
**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): May 9, 2023

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

Delaware
(State or other jurisdiction
of incorporation)

001-37507
(Commission
File Number)

43-1979754
(IRS Employer
Identification No.)

**3530 John Hopkins Court
San Diego, California 92121**
(Address of principal executive offices, including zip code)

Registrant's telephone number, including area code: (844) 696-5235

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(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	IBRX	The Nasdaq Global Select 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.

BLA Update

ImmunityBio, Inc. (the “Company”) announces that it has received a complete response letter from the U.S. Food and Drug Administration (“FDA”) on May 9, 2023 regarding its Biologics License Application (“BLA”) for its product candidate, Anktiva™ (N-803) in combination with Bacillus Calmette-Guérin (“BCG”) for the treatment of patients with BCG-unresponsive non-muscle invasive bladder cancer (“NMIBC”) with carcinoma in situ (“CIS”) with or without Ta or T1 disease. The letter indicates that the FDA has determined that it cannot approve the BLA in its present form, and the FDA has made recommendations to address the issues raised.

The deficiencies relate to the FDA’s pre-license inspection of the Company’s third-party contract manufacturing organizations. Satisfactory resolution of the observations noted at the pre-license inspection is required before the BLA may be approved. The FDA further provided recommendations specific to additional Chemistry, Manufacturing and Controls (“CMC”) issues and assays to be resolved.

No new preclinical studies or Phase 3 clinical trials to evaluate safety or efficacy were requested by the FDA. The FDA requested that the Company provide updated duration of response data of the efficacy population as identified by the FDA in the Company’s resubmission, as well as a safety update.

The Company plans to request a meeting with the FDA as soon as possible to address the subject matter of the letter and a response timeline, and plans to diligently address and resolve the issues identified and seek approval as expeditiously as possible.

Business Development Updates

On May 9, 2023, the Company’s Executive Chairman and Global Chief Scientific and Medical Officer agreed to provide immediate non-convertible debt financing to the Company in an amount of \$30.0 million on substantially similar terms as prior financings, including an interest rate of Term Secured Overnight Financing Rate (“SOFR”) plus 8% per annum and a maturity date of December 31, 2023.

As previously disclosed, the Company has been exploring partnering with a large biopharmaceutical company for commercialization of N-803 for intravesical administration. The Company has confirmed with the potential partner that these negotiations will continue notwithstanding the letter referenced above, with the view of completing such a transaction during 2023, though there can be no assurance that the Company will complete a transaction on acceptable terms in accordance with this timeline or at all.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, such as statements regarding the regulatory review process and timing thereof, the Company's commercialization strategy for N-803 for intravesical administration, financing transactions, and potential strategic partnering transactions, among others. Statements that are not statements of historical fact are considered forward-looking statements, which are usually identified by the use of words such as "anticipates," "believes," "continues," "goal," "could," "estimates," "scheduled," "expects," "intends," "may," "plans," "potential," "predicts," "indicate," "projects," "seeks," "should," "will," "strategy," and variations of such words or similar expressions. Statements of past performance, efforts, or results of our preclinical and clinical trials, about which inferences or assumptions may be made, can also be forward-looking statements and are not indicative of future performance or results. Forward-looking statements are neither forecasts, promises nor guarantees, and are based on the current beliefs of ImmunityBio's management as well as assumptions made by and information currently available to ImmunityBio. Such information may be limited or incomplete, and ImmunityBio's statements should not be read to indicate that it has conducted a thorough inquiry into, or review of, all potentially available relevant information. Such statements reflect the current views of ImmunityBio with respect to future events and are subject to known and unknown risks, including business, regulatory, economic and competitive risks, uncertainties, contingencies and assumptions about ImmunityBio, including, without limitation, (i) the risks and uncertainties associated with the regulatory review process, (ii) the ability of ImmunityBio and its third party contract manufacturing organizations to adequately address the issues raised in the FDA's complete response letter, (iii) the ability of ImmunityBio to execute a partnering relationship with a large biopharmaceutical company for commercialization of N-803 plus BCG for intravesical administration on acceptable terms, if at all, (iv) the ability of ImmunityBio to continue its planned preclinical and clinical development of its development programs, and the timing and success of any such continued preclinical and clinical development and planned regulatory submissions, (v) ImmunityBio's ability to retain and hire key personnel, (vi) ImmunityBio's ability to obtain additional financing to fund its operations and complete the development and commercialization of its various product candidates, (vii) ImmunityBio's ability to successfully commercialize its product candidates and uncertainties around regulatory reviews and approvals, (viii) ImmunityBio's ability to scale its manufacturing and commercial supply operations for its product candidates and future approved products, and (ix) ImmunityBio's ability to obtain, maintain, protect and enforce patent protection and other proprietary rights for its product candidates and technologies. More details about these and other risks that may impact ImmunityBio's business are described under the heading "Risk Factors" in the Company's Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission ("SEC") on March 1, 2023 and in subsequent filings made by ImmunityBio with the SEC, which are available on the SEC's website at www.sec.gov. ImmunityBio cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date hereof. ImmunityBio does not undertake any duty to update any forward-looking statement or other information.

Item 9.01 Financial Statements and Exhibits.

- (a) *Financial statements of businesses or funds acquired.*
None.
- (b) *Pro forma financial information.*
None.
- (c) *Shell company transactions.*
None.
- (d) *Exhibits.*

Exhibit Number	Description of Exhibit
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 hereunto duly authorized.

IMMUNITYBIO, INC.

Registrant

Date: May 11, 2023

By: /s/ David C. Sachs

David C. Sachs

Chief Financial Officer