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IMMUNITYBIO, INC.

FORM 8-K
(Current report filing)

Filed 12/12/25 for the Period Ending 12/12/25

Address	3530 JOHN HOPKINS COURT
	SAN DIEGO, CA, 92121
Telephone	(844) 696-5235
CIK	0001326110
Symbol	IBRX
SIC Code	2836 - Biological Products, (No Diagnostic Substances)
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

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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): December 12, 2025

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 8.01 Other Events.

On December 12, 2025, ImmunityBio, Inc. issued a press release announcing certain regulatory updates. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated into this Item 8.01 by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description of Exhibit
99.1*	Press release dated December 12, 2025.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

* Filed 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.
Registrant

Date: December 12, 2025

By: /s/ Richard Adcock
Richard Adcock
President and Chief Executive Officer

ImmunityBio Receives Conditional Marketing Authorization Recommendation from the European Medicines Agency for ANKTIVA® with BCG for Non-Muscle Invasive Bladder Cancer Carcinoma in Situ—A First in Europe

- ANKTIVA plus BCG is the first immunotherapy for non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS), with or without papillary tumors, to receive a positive recommendation for marketing authorization in Europe. For patients whose disease does not respond to BCG, there are currently no authorized treatment options; the primary option is surgical removal of the bladder.
- Unlike the U.S., where only one BCG substrain is approved, Europe recognizes and has approved approximately six major BCG substrains, making standard-of-care therapy broadly available across the region.
- The recommendation is based on the EMA's determination that the benefit of making ANKTIVA available to patients now outweighs the risks associated with earlier access, providing an important option for adults with BCG-unresponsive NMIBC, and builds on existing approvals in the U.S. and United Kingdom.
- Each year, more than 150,000 people in Europe are diagnosed with NMIBC.

CULVER CITY, Calif., December 12, 2025 – ImmunityBio (NASDAQ: IBRX), a leading immunotherapy company, announced today that the European Medicines Agency has recommended granting a conditional marketing authorization in the EU for ANKTIVA® (nogapendekin alfa inbakicept) in combination with Bacillus Calmette-Guérin (BCG) for the treatment of BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) carcinoma in situ. This recommendation will help facilitate early access to medicines that address conditions where the remaining treatment option is surgery to remove the bladder.

"ANKTIVA represents an important evolution in the treatment of NMIBC CIS, strengthening the immune response and improving the durability of BCG," said Dr. Patrick Soon-Shiong, Founder, Executive Chairman and Global Chief Scientific and Medical Officer of ImmunityBio. "Hundreds of patients in the U.S. are already experiencing the benefits of this therapy, and our goal is to make it available to patients in Europe and other parts of the world as quickly and responsibly as possible, to ensure avoidance of a radical cystectomy. We are pleased that the EMA issued this positive recommendation based on our single-arm trial and through a regulatory process that allows earlier access to ANKTIVA, when as stated in the EMA announcement, *the benefit of a medicine's immediate availability to patients outweighs the inherent risks*."

"ANKTIVA offers a new treatment option for patients and addresses an important unmet need," the EMA noted in an announcement on the recommendation. "There are currently no authorised treatments for NMIBC that does [sic] not respond to BCG."

Bladder cancer is a serious public health concern in the European Union, ranking as the fifth-most common cancer and the seventh most frequently diagnosed cancer in men. The European Association of Urology and World Bladder Cancer Patient Coalition estimate that more than 200,000 patients will be diagnosed with bladder cancer in 2025. Approximately 75% of these patients (150,000) will have NMIBC, which is cancer that has grown only on the lining of the bladder and not into the muscle layer underneath, and is the most common form of bladder cancer.

“We are looking forward to finalizing plans to bring our innovative treatment to qualified EU patients,” said Richard Adcock, President and CEO of ImmunityBio. “With the United States’ new Most-Favored-Nation Prescription Drug Pricing policy now in effect, we are thoughtfully assessing our approach to launching in Europe to ensure broad, equitable, and sustainable access.”

The decision was based on a review of the results of a single-arm clinical trial in 100 adults with BCG-unresponsive NMIBC who received ANKTIVA in combination with BCG. In 71% of patients, signs of cancer disappeared (complete response rate) with responses ranging up to 54+ months; these responses lasted for approximately 27 months on average. The complete response rate of responders at 12 months was 66% and at 24 months was 42%. As part of the recommendation, ImmunityBio will continue to follow up with trial participants and submit long-term safety and efficacy post-marketing results to the EMA.

“Six BCG strains are available in Europe for use in combination with ANKTIVA, and we are expeditiously developing our recombinant BCG candidate to address ongoing BCG shortages in the U.S. and help ensure that all eligible patients can benefit from this treatment,” said Adcock.

ANKTIVA has been recommended for a conditional marketing authorization, an EU regulatory mechanism designed to facilitate early access to medicines that address an unmet medical need. This pathway allows the EMA to recommend marketing authorization when the benefit of a medicine’s immediate availability to patients outweighs the potential risks associated with the data, in this case, from a single-arm trial. The EMA’s opinion will now be forwarded to the European Commission for final approval of EU-wide marketing authorization.

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 Prescribing Information for ANKTIVA® at Anktiva.com.

About ImmunityBio

ImmunityBio is a vertically-integrated commercial stage biotechnology company developing next-generation therapies that bolster the natural immune system to defeat cancers and infectious diseases. The Company’s range of immunotherapy and cell therapy platforms, alone and together, act to drive and sustain an immune response with the goal of creating durable and safe protection against disease. Designated an FDA Breakthrough Therapy, ANKTIVA is the first FDA-approved immunotherapy for non-muscle invasive bladder cancer CIS that activates NK cells, T cells, and memory T cells for a long-duration response. The Company is applying its science and platforms to treating cancers, including the development of potential cancer vaccines, as well as developing immunotherapies and cell therapies that we believe sharply reduce or eliminate the need for standard high-dose chemotherapy. These platforms and their associated product candidates are designed to be more effective, accessible, and easily administered than current standards of care in oncology and infectious diseases. For more information, visit ImmunityBio.com (Founder’s Vision) and connect with us on X (Twitter), Facebook, LinkedIn, and Instagram.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, such as statements regarding the European Commission's recommendation facilitating early access to medicine and the benefits of the immediate availability of ANKTIVA, the development of therapeutics for cancer and infectious diseases, potential benefits to patients, potential treatment outcomes for patients, the described mechanism of action and results and contributions therefrom, the application of the Company's science and platforms to treat cancers or develop cancer vaccines, immunotherapies and cell therapies that has the potential to change the paradigm in cancer care, the Company's ability to distribute treatment broadly to patients in the EU, the Company's follow up with trial participants and the submission of long-term trial results to the EMA, the European Commission's recommendation of final approval of broader marketing of ANKTIVA®, the Company's development of a recombinant Bacillus Calmette-Guérin (BCG) candidate to address BCG shortages to ensure that patients access to treatment, and ImmunityBio's approved product and investigational agents as compared to existing treatment options, among others. Statements in this press release 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," "is," "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) risks and uncertainties regarding participation and enrollment and potential results from the clinical trial described herein, (ii) whether clinical trials will result in registrational pathways, (iii) whether clinical trial data will be accepted by regulatory agencies, (iv) the ability of ImmunityBio to fund its ongoing and anticipated clinical trials, (v) the ability of ImmunityBio to continue its planned preclinical and clinical development of its development programs through itself and/or its investigators, and the timing and success of any such continued preclinical and clinical development, patient enrollment and planned regulatory submissions, (vi) potential delays in product availability and regulatory approvals, (vii) ImmunityBio's ability to retain and hire key personnel, (viii) ImmunityBio's ability to obtain additional financing to fund its operations and complete the development and commercialization of its various product candidates, (ix) potential product shortages or manufacturing disruptions that may impact the availability and timing of product, (x) ImmunityBio's ability to successfully commercialize its approved product and product candidates, (xi) ImmunityBio's ability to scale its manufacturing and commercial supply operations for its approved product and future approved products, and (xii) 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 Form 10-K filed with the U.S. Securities and Exchange Commission (SEC) on March 3, 2025, and the Company's Form 10-Q filed with the SEC on November 5, 2025 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 in this press release, except to the extent required by law.

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