

**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 6, 2020**

**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)

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.

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**Item 8.01 Other Events.**

On August 6, 2020, Baudax Bio, Inc. issued a press release announcing a new permanent J-code for ANJESO® (meloxicam) injection facilitating reimbursement in the hospital outpatient, ambulatory surgery center and physician office settings of care. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

**Item 9.01 Financial Statements and Exhibits.****(d) Exhibits**

The following exhibits are being filed herewith:

<b>Exhibit No.</b>	<b>Document</b>
99.1	<a href="#"><u>Press Release of Baudax Bio, Inc., dated August 6, 2020.</u></a>

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**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: *Chief Executive Officer*

Date: August 6, 2020



**Baudax Bio Secures Permanent J-Code (J1738) for ANJESO® from Centers for Medicare and Medicaid Services**

— Effective October 1, 2020, New Code Expected to Expand Reimbursement —

**MALVERN, Pa., August 6, 2020** — Baudax Bio, Inc. (NASDAQ:BXRX), a pharmaceutical company focused on therapeutics for acute care settings, today announced that the Centers for Medicare and Medicaid Services (CMS) established a new permanent J-code for ANJESO (meloxicam) injection facilitating reimbursement in the hospital outpatient, ambulatory surgery center and physician office settings of care. The code, J1738 (Injection, meloxicam, 1 mg), published online on the CMS website at <https://www.cms.gov/files/document/2020-hcpcs-application-summary-quarter-2-2020-drugs-and-biologicals-updated-07312020.pdf> (page 25) will take effect on October 1, 2020 and it is expected to replace the previously issued C-code.

“We are very pleased that ANJESO® will have its own product-specific J-code beginning on October 1, 2020,” said Gerri Henwood, President and Chief Executive Officer of Baudax Bio. “This J-code brings us one step closer to ensuring greater patient access to non-opioid alternatives by providing outpatient providers and physician offices with a uniform code and clearer reimbursement pathway when administering ANJESO and further supports our efforts during our ongoing launch.”

J codes are routine reimbursement codes assigned to outpatient and physician administered “buy and bill” products under Medicare Part B. With the J-code taking effect in October, all hospital outpatient departments, ambulatory surgery centers and physician offices in the United States will have one consistent Healthcare Common Procedure Coding System (HCPCS) code to standardize the submission and payment of ANJESO insurance claims across Medicare, Medicare Advantage, Medicaid and commercial plans.

CMS announced the new J-code for ANJESO in July, allowing time for Medicare Administrative Contractors as well as Medicare Advantage plans and commercial payers to program the new code into their systems in advance of the October 1, 2020 effective date.

**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).

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## About Baudax Bio

Baudax Bio is a specialty pharmaceutical company focused on therapeutics for acute care settings. The Company's first commercial product, ANJESO<sup>®</sup>, 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](http://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. Baudax Bio assumes no obligation to update any such 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<sup>®</sup> 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](http://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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