UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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 14, 2026

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

Delaware	**001-37507**	**43-1979754**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(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 1.01. Entry into a Material Definitive Agreement.

On May 14, 2026, ImmunityBio, Inc., a Delaware corporation ("ImmunityBio" or the "Company"), entered into an exclusive development and supply agreement (the "Agreement") with Japan BCG Laboratory, a Japanese corporation ("JBL"). Pursuant to the Agreement, JBL will manufacture and exclusively supply Tokyo-172 strain of Bacillus Calmette-Guerin ("BCG") (the "Product") to ImmunityBio for use in the United States and its territories (the "Territory"), pursuant to the terms and subject to the limitations set forth in the Agreement.

JBL will manufacture and supply the Product to ImmunityBio, and ImmunityBio will be solely responsible for all development activities, including preclinical studies and clinical trials, as well as obtaining and maintaining all regulatory approvals required to market and sell the Product in the Territory.

The Agreement grants ImmunityBio exclusive rights to purchase, import, sell and distribute Product in the Territory for an initial term of ten (10) years from the date of FDA approval of the Product. The Agreement also provides ImmunityBio with a right of first negotiation to obtain rights to develop and commercialize the Product in jurisdictions outside the Territory (excluding certain Asian regions including Japan) following the commencement of commercial production.

No payment is due from ImmunityBio to JBL prior to FDA approval of the Product. All vials supplied for regulatory submission shall be provided at no cost to ImmunityBio. Following FDA approval, ImmunityBio has committed to purchase at least 2 batches of Product per year. ImmunityBio shall use commercially reasonable efforts to launch and commercialize the Product in the Territory upon obtaining FDA approval.

The Agreement contains customary representations, warranties, indemnification, and confidentiality provisions. Either party may terminate the Agreement upon written notice in the event of an uncured material breach by the other party or upon the other party's insolvency. ImmunityBio may also terminate the Agreement for convenience upon prior written notice.

The foregoing is only a brief description of the material terms of the Agreement, does not purport to be a complete description of the rights and obligations of the parties thereunder, and is qualified in its entirety by reference to the full text of the Agreement, a copy of which will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the quarter ending June 30, 2026.

Item 7.01. Regulation FD Disclosure.

On May 16, 2026, the Company issued a press release announcing the Agreement described in Item 1.01 above (the "Agreement Press Release"). The Agreement Press Release is attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated into this Item 7.01 by reference.

The information in this Item 7.01, including Exhibit 99.1 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description of Exhibit
99.1**	Press Release dated May 16, 2026.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

** Furnished herewith.

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.

Date: May 18, 2026

By: /s/ David C. Sachs
David C. Sachs
Chief Financial Officer

ImmunityBio Signs Exclusive U.S. Agreement with Japan BCG Laboratory for the Tokyo Strain of BCG to Enhance BCG Supply in the United States

- Positive Phase III readout of National Cancer Institute sponsored SWOG S1602 randomized clinical trial demonstrating non-inferior efficacy of the Tokyo strain of BCG (Tokyo-172 BCG) versus TICE BCG in BCG-naïve high-grade non-muscle invasive bladder cancer
- ImmunityBio to serve as sole U.S. Biologics License Application applicant for the Tokyo strain of BCG and plans to engage with U.S. Food and Drug Administration (FDA) on regulatory pathway to address the over decade long unresolved BCG shortage in the United States
- Agreement positions ImmunityBio with second potential BCG source to help address U.S. supply needs
- Through ImmunityBio's ongoing partnership with Serum Institute of India, recombinant BCG (rBCG) remains available to eligible patients under ImmunityBio's FDA Expanded Access Program
- Details of the Japan BCG Laboratory agreement will be shared during Dr. Patrick Soon-Shiong's presentation at the American Urological Association Annual Meeting (AUA 2026) in Washington, DC, on May 16, 2026 at 1:30 p.m. EDT. A link to the livestream is included below.

WASHINGTON, May 16, 2026 — ImmunityBio, Inc. (NASDAQ: IBRX), a commercial-stage immunotherapy company, today announced an exclusive U.S. Development and Supply Agreement with Japan BCG Laboratory ("JBL"), the Tokyo-based developer and manufacturer of the Tokyo strain of BCG (Tokyo-172 BCG). The agreement provides ImmunityBio exclusive U.S. rights to develop, import, and commercialize intravesical Tokyo-172 BCG.

JBL's Tokyo strain of BCG is supported by the February 2026 positive Phase III readout of SWOG S1602, a randomized Phase III study sponsored by the National Cancer Institute (NCI), which demonstrated non-inferiority of the Tokyo strain of BCG to TICE BCG in BCG-naïve high-grade non-muscle invasive bladder cancer (NMIBC). The pre-specified non-inferiority margin was a hazard ratio of 1.34 (hazard ratio 0.82; 95.8% CI 0.63–1.08). The Tokyo strain of BCG is investigational in the United States and has not been approved by the FDA.

Dr. Patrick Soon-Shiong will discuss the JBL agreement and provide updates on ImmunityBio's efforts to expand BCG access and advance research in the BCG-naïve setting during his presentation, "The Role of IL-15 in the Urological Setting," at the American Urological Association Annual Meeting on May 16, 2026 at 1:30 EDT. The presentation will also highlight the role of IL-15 in urological oncology, including mechanisms driving T cell and natural killer (NK) cell activation, current clinical evidence, and emerging combination approaches in bladder and prostate cancer. A livestream of the presentation will be available through the 2026 AUA Annual Meeting website.

"For more than 70 years, Japan BCG Laboratory has been dedicated to the development and manufacture of high-quality BCG products," said Seiichi Inoue, President of Japan BCG Laboratory.

“We are pleased to partner with ImmunityBio to bring the Tokyo strain of BCG to patients in the United States, and we look forward to supporting ImmunityBio in its engagement with the FDA.”

ImmunityBio plans to engage with the FDA to pursue U.S. approval of the Tokyo strain of BCG and will lead all regulatory submissions, clinical development, and commercialization in the United States as the sole BLA applicant. Upon any approval, ImmunityBio will be the sole Marketing Authorization Holder. The Tokyo strain of BCG has been used in Japan for almost 30 years for the treatment of high-risk NMIBC.

SWOG S1602 (NCT03091660) is a Phase III randomized controlled trial that enrolled 1,000 patients (984 eligible) between February 2017 and December 2020 with BCG-naïve high-grade NMIBC, randomized 1:1:1 to intravesical TICE BCG (n=330), intravesical Tokyo-172 BCG (n=327), or intradermal priming, followed by intravesical Tokyo-172 BCG (n=327). The pre-specified non-inferiority margin for the primary endpoint of high-grade recurrence-free survival (HGRFS) was a hazard ratio of 1.34.

At a median follow-up of 4.6 years, results presented at the February 2026 ASCO Genitourinary Cancers Symposium (Svatek RS, et al. J Clin Oncol. 2026;44[7 suppl]:LBA629) demonstrated non-inferiority of intravesical Tokyo strain of BCG versus intravesical TICE BCG on the primary endpoint of HGRFS (HR 0.82; 95.8% CI 0.63–1.08), with the upper confidence bound well below the pre-specified non-inferiority margin of HR 1.34. Complete response (CR) in carcinoma in situ (CIS) at 6 months was 66.4% (Tokyo) versus 70.2% (TICE). Progression-free survival was similar across arms. The estimated 5-year HGRFS was 64% in the Tokyo arm, 58% in the TICE arm.

ImmunityBio is in discussions with the SWOG Cancer Research Network, the NCI, and Fred Hutchinson Cancer Research Center to establish a Data Use Agreement that would allow incorporation of the S1602 data into the company’s planned BLA submission.

“SWOG and the National Cancer Institute have our deep respect for designing and completing SWOG S1602, a randomized controlled trial of approximately one thousand patients in BCG-naïve high-grade NMIBC that took nearly a decade to read out,” said Patrick Soon-Shiong, M.D., Founder, Executive Chairman and Global Chief Scientific and Medical Officer of ImmunityBio. “S1602 is the kind of rigorous, publicly funded science that should inform FDA decision-making. Its non-inferiority finding for the Tokyo strain of BCG, alongside our rBCG partnership with Serum Institute and the FDA-approved use of ANKTIVA® with BCG in BCG-unresponsive disease, points to a future where U.S. patients with bladder cancer will have the supply and the treatment options they need.”

With the JBL agreement, ImmunityBio now has a second potential BCG source for the United States. The Company’s ongoing partnership with Serum Institute of India, one of the world’s largest vaccine manufacturers, supports the supply of recombinant BCG (rBCG), an investigational product. ImmunityBio will continue its FDA Expanded Access Program (EAP) for rBCG, so eligible patients can receive treatment while the regulatory path for the Tokyo strain of BCG moves forward. Taken together, the two partnerships aim to give U.S. urologists and their patients a more reliable BCG supply.

“U.S. urologists and their patients have lived with a chronic BCG shortage for more than a decade,” said Richard Adcock, President and Chief Executive Officer of ImmunityBio. “This agreement with Japan BCG Laboratory for the Tokyo strain of BCG gives ImmunityBio a second potential BCG source for the United States. We plan to work with the FDA on the regulatory path for the Tokyo strain of BCG. In the meantime, through our ongoing partnership with the Serum Institute of India, rBCG remains available to eligible patients through our FDA Expanded Access Program.”

ANKTIVA is approved by the FDA in combination with BCG for the treatment of adult patients with BCG-unresponsive NMIBC with carcinoma in-situ (CIS), with or without papillary tumors. ImmunityBio expects to provide further updates on the U.S. regulatory pathway for the Tokyo strain of BCG, including the timing of pre-FDA interactions and any anticipated BLA submission, in future communications.

Important Safety Information

U.S. IMPORTANT SAFETY INFORMATION

INDICATION AND USAGE: ANKTIVA® is an interleukin-15 (IL-15) receptor agonist indicated with Bacillus Calmette-Guérin (BCG) for the treatment of adult patients with BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.

WARNINGS AND PRECAUTIONS: Risk of Metastatic Bladder Cancer with Delayed Cystectomy. Delaying cystectomy can lead to the development of muscle-invasive or metastatic bladder cancer, which can be lethal. If patients with CIS do not have a complete response to treatment after a second induction course of ANKTIVA® with BCG, reconsider cystectomy.

DOSAGE AND ADMINISTRATION: For Intravesical Use Only. Do not administer by subcutaneous or intravenous routes. Please see the complete Indication and Important Safety Information and Prescribing Information for ANKTIVA® at Anktiva.com.

Investigational Use Notice: The Tokyo strain of BCG (manufactured by Japan BCG Laboratory) and recombinant BCG or rBCG (manufactured by Serum Institute of India under ongoing partnership with ImmunityBio) are investigational in the United States and have not been approved by the FDA. The safety and effectiveness of these investigational products have not been established. Availability of rBCG is limited to ImmunityBio's FDA Expanded Access Program for eligible patients. To enroll in the Expanded Access Program for recombinant BCG, please visit https://immunitybio.com/rbcg/

About ImmunityBio

ImmunityBio, Inc. is a biotechnology company focused on innovating, developing, and commercializing next-generation immunotherapies designed to activate the patient's immune system and deliver durable protection against cancer and infectious diseases. Our approach harnesses both the adaptive and innate immune systems with the goal of restoring immune function and generating lasting immunological memory in patients. At the core of our strategy is the Cancer BioShield™ platform, which is designed to stimulate critical lymphocytes, including natural killer (NK) cells, cytotoxic T cells, and memory T cells via our proprietary IL-15 superagonist. Our Cancer BioShield platform is anchored by this antibody-cytokine fusion protein and is complemented by an investigational portfolio that includes adenovirus-vectored vaccines, allogeneic (off-the-shelf) and autologous NK-cell therapies, and additional immunomodulators intended to promote immunogenic cell death and support durable immune responses while potentially reducing reliance on high-dose chemo-radiation therapy. For more information, visit ImmunityBio.com and connect with us on X (Twitter), Facebook, LinkedIn, and Instagram.

About Japan BCG Laboratory

Japan BCG Laboratory, headquartered in Tokyo, Japan, is a developer and manufacturer of Bacillus Calmette-Guérin (BCG) products, including intravesical BCG for bladder cancer and BCG vaccines for tuberculosis prevention. JBL has supplied BCG for more than 70 years.

About ImmunityBio's Partnership with Serum Institute of India

Serum Institute of India is one of the world's largest vaccine manufacturers and is ImmunityBio's manufacturing partner for recombinant BCG (rBCG). The ongoing partnership supports the continued availability of rBCG under ImmunityBio's FDA Expanded Access Program for eligible patients in the United States.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements include, without limitation, statements regarding the Development and Supply Agreement with Japan BCG Laboratory; the development, regulatory pathway, manufacturing, supply, and potential U.S. commercialization of the Tokyo strain of BCG; ImmunityBio's plans to engage with the U.S. Food and Drug Administration to pursue U.S. approval of the Tokyo strain of BCG; the SWOG S1602 trial, including the interpretation and use of S1602 data in the planned BLA, and the Company's ability to enter into a Data Use Agreement with SWOG, the National Cancer Institute, and Fred Hutchinson Cancer Research Center; the continuation, scope, and impact of ImmunityBio's Expanded Access Program for recombinant BCG (rBCG) and its role in helping address the U.S. BCG shortage; the potential complementary use of the Tokyo strain of BCG with ANKTIVA®; and statements regarding ImmunityBio's pipeline and strategy.

These forward-looking statements are based on ImmunityBio's current expectations and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks related to: the FDA's review and acceptance of any future BLA submission for the Tokyo strain of BCG; ImmunityBio's ability to secure a Data Use Agreement with SWOG, the NCI, and Fred Hutchinson Cancer Research Center on acceptable terms; manufacturing, supply, and import logistics for the Tokyo strain of BCG and rBCG; the continued availability of rBCG under the Expanded Access Program; clinical, regulatory, and commercial risks associated with ANKTIVA® and the Company's broader pipeline; competition; intellectual property; macroeconomic and geopolitical conditions; and the additional risks and uncertainties identified in ImmunityBio's filings with the U.S. Securities and Exchange Commission, including its most recent Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q, available at www.sec.gov. The forward-looking statements in this press release speak only as of the date hereof, and ImmunityBio undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

ImmunityBio Contacts:

Investors
Hemanth Ramaprakash, PhD, MBA
ImmunityBio, Inc.
+1-858-746-9289
Hemanth.Ramaprakash@ImmunityBio.com

Media
Sarah Singleton
ImmunityBio, Inc.
+1-415-290-8045
Sarah.Singleton@ImmunityBio.com