of $4.795 per share (or pre-funded warrant) and accompanying warrants. The Series A-3 warrants have an exercise price of $4.50 per share, are exercisable immediately upon issuance and expire five years from the date of issuance, and the Series A-4 warrants have an exercise price of $4.50 per share, are exercisable immediately and expire thirteen months from the date of issuance. The Company intends to use the net proceeds from this offering for working capital, pipeline development activities and general corporate purposes. In January 2023, 961,787 warrants were exercised providing $4.3 million in cash to the Company.

Financial Results for the Three Months Ended December 31, 2022

As of December 31, 2022, Baudax had cash and cash equivalents of $5.3 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, 2022 was $0.3 million. This compares to $0.4 million for the three months ended December 31, 2021, a decrease of $0.1 million, resulting from the impact of the reduction in our field staff in 2022 and the impact of our discontinuation of commercialization in the fourth quarter of 2022. While utilizing the title model of distribution, product revenue was recognized as shipments were made to the Company's third-party logistics provider.

Cost of sales for the three months ended December 31, 2022 was $4.8 million, compared to $0.6 million for the three months ended December 31, 2021, an increase of $4.2 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 increase of $4.2 million was primarily a result of an increase in the non-cash charge for inventory reserve expense of $4.4 million, partially offset by the decrease in fixed personnel related costs of $0.2 million. Certain product costs of ANJESO units recognized as revenue during the three months ended December 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.

Research and development expense for the three months ended December 31, 2022 was $1.0 million compared to $0.5 million for the three months ended December 31, 2021, an increase of $0.5 million, which was a result of an increase in NMB clinical trial costs of $0.9 million, partially offset by a decrease in personnel costs of $0.3 million.

Selling, general and administrative expenses for the three months ended December 31, 2022 were $2.1 million, of which $0.2 million was attributable to selling expense and $1.9 million was attributable to general and administrative expense. This compares to $11.5 million for the same prior year period, of which $6.5 million was attributable to selling expense and $5.0 million was attributable to general and administrative expense. Selling expenses decreased $6.3 million, primarily as a result of a reduction in personnel costs of $4.4 million, a decrease in marketing costs of $1.6 million and a decrease in associated

travel expenses of $0.3 million. The decrease of $3.1 million in general and administrative costs was primarily a result of a decrease in personnel costs of $2.2 million, a decrease in public company costs of $0.5 million and a decrease in both consulting costs and travel expenses of $0.2 million.

As a result of the discontinuation of commercialization of ANJESO, Baudax Bio evaluated the intangible asset carrying value attributed to ANJESO as of December 31, 2022 and recorded a non-cash impairment loss of $1.9 million to eliminate the carrying value of the asset. The value of its construction in progress related to the construction of an additional manufacturing suite for ANJESO was further reduced by $0.5 million.

Baudax Bio reported net loss of $9.2 million, or $(12.33) per share, including non-cash charges of $6.1 million (primarily related to the inventory reserve expense discussed above), for the three months ended December 31, 2022. Adjusted net loss* was $3.1 million for the three months ended December 31, 2022. Net income for the three months ended December 31, 2021 was $29.4 million, or $437.19 per diluted share, including a non-cash benefit of $41.3 million. Adjusted net loss* was $11.9 million for the three months ended December 31, 2021.

Financial Results for the Year Ended December 31, 2022

Net product revenue related to sales of ANJESO in the U.S., recognized according to U.S. GAAP, for the year ended December 31, 2022 was $1.3 million. This compares to $1.1 million for the year ended December 31, 2021, an increase of $0.2 million, which was attributable to increased demand at existing accounts. While utilizing the title model of distribution, product revenue was recognized as shipments were made to the Company's third-party logistics provider.

Cost of sales for the year ended December 31, 2022 was $7.0 million, compared to $2.4 million for the year ended December 31, 2021, an increase of $4.6 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 increase of $4.6 million was primarily a result of the increase in the non-cash charge for inventory reserve expense of $5.2 million, partially offset by the reduction in personnel related costs of $0.4 million and the reduction in production and storage costs of $0.2 million. Certain product costs of ANJESO units recognized as revenue during the year ended December 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.

Research and development expenses for the year ended December 31, 2022 were $3.9 million compared to $3.1 million for the year ended December 31, 2021. The increase of $0.8 million was primarily due to the increase in the NMB portfolio clinical trial costs of $1.0 million and an increase of $0.2 million related to the pediatric clinical trial costs for ANJESO. These costs were partially offset by a decrease in personnel related costs of $0.4 million.

Selling, general and administrative expenses for the year ended December 31, 2022 were $24.1 million, of which $9.4 million was attributable to selling expense and $14.7 million was attributable to general and administrative expense. This compares to $45.3 million for the same prior year period, of which $22.4 million was attributable to selling expense and $22.9 million was attributable to general and administrative expense. Selling expenses decreased

$13.0 million, primarily as a result of a reduction in personnel costs of $7.9 million, a decrease in marketing costs of $4.7 million and a decrease in travel expenses of $0.4 million compared to 2021. The decrease of $8.2 million in general and administrative expenses was primarily a result of a decrease in personnel costs of $4.7 million, a decrease in public company costs of $2.3 million, a decrease in consulting costs of $0.9 million and a decrease in other costs of $0.3 million.

As a result of the discontinuation of commercialization of ANJESO, Baudax Bio evaluated the intangible asset carrying value attributed to ANJESO as of December 31, 2022 and recorded a non-cash impairment loss of $19.7 million to eliminate the carrying value of the asset. Additionally, the value of its construction in progress related to the construction of an additional manufacturing suite for ANJESO was reduced by $4.2 million.

Baudax Bio reported net loss of $58.8 million, or $(177.30) per share, including net non-cash charges of $30.9 million, for the year ended December 31, 2022. Adjusted net loss* was $27.9 million for the year ended December 31, 2022. For the year ended December 31, 2021 net loss was $19.8 million, or $(361.16) per share, including net non-cash benefit of $26.4 million. Adjusted net loss* was $46.2 million for the year ended December 31, 2021.

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, stock-based compensation, losses on impairment of construction in progress and intangible assets and the write off of inventory. 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 Baudax Bio

Baudax Bio is a pharmaceutical company focused on innovative products for hospital and related settings. The Company has a pipeline of innovative pharmaceutical assets including two clinical-stage, novel neuromuscular blocking (NMBs) agents, one undergoing a Phase II clinical trial and an additional unique NMB undergoing a dose escalation Phase I clinical trial, as well as a proprietary chemical reversal agent specific to these NMBs, which is currently undergoing nonclinical and manufacturing studies to prepare for an expected IND filing in the summer of 2023. 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 market, economic and other conditions, 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 BX1000, BX2000 and BX3000, 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; Baudax Bio's ability to maintain listing on the Nasdaq Capital Market; 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.

CONTACTS:

Investor Relations Contact:

Mike Moyer
LifeSci Advisors
mmoyer@lifesciadvisors.com

BAUDAX BIO, INC.
Consolidated Balance Sheets

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

Assets	**December 31, 2022**	**December 31, 2021**
Current assets:		
Cash and cash equivalents	$ 5,259	$ 15,891
Accounts receivable, net	335	542

Inventory	—	5,002
Prepaid expenses and other current assets	753	2,059
Total current assets	$ 6,347	$ 23,494
Property and equipment, net	704	5,015
Intangible assets, net	—	21,678
Goodwill	2,127	2,127
Other long-term assets	854	963
Total assets	$ 10,032	$ 53,277
Liabilities and Shareholders' (Deficit) Equity		
Current liabilities:		
Accounts payable	3,927	1,468
Accrued expenses and other current liabilities	2,729	5,540
Current portion of long-term debt, net	5,600	2,222
Current portion of contingent consideration	9,204	6,416
Total current liabilities	21,460	15,646
Long-term debt, net	1,519	6,309
Long-term portion of contingent consideration	10,697	17,446
Other long-term liabilities	598	650
Total liabilities	34,274	40,051
Shareholders' (deficit) equity:		
Preferred stock, $0.01 par value. Authorized, 10,000,000 shares; issued and outstanding, 0 shares at December 31, 2022 and 8,289 shares at December 31, 2021	—	—
Common stock, $0.01 par value. Authorized, 190,000,000 shares; issued and outstanding, 1,623,913 shares at December 31, 2022 and 70,181 shares at December 31, 2021	16	1
Additional paid in-capital	166,646	145,314
Accumulated deficit	(190,904)	(132,089)
Total shareholders' (deficit) equity	(24,242)	13,226
Total liabilities and shareholders' (deficit) equity	$ 10,032	$ 53,277

BAUDAX BIO, INC.

Consolidated Statements of Operations

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

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Revenue, net	$ 310	$ 400	$ 1,269	$ 1,080
Operating expenses:				
Cost of sales (excluding amortization of intangible assets)	4,792	576	7,009	2,445
Research and development	1,038	502	3,887	3,125
Selling, general and administrative	2,092	11,540	24,119	45,310
Amortization of intangible assets	65	644	1,997	2,576
Change in warrant valuation	—	(11)	(7)	(58)
Change in contingent consideration valuation	(1,507)	(42,863)	(2,761)	(33,312)
Loss on impairment of property and equipment	495	—	4,157	—
Loss on impairment of intangible asset	1,935	—	19,681	—
Total operating expenses	8,910	(29,612)	58,082	20,086
Operating (loss) income	(8,600)	30,012	(56,813)	(19,006)
Other expense:				
Other expense, net	(649)	(578)	(1,982)	(763)
Net (loss) income	$ (9,249)	$ 29,434	$ (58,795)	$ (19,769)
Per share information:				
Net (loss) income per share of common stock, basic	$ (12.33)	$ 486.26	$ (177.30)	$ (361.16)
Net (loss) income per share of common stock, diluted	$ (12.33)	$ 437.19	$ (177.30)	$ (361.16)
Weighted average common shares outstanding, basic	750,054	60,532	331,615	54,738
Weighted average common shares outstanding, diluted	750,054	67,325	331,615	54,738

BAUDAX BIO, INC.

Reconciliation of GAAP to Non-GAAP Measures

(Unaudited)

	For the Three Months Ended December 31,		For the Year Ended December 31,	
(amounts in thousands)	**2022**	**2021**	**2022**	**2021**

Net loss (GAAP)	$ (9,249)	$ 29,434	$ (58,795)	$ (19,769)
Stock-based compensation	229	657	1,401	4,789
Non-cash interest expense	366	224	1,017	897
Gain on extinguishment of debt	—	—	—	(1,553)
Depreciation expense	40	45	165	240
Amortization expense	65	644	1,997	2,576
Non-cash loss on retirement of fixed assets	—	—	8	—
Change in warrant valuation	—	(11)	(7)	(58)
Change in contingent consideration valuation	(1,507)	(42,863)	(2,761)	(33,312)
Loss on impairment of property and equipment	495	—	4,157	—
Loss on impairment of intangible asset	1,935	—	19,681	—
Write off of inventory	4,439	—	5,282	—
Adjusted net loss (non-GAAP)	$ (3,187)	$ (11,870)	$ (27,855)	$ (46,190)

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, stock-based compensation, losses on impairment of construction in progress and intangible assets and the write off of inventory.

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.

Source: Baudax Bio, Inc.