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): July 29, 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 7.01 Regulation FD Disclosure.

On July 29, 2026, ImmunityBio, Inc. ("ImmunityBio" or the "Company") issued a press release announcing that the Emirates Drug Establishment ("EDE") of the United Arab Emirates ("UAE") has granted marketing authorization for ANKTIVA® across two indications.

A copy of the press release is attached hereto as Exhibit 99.1 to this Current Report on Form 8-K and is furnished as Exhibit 99.1 hereto.

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 July 29, 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.
Registrant

Date: July 30, 2026

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

ImmunityBio Receives United Arab Emirates (UAE) Marketing Authorization for ANKTIVA® Across BCG-Unresponsive Non-Muscle Invasive Bladder Cancer for CIS and Papillary Disease and Metastatic Non-Small Cell Lung Cancer

- The UAE authorization further expands ANKTIVA's global regulatory footprint to 34 countries. The BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) authorization is the first worldwide to span the full spectrum of BCG-unresponsive disease: carcinoma *in situ* (CIS) with or without papillary tumors, and papillary disease alone without CIS.
- The Emirates Drug Establishment (EDE) of the United Arab Emirates (UAE) granted Marketing Authorization for two ANKTIVA presentations, the broadest approval to date for ANKTIVA including papillary disease and CIS in non-muscle invasive bladder cancer and non-small cell lung cancer in patients who failed checkpoint inhibitors and chemotherapy.
- Each approval covers a distinct indication: ANKTIVA 0.4 mg/0.4 mL (solution for intravesical instillation) in combination with Bacillus Calmette-Guérin (BCG) for BCG-unresponsive NMIBC, and ANKTIVA 1.2 mg/0.6 mL (solution for subcutaneous injection) in combination with immune checkpoint inhibitors for metastatic non-small cell lung cancer (NSCLC).
- NMIBC evidence (QUILT-3.032): in the CIS cohort (N=100), ANKTIVA plus BCG produced a complete response rate of 71% (95% CI: 61,80), with duration of complete response extending beyond 54 months; in the papillary-only cohort (N=80), 12-month disease-free survival rate was 58.2% (95% CI: 46.6, 68.2), with a cystectomy free rate at 36-months of 83%.
- In the NSCLC indication, ANKTIVA plus a checkpoint inhibitor is authorized for adult patients with metastatic disease that progressed on or after standard of care including checkpoint failure. NSCLC evidence (QUILT-3.055): in checkpoint-refractory advanced NSCLC (N=79), median overall survival was 14.6 months (95% CI: 12.0, 19.5), with subjects of mean on-treatment ALC ≥ 1,000 achieving of median OS of 16.2 months (95% CI: 13.8, 22.0).

CULVER CITY, Calif., July 29, 2026 — ImmunityBio, Inc. (NASDAQ: IBRX), a vertically integrated commercial-stage biotechnology company, today announced that the Emirates Drug Establishment (EDE) of the United Arab Emirates (UAE) has granted Marketing Authorization for ANKTIVA® (nogapendekin alfa inbakicept) across two indications. The authorization covers ANKTIVA 0.4 mg in combination with BCG for the treatment of adult patients with BCG-unresponsive NMIBC, and ANKTIVA 1.2 mg in combination with immune checkpoint inhibitors for the treatment of adult patients with metastatic NSCLC. With this action, the UAE becomes the fifth regulatory jurisdiction to authorize ANKTIVA, expanding its global footprint to 34 countries. The UAE has taken the lead in the broadest approval of ANKTIVA to date. The NMIBC authorization is the first anywhere in the world to span carcinoma *in situ* (CIS) and papillary disease, including patients with papillary-only tumors in the absence of CIS.

World's First Approval Spanning the Full Spectrum of BCG-Unresponsive Disease in NMIBC

Per the approved UAE Summary of Product Characteristics, ANKTIVA is indicated with BCG for the treatment of adult patients with BCG-unresponsive NMIBC with carcinoma *in situ* (CIS) with or without papillary tumors and BCG-unresponsive NMIBC with papillary tumors. Eligible patients therefore include those with CIS alone, CIS accompanied by papillary tumors, and papillary disease alone without CIS.

BCG-unresponsive NMIBC carries a high risk of progression and, historically, radical cystectomy has been the standard option for patients who fail BCG. An approval that spans CIS and papillary disease addresses a defined unmet need across the disease spectrum by offering an alternative immunotherapy option.

“For patients with BCG-unresponsive bladder cancer, the choice has too often been between losing the bladder and running out of options. This approval by the Emirates Drug Establishment is the first in the world to reach across the entire spectrum of non-muscle invasive bladder cancer from carcinoma in situ with or without papillary tumors, and, for the first time, papillary disease alone. Since the National Cancer Institute ranked IL-15 as the number one priority cytokine for cancer immunotherapy in 2007, we have worked to translate that biology into an immunotherapy that activates the trifecta of natural killer cells, CD8+ killer T cells, and memory T cells to deliver durable responses. That same immunological backbone now extends to lung cancer, where ANKTIVA, by stimulating NK cells which target tumor cells that have lost MHC-I T cell receptors, can restore the immune response in patients whose disease has progressed on checkpoint therapy. This approval in lung cancer patients who failed checkpoint inhibitors supports the evidence that the MHC-I receptor is lost in patients who progressed on checkpoint inhibitors,” said Patrick Soon-Shiong, M.D., Founder, Executive Chairman and Global Chief Medical and Scientific Officer of ImmunityBio.

Authorization in Checkpoint-Refractory Metastatic Non-Small Cell Lung Cancer

Per the approved UAE Summary of Product Characteristics, ANKTIVA is indicated in combination with immune checkpoint inhibitors for the treatment of adult patients with metastatic NSCLC with disease progression on or after standard of care (immune checkpoint inhibitors alone or in combination with chemotherapy). Patients with actionable genomic alterations should have disease progression on approved therapy for those alterations, before receiving ANKTIVA in combination with immune checkpoint inhibitors. In this indication, ANKTIVA is administered as a fixed 1 mg subcutaneous dose once every 21 days for the duration of checkpoint inhibitor therapy.

Checkpoint inhibitor resistance represents a defined unmet need in metastatic NSCLC, with limited options and poor survival after progression. By activating the natural killer and memory T cells that checkpoint inhibitors alone do not reach, ANKTIVA is designed to restore anti-tumor immunity in this setting.

Clinical Evidence Supporting the Approvals

NMIBC Indication: The NMIBC authorization is supported by QUILT-3.032, the multicenter registrational trial of ANKTIVA plus BCG in BCG-unresponsive NMIBC.

CIS with or without Papillary Disease (QUILT-3.032, Cohort A): In the CIS cohort (N=100), ANKTIVA plus BCG produced a complete response rate of 71% (95% CI: 61, 80) as shown in table below.

Table 2. Efficacy Results in QUILT-3.032: NMIBC CIS (Cohort A)

Endpoint	ANKTIVA with BCG (n=100)
Complete response rate (95% CI)	71% (61, 80)
Median duration of complete response (DoR), months (95% CI) (n=71)	26.6 (13.0, 49.9)
Range in months[a]	0.0, 54+ months
CR rate of responders at 12 and 24 months	
% (n) with CR at 12 months	66% (47/71)
% (n) with CR at 24 months	42% (30/71)

+ Denotes ongoing response.

[a] Based on 71 patients that achieved a complete response at any time; reflects period from the time complete response was achieved.

Papillary Disease Alone (QUILT-3.032, Cohort B): In the papillary-only cohort (papillary disease without CIS; N=80), the 12-month disease-free survival rate was 58.2% (95% CI: 46.6, 68.2), with a median disease-free survival of 25.3 months, and 83.1% of patients avoided cystectomy at 36 months as shown in the table below.

Table 3. Efficacy Results in QUILT-3.032: Papillary NMIBC (Cohort B)

Endpoint	ANKTIVA with BCG (n=80)
Disease-Free Survival (DFS) Rate at 12 Months (95% CI)[1]	58.2% (46.6, 68.2)
Median Disease-Free Survival (DFS), months (95% CI)[1]	25.3 (9.8, 33.5)
Cystectomy-Free Rate[2]	
Median Time to Cystectomy (months)	Not Reached
Rate at Month 12 (95% CI)	92.2% (83.4, 96.4)
Rate at Month 18 (95% CI)	87.9% (78.0, 93.5)
Rate at Month 24 (95% CI)	87.9% (78.0, 93.5)
Rate at Month 36 (95% CI)	83.1% (70.8, 90.5)

[1] DFS defined as time from initial study drug administration until recurrence of high-grade Ta (excluding low-grade Ta) or any grade T1, persistent CIS ≥6 months, new CIS, disease progression, cystectomy, change in therapy indicative of more advanced disease, or death (any cause), whichever occurred first. Patients who didn't have any evidence of disease at end of study were censored at last known date the patient was disease-free. DFS rate was estimated and DFS was analyzed using Kaplan-Meier analysis method.

[2] Time to cystectomy defined as time from initial study drug administration to cystectomy using Kaplan-Meier analysis method. Patients who did not have documented cystectomy during the study were censored at the last date of follow up visits. Cystectomy-free rates were estimated using Kaplan Meier analysis method.

In the QUILT-3.032 program, most treatment-related adverse events were Grade 1 or 2; Grade 3 treatment-related adverse events occurred in 1% of patients, and no Grade 4 or Grade 5 treatment-related events were reported.

NSCLC Indication: The NSCLC authorization is supported by QUILT-3.055, a Phase 2 study of ANKTIVA in combination with a checkpoint inhibitor in patients with advanced NSCLC whose disease had progressed on prior checkpoint inhibitor therapy (N=79). Median overall survival was 14.6 months (95% CI: 12.0, 19.5). Among the 77% of patients who achieved an absolute lymphocyte count of at least 1,000 cells/µL, median overall survival was 16.2 months (95% CI: 13.8, 22.0). The table below summarizes these findings.

OS Results in QUILT-3.055 – Safety Population

	ANKTIVA plus CPI All NSCLC (N=79)	Mean On-Treatment ALC < 1000/µL (N=18)	Mean On-Treatment ALC ≥ 1000/µL (N=61)	Log-rank P-value	Hazard Ratio (95% CI)
Number of deaths	58 (73%)	14 (78%)	44 (72%)	0.0369	0.52 (0.28, 0.97)
Median OS[a] (months)	14.6	11.8	16.2		
95% CI for the Median OS	12.0, 19.5	6.9, 14.1	13.8, 22.0		
Overall survival (OS) rate[b] at:					
Month 12	61.4% (49.5, 71.4)	44.1% (20.0, 65.9)	66.1% (52.6, 76.6)	-	-
Month 24	29.8% (19.8, 40.4)	12.6% (2.1, 33.0)	34.6% (22.7, 46.8)	-	-

ALC, absolute lymphocyte count; CI, confidence interval; CPI, checkpoint inhibitor; NSCLC, non-small cell lung cancer; OS, overall survival.

[a] OS defined as time from date of first study drug administration to date of death from any cause. Participants who were alive at end of follow-up were censored at the last known date the participant was alive.

[b] OS rates estimated using Kaplan-Meier analysis method.

In QUILT-3.055, the most common NAI-related adverse drug reactions were injection site reaction (86%), chills (46%), fatigue (32%), pyrexia (28%), nausea (16%), injection site erythema and injection site pruritus (15% each), injection site pain (14%), influenza like illness (13%), decreased appetite (10%).

Regulatory Details

The EDE issued Marketing Authorization approval for both presentations with first registration in July 2026 and validity through July 2031. ANKTIVA 0.4 mg (solution for intravesical instillation), indicated for BCG-unresponsive NMIBC, is registered under No. 78609-45860-260486. ANKTIVA 1.2 mg (solution for subcutaneous injection), indicated for metastatic NSCLC, is registered under No. 78609-1572-260487. ImmunityBio, Inc. is the Marketing Authorization Holder, with Modern Pharmaceutical Company serving as the local agent in the United Arab Emirates. The UAE is the fifth regulatory jurisdiction to authorize ANKTIVA, following the United States, the United Kingdom, the Kingdom of Saudi Arabia, and the European Union, and expands the global footprint of ANKTIVA to more than 30 countries.

“With this authorization, the global regulatory footprint for ANKTIVA now includes 34 countries. Securing approvals across two distinct indications, bladder cancer and lung cancer, on the strength of the same data packages we submitted to the FDA, positions us to broaden access across the Gulf region through our partnership with Modern Pharmaceutical Company, in markets where the need for new treatment options is significant,” said Richard Adcock, President and Chief Executive Officer of ImmunityBio.

Sources

1. Chamie K, et al. IL-15 Superagonist NAI (N-803) plus BCG for BCG-Unresponsive Non-Muscle Invasive Bladder Cancer. *NEJM Evidence*. 2023;2(1). (CIS cohort complete response rate.)
2. QUILT-3.032 updated analyses, including the papillary-only (Ta/T1) cohort and extended duration-of-response follow-up, as presented at AUA 2025 and disclosed by ImmunityBio, Inc.
3. QUILT-3.055 Phase 2 overall survival results in checkpoint-refractory advanced NSCLC, as disclosed by ImmunityBio, Inc.

4. ClinicalTrials.gov Identifiers (QUILT-3.032) and (QUILT-3.055).
5. Emirates Drug Establishment, Product Marketing Authorization Approval certificates and approved Summaries of Product Characteristics, Registration Nos. 78609-45860-260486 (NMIBC) and 78609-1572-260487 (NSCLC), first registration 24 July 2026.
6. Immunotherapy Agent Workshop, July 12, 2007 NCI, https://sitc.sitcancer.org/news/nci_manuscript.pdf
7. Cancer Immune Evasion Through Loss of MHC Class I Antigen Presentation. Karthik Dhatchinamoorthy, et. al. https://pmc.ncbi.nlm.nih.gov/articles/PMC7986854/#s14

About ANKTIVA® (nogapendekin alfa inbakicept-pmln)

The interleukin-15 (IL-15) cytokine plays a crucial role in the immune system by affecting the development, maintenance, and function of key immune cells, NK and CD8+ killer T cells, that are involved in killing cancer cells. By activating NK cells, ANKTIVA overcomes the tumor escape phase of clones resistant to T cells and restores memory T cell activity with resultant prolonged duration of complete response. ANKTIVA is a first-in-class IL-15 receptor agonist IgG1 fusion complex, consisting of an IL-15 mutant (IL-15N72D) fused with an IL-15 receptor alpha, which binds with high affinity to IL-15 receptors on NK, CD4+, and CD8+ T cells. This fusion complex of ANKTIVA mimics the natural biological properties of the membrane-bound IL-15 receptor alpha, delivering IL-15 independent of dendritic cells and driving the activation and proliferation of NK cells with the generation of memory killer T cells that have retained immune memory against these tumor clones.

About ImmunityBio, Inc.

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 receptor superagonist, ANKTIVA® (nogapendekin alfa inbakicept). Our Cancer BioShield platform is anchored by this antibody-cytokine fusion protein and is complemented by a 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 U.S. Indication

U.S. Indication and Important Safety Information: The following U.S. Prescribing Information applies only to ANKTIVA® as approved in the United States for the treatment of adults with BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) carcinoma in situ (CIS), with or without papillary tumors, in combination with BCG. ANKTIVA has not been approved in the United States for the treatment of metastatic non-small cell lung cancer (NSCLC).

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.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements involve substantial risks and uncertainties that could cause the Company's clinical development programs, commercial success of its products and product candidates, manufacturing capabilities, continued collaboration with third parties, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such statements include, but are not limited to, statements regarding the commercial availability and uptake of ANKTIVA in the United Arab Emirates, the scope and interpretation of the Marketing Authorizations granted by the Emirates Drug Establishment for the NMIBC and NSCLC indications, the number of jurisdictions and countries in which ANKTIVA is authorized, the timing and outcome of pending and future regulatory submissions in the United States and other jurisdictions, including for papillary disease and for lung cancer, and the clinical benefit, durability of response, overall survival benefit, and safety profile of ANKTIVA in combination with BCG and in combination with immune checkpoint inhibitors Additional risks related to international commercialization include: our reliance on our regional partner in the UAE and their ability to successfully launch and distribute ANKTIVA; the timing and outcome of pricing and reimbursement decisions by UAE health authorities; continued global BCG supply shortages that could limit combination therapy availability; manufacturing and supply chain complexities for international distribution; regulatory actions in any of the 34 countries where ANKTIVA is authorized that could affect labeling or market access; and competition from existing or new therapies in the UAE and broader Gulf region.

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. Actual results may differ materially. For a discussion of factors that could cause actual results to differ, please refer to ImmunityBio's filings with the Securities and Exchange Commission, including its most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q. ImmunityBio does not undertake any obligation to update forward-looking statements.

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