
**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): **March 2, 2022**

Baudax Bio, Inc.

(Exact name of registrant as specified in its charter)

Pennsylvania
(State or other jurisdiction of
incorporation or organization)

001-39101
(Commission
File Number)

47-4639500
(I.R.S. Employer
Identification No.)

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

19355
(Zip Code)

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

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

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))

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	BXXR	Nasdaq Capital Market

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 8.01 Other Events.

On March 2, 2022, Baudax Bio, Inc. issued a press release announcing the recent issuance of United States Patent No. 11,253,478 (the “Patent”) on February 22, 2022. The Patent covers ANJESO® (“ANJESO”) and other injectable, nanoparticulate meloxicam compositions and methods of administering such compositions by intravenous, intramuscular or subcutaneous injection. The Patent has been listed in the *United States Food and Drug Administration’s Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* as it relates to ANJESO.

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 March 2, 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: March 2, 2022



Baudax Bio Announces Seventh Orange Book Listable Patent for ANJESO®

MALVERN, Pa., March 02, 2022 (GLOBE NEWSWIRE) — Baudax Bio, Inc. (NASDAQ:BXRX), a pharmaceutical company focused on commercializing and developing innovative products for acute care settings, today announced that it has secured the issuance of United States Patent No. 11,253,478 (the ‘478 Patent). The ‘478 Patent covers ANJESO® and other injectable, nanoparticulate meloxicam compositions and methods of administering such compositions by intravenous, intramuscular or subcutaneous injection. The ‘478 Patent will be listed in the *United States Food and Drug Administration’s (FDA) Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* as it relates to ANJESO®. The ‘478 Patent is exclusively licensed from Alkermes Pharma Ireland Limited (APIL).

The ANJESO® ‘478 patent, with an expiry date of May of 2030, joins two other ANJESO Orange Book listed patents with the same expiry month. The ‘478 Patent will join a total of six other patents listed in the Orange Book, amongst others owned or licensed by Baudax Bio that currently provide exclusivity to the ANJESO® franchise. The ‘478 Patent emphasizes ANJESO’s® superior stability.

“We are pleased by the progress we have made in the United States Patent and Trademark Office and the continued recognition of the inventive nature of our ANJESO® franchise,” said Gerri Henwood, Baudax Bio’s President and Chief Executive Officer. “The ‘478 Patent is expected to provide a significant barrier for generic entry and we believe it will likely be joined by other patents currently pending in the USPTO.”

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. 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 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 (NMBs) 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 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, including, but not limited to, risks related to 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 BX-1000, BX-2000 and BX-3000, 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, 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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