UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 11, 2022

Baudax Bio, Inc.
(Exact name of registrant as specified in its charter)

Pennsylvania	001-39101	47-4639500
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

490 Lapp Road, Malvern, Pennsylvania	19355
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (484) 395-2470

Not Applicable
(Former name or former address, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol	Name of Exchange on Which Registered
Common Stock, par value $0.01	**BXRX**	**Nasdaq Capital Market**

Securities registered pursuant to Section 12(g) of the Act:

None

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

Item 2.02 Results of Operations and Financial Condition.

On August 11, 2022, Baudax Bio, Inc. (the "**Company**") issued a press release announcing its financial results for the second quarter ended June 30, 2022. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information disclosed under Item 2.02, including Exhibit 99.1, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and shall not be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The following exhibits are being filed herewith:

Exhibit No.	Document
99.1	Press release of Baudax Bio, Inc., dated August 11, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Baudax Bio, Inc.

By: /s/ Gerri A. Henwood
Name: Gerri A. Henwood
Title: President and Chief Executive Officer

Date: August 11, 2022

Baudax Bio Reports Second Quarter 2022 Financial Results and Business Highlights

ANJESO® Net Product Revenue Up 49% Year-Over-Year; Vials Sold to End-Users Up 67% Year-Over-Year

Dosing Complete in the First Cohort of the Phase I BX2000 Study; On Track to Complete Enrollment in Remaining Cohorts by Early 2023

MALVERN, Pa., August 11, 2022 — 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 and six months ended June 30, 2022, provided key metrics around the ongoing commercialization of ANJESO (meloxicam) injection, updated status of the neuromuscular blocking (NMB) agent development program, and provided an overview of other corporate and financial developments.

"ANJESO continued its solid sales performance during the second quarter of 2022 with 49% growth year-over-year," said Gerri Henwood, President and CEO of Baudax Bio. "The development programs for our neuromuscular blocking (NMB) agents continue to advance with the commencement of a Phase I clinical study evaluating BX2000, our ultra-short acting NMB, in healthy volunteers. We are on track to progress through the remaining dosing cohorts and expect to complete enrollment of the study by early 2023. We are also working toward initiation of a Phase II study evaluating our intermediate-acting NMB, BX1000, in surgical patients and we look forward to keeping you updated on our progress."

Second Quarter 2022 and Recent Business Highlights

ANJESO

- **ANJESO U.S. Commercialization.** ANJESO is indicated for the management of moderate to severe pain in adults, alone or in combination with other non-NSAID analgesics. For the second quarter of 2022, ANJESO achieved net product revenue of $0.3 million, reflecting 49% growth year-over-year. Vials sold to end-users increased by approximately 67% compared to the same prior year period. In terms of site of care usage of ANJESO, there was a 12% increase in vials sold to hospitals in the second quarter of 2022 compared to the first quarter of 2022. In the second quarter of 2022 the re-order rate from existing accounts was 72%.
- **Impacts from COVID-19.** The newer Omicron variants of COVID-19 as well as hospital and ambulatory surgical center staffing issues, although beginning to stabilize, continued to impact the number of elective surgeries performed during the quarter. Cancellations of elective surgeries were primarily due to patients or ASC and hospital staff testing positive for COVID-19, as well as reduced availability of staff at ambulatory surgical centers and hospitals.

NMBs

- **BX1000 (IV Intermediate-action).** A dose-escalation Phase I study evaluating BX1000 in 58 healthy volunteers was completed and results 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, the Company expects to begin enrollment in a Phase II study in surgical patients during 2022.
- **BX2000 (IV Ultra-short action).** Dosing was completed for the first cohort of the Phase I dose escalation study evaluating the safety, tolerability and pharmacokinetics of BX2000 in healthy volunteers. This study is comprised of up to 10 dosing cohorts and each cohort is planned to enroll 8 patients. The Company expects to complete enrollment of the remaining cohorts in the study by early 2023.

- **BX3000 (Reversal agent).** Additional work to enhance the formulation of the BX3000 reversal agent is complete and the Company believes this data, along with certain non-clinical data, which will be submitted to FDA by early 2023, will support and IND filing for a Phase I study in healthy volunteers the first half of 2023.

Corporate and Financial

- **Secured $2.0 Million in Financing.** In May, Baudax Bio completed a registered direct offering with institutional investors securing approximately $2.0 million, before deducting placement agent fees and other offering expenses. The financing was priced at-the-market and the Company issued and sold approximately 1.6 million shares of its common stock, at a purchase price of $1.215 per share. The Company also agreed to issue to the investors, in a concurrent private placement, unregistered warrants to purchase up to 1.6 million shares of its common stock.

Second Quarter 2022 Financial Results

As of June 30, 2022, Baudax Bio had cash and cash equivalents of $5.2 million.

Net product revenue related to sales of ANJESO in the U.S., recognized according to U.S. GAAP, for the three months ended June 30, 2022 was $0.3 million. This compares to $0.2 million for the three months ended June 30, 2021, an increase of $0.1 million, or 49%, despite a decrease of approximately 80% of the field staff in the current year. 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 increased demand at existing accounts as well as securing additional formulary approvals.

Cost of sales for the three months ended June 30, 2022 was $0.4 million, compared to $0.6 million for the three months ended June 30, 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 in manufacturing costs, including production and storage costs, in the current year compared to the prior year. Certain product costs of ANJESO units recognized as revenue during the three months ended June 30, 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 modestly 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 June 30, 2022 and 2021 were $0.9 million.

Selling, general and administrative expenses for the three months ended June 30, 2022 were $4.0 million, of which $1.1 million was attributable to selling expense and $2.9 million was attributable to general and administrative expense. This compares to $10.6 million for the same prior year period, of which $5.0 million was attributable to selling expense and $5.6 million was attributable to general and administrative expense. Selling expenses decreased $3.9 million, primarily as a result of a reduction in personnel costs of $2.4 million and a decrease in marketing costs of $1.4 million. The decrease of $2.7 million in general and administrative costs was primarily a result of a decrease in personnel costs of $1.4 million, a decrease in public company costs of $0.9 million and a decrease in consulting costs of $0.3 million.

Baudax Bio reported a net loss of $7.5 million, or $(1.05) per share, including non-cash charges of $2.6 million, for the three months ended June 30, 2022. Adjusted net loss* was $4.9 million.

Six Months Ended June 30, 2022 Financial Results

Net product revenue related to sales of ANJESO in the U.S., recognized according to U.S. GAAP, for the six months ended June 30, 2022 was $0.7 million. This compares to $0.4 million for the six months ended June 30, 2021, an increase of $0.3 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 increased demand at existing accounts as well as securing additional formulary approvals.

Cost of sales for the six months ended June 30, 2022 was $1.0 million, compared to $1.4 million for the six months ended June 30, 2021, a decrease of $0.4 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 $0.4 million was primarily a result of the reduction in scrap expense recorded in the current year compared to the prior year of $0.2 million and a decrease in manufacturing costs, including reductions in production and storage costs, of $0.2 million. Certain product costs of ANJESO units recognized as revenue during the six months ended June 30, 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 modestly increase as sales increase and inventory associated with the units manufactured prior to FDA approval have been sold.

Research and development expenses for the six months ended June 30, 2022 were $2.2 million compared to $2.0 million for the six months ended June 30, 2021. The increase of $0.2 million was primarily due to the initiation of the pediatric trial for ANJESO of $0.2 million.

Selling, general and administrative expenses for the six months ended June 30, 2022 were $18.2 million, of which $8.3 million was attributable to selling expense and $9.9 million was attributable to general and administrative expense. This compares to $22.7 million for the same prior year period, of which $10.1 million was attributable to selling expense and $12.6 million was attributable to general and administrative expense. Selling expenses decreased $1.8 million, primarily as a result of a decrease in marketing costs of $1.1 million and a reduction in personnel costs of $0.7 million. The decrease of $2.7 million in general and administrative was primarily a result of a decrease in public company costs of $1.4 million, a decrease in personnel costs of $0.9 million and a decrease in consulting costs of $0.4 million.

Baudax Bio reported net loss of $20.3 million, or $(3.63) per share, including net non-cash charges of $0.2 million, for the six months ended June 30, 2022. Adjusted net loss* was $20.1 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.

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. 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. Baudax Bio markets ANJESO®, 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, the Company has a pipeline of other innovative pharmaceutical assets including two clinical-stage, novel neuromuscular blocking (NMBs) agents 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 future expenses, product costs, and the development of each of BX1000, BX2000, and BX3000, 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.

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BAUDAX BIO, INC.
Consolidated Balance Sheets
(Unaudited)

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

Assets	June 30, 2022	December 31, 2021
Current assets:		
Cash and cash equivalents	$ 5,210	$ 15,891
Accounts receivable, net	616	542
Inventory	5,255	5,002
Prepaid expenses and other current assets	1,398	2,059
Total current assets	$ 12,479	$ 23,494
Property, plant and equipment, net	4,941	5,015
Intangible assets, net	20,390	21,678
Goodwill	2,127	2,127
Other long-term assets	897	963
Total assets	$ 40,834	$ 53,277
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	3,064	1,468
Accrued expenses and other current liabilities	3,812	5,540
Current portion of long-term debt, net	3,611	2,222
Current portion of contingent consideration	7,694	6,416
Total current liabilities	18,181	15,646
Long-term debt, net	5,099	6,309
Long-term portion of contingent consideration	12,692	17,446
Other long-term liabilities	632	650
Total liabilities	36,604	40,051
Shareholders' equity:		
Preferred stock, $0.01 par value. Authorized, 10,000,000 shares; none issued and outstanding.	—	—
Common stock, $0.01 par value. Authorized, 190,000,000 shares; issued and outstanding, 8,068,853 shares at June 30, 2022 and 2,807,239 shares at December 31, 2021	81	28
Additional paid in-capital	156,578	145,287
Accumulated deficit	(152,429)	(132,089)
Total shareholders' equity	4,230	13,226
Total liabilities and shareholders' equity	$ 40,834	$ 53,277

BAUDAX BIO, INC.
Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenue, net	$ 300	$ 201	$ 722	$ 399
Operating expenses:				
Cost of sales (excluding amortization of intangible assets)	361	586	1,009	1,407
Research and development	912	857	2,205	1,965
Selling, general and administrative	4,029	10,608	18,219	22,696
Amortization of intangible assets	644	644	1,288	1,288
Change in warrant valuation	(1)	(59)	(6)	(41)
Change in contingent consideration valuation	1,327	3,881	(2,476)	5,722
Total operating expenses	7,272	16,517	20,239	33,037
Operating loss	(6,972)	(16,316)	(19,517)	(32,638)
Other expense:				
Other (expense) income, net	(559)	987	(823)	397
Net loss	$ (7,531)	$ (15,329)	$ (20,340)	$ (32,241)
Per share information:				
Net loss per share of common stock, basic	$ (1.05)	$ (7.17)	$ (3.63)	$ (16.43)
Net loss per share of common stock, diluted	$ (1.05)	$ (7.18)	$ (3.63)	$ (16.43)
Weighted average common shares outstanding, basic	7,181,640	2,137,191	5,610,037	1,962,655
Weighted average common shares outstanding, diluted	7,181,640	2,138,100	5,610,037	1,962,655

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.

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
(amounts in thousands)	**2022**	**2021**	**2022**	**2021**
Net loss (GAAP)	$ (7,531)	$ (15,329)	$ (20,340)	$ (32,241)
Stock-based compensation	337	903	858	3,207
Non-cash interest expense	223	229	449	458
Gain on extinguishment of debt	—	(1,553)	—	(1,553)
Depreciation expense	43	63	86	149
Amortization expense	644	644	1,288	1,288
Non-cash loss on retirement of fixed assets	8	—	8	—
Change in warrant valuation	(1)	(59)	(6)	(41)
Change in contingent consideration valuation	1,327	3,881	(2,476)	5,722
Adjusted net loss (non-GAAP)	$ (4,950)	$ (11,221)	$ (20,133)	$ (23,011)