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): October 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 (17 CFR §230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §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 Section13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On October 14, 2026, ImmunityBio, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration (FDA) has expanded the approved indication for ANKTIVA® (nogapendekin alfa inbakicept-pmln) in combination with Bacillus Calmette-Guérin (BCG) to include patients with BCG-unresponsive NMIBC with papillary-only tumors. The full text of the Company's press release 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 October 14, 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: October 14, 2026

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

NEWS RELEASE

FDA Expands ANKTIVA® Approval for BCG-Unresponsive Non-Muscle- Invasive Bladder Cancer to Cover Both Papillary and CIS Disease

- Expanded indication extends ANKTIVA plus BCG to patients with BCG-unresponsive non-muscle-invasive bladder cancer (NMIBC), including those with carcinoma in situ (CIS), with or without papillary tumors, and those with papillary-only tumors
- Papillary disease represents approximately 85% of the NMIBC patient population[1]
- This is the first FDA approval to include BCG-unresponsive NMIBC with papillary-only tumors
- With this FDA approval, access to ANKTIVA plus BCG expands to include all patients with BCG-unresponsive NMIBC

CULVER CITY, Calif., October 14, 2026 — ImmunityBio, Inc. (NASDAQ: IBRX), a commercial-stage immunotherapy company, today announced that the U.S. Food and Drug Administration (FDA) has expanded the approved indication for ANKTIVA® (nogapendekin alfa inbakicept-pmln) in combination with Bacillus Calmette-Guérin (BCG) to include patients with BCG-unresponsive NMIBC with papillary-only tumors.

The expanded FDA label reads as follows: Anktiva, in combination with Bacillus Calmette-Guérin (BCG), is indicated for the treatment of adult patients with BCG-unresponsive non-muscle invasive bladder cancer.[2]

The broadened indication builds on the FDA's April 2024 approval of ANKTIVA plus BCG for patients with BCG-unresponsive NMIBC with carcinoma in situ (CIS).[3] with or without papillary tumors. CIS and papillary tumors are aggressive and associated with high risk of recurrence and progression in the BCG-unresponsive setting. This is the first FDA approval to include BCG-unresponsive NMIBC with papillary-only tumors.

"This approval marks an important expansion of ANKTIVA plus BCG for patients with BCG-unresponsive NMIBC and advances our goal of harnessing the patient's own immune system to achieve durable, tumor-free outcomes," said Dr. Patrick Soon-Shiong, Founder, Executive Chairman, and Global Chief Scientific and Medical Officer of ImmunityBio. "An important first step as we develop immunotherapy 2.0."

The expanded approval is based on the FDA's review of available scientific information, including the previously demonstrated efficacy of ANKTIVA plus BCG in patients with BCG-unresponsive NMIBC with CIS, with or without papillary tumors. In Cohort A of the QUILT-3.032 trial, 62% of 77 patients achieved a complete response (95% CI: 51, 73); among responders, 58% maintained a response for at least 12 months and 40% for at least 24 months.[4]

The combination of ANKTIVA plus BCG has a tolerable safety profile, with the most common treatment-related adverse events (TRAEs) related to bladder instillation (e.g., dysuria, pollakiuria, and hematuria), and most of these TRAEs were grade 1 to 2. This is consistent with the side effects of BCG alone.[4] The prescribing information includes a warning that delaying cystectomy can lead to the development of metastatic bladder cancer, which can be lethal.[2]

Expanding Treatment Options for BCG-Unresponsive NMIBC

Bladder cancer has among the most expensive cancers to treat over a patient's lifetime, reflecting the substantial costs associated with ongoing surveillance, treatment, and disease management.[5] NMIBC accounts for approximately 80% of all bladder cancer diagnoses in the U.S. and includes both CIS and papillary tumors.[6] An estimated 85% to 90% of patients diagnosed with NMIBC present with papillary disease.[7] Patients with high-grade papillary disease that becomes unresponsive to BCG face an increased risk of recurrence and progression and often have limited nonsurgical treatment options.

"Patients with high-grade papillary disease that no longer responds to BCG remain at meaningful risk for recurrence and progression and historically have had limited nonsurgical treatment options," said Sam S. Chang, M.D., Professor of Urology and Chief Surgical Officer of the Vanderbilt Ingram Cancer Center. "The availability of an FDA-approved treatment for this population represents an important addition to the treatment landscape, providing appropriate patients with BCG-unresponsive disease another treatment option that may help preserve the bladder."

ANKTIVA's expansion into BCG-unresponsive high-grade papillary-only NMIBC significantly increases its U.S. addressable patient population beyond the currently approved CIS with or without papillary indication.

"The expansion of ANKTIVA plus BCG into papillary-only disease broadens the eligible patient population and establishes it as the first FDA-approved therapy for both CIS and papillary-only disease in BCG-unresponsive NMIBC," added Richard Adcock, President and CEO of ImmunityBio. "Building on strong commercial growth since ANKTIVA's initial approval, we remain focused on helping eligible patients access this therapy and are grateful to the patients, families, investigators, and clinical teams who made this progress possible."

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.

IMPORTANT SAFETY INFORMATION

INDICATION AND USAGE: ANKTIVA® is an interleukin-15 (IL-15) receptor agonist indicated in combination with Bacillus Calmette-Guérin (BCG) for the treatment of adult patients with BCG-unresponsive nonmuscle invasive bladder cancer (NMIBC).

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 BCG-unresponsive NMIBC have evidence of high-grade disease 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.

USE IN SPECIFIC POPULATIONS: Pregnancy: May cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception.

ADVERSE REACTIONS: The most common (≥15%) adverse reactions, including laboratory test abnormalities, are increased creatinine, dysuria, hematuria, urinary frequency, micturition urgency, urinary tract infection, increased potassium, musculoskeletal pain, chills, and pyrexia. For more information, please see the Prescribing Information for ANKTIVA® at Anktiva.com.

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 receptor agonist, 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.

References

1. Anastasiadis A, de Reijke TM. Best practice in the treatment of nonmuscle invasive bladder cancer. Ther Adv Urol. 2012 Feb;4(1):13-32. doi: 10.1177/1756287211431976. PMID: 22295042; PMCID: PMC3263923. Available at https://pmc.ncbi.nlm.nih.gov/articles/PMC3263923/
2. https://anktiva.com/wp-content/uploads/ANKTIVA-Annotated-Approved-Label-Clean.pdf U.S. Food and Drug Administration (FDA). FDA approves nogapendekin alfa inbakicept-pmln for BCG-unresponsive nonmuscle invasive bladder cancer. U.S. FDA April 2024.
3. https://immunitybio.com/immunitybio-announces-fda-approval-of-anktiva-first-in-class-il-15-receptor-agonist-for-bcg-unresponsive-non-muscle-invasive-bladder-cancer/

4. Chang SS, et al. J Urol. 2026;215(1):44–56. doi:10.1097/JU.0000000000004782.

5. Mossanen M, Gore JL. The burden of bladder cancer care: direct and indirect costs. *Curr Opin Urol.* 2014;24(5):487–491. doi:10.1097/MOU.0000000000000078.

6. PubMed Central. https://pmc.ncbi.nlm.nih.gov/articles/PMC3263923/.

7. Song J, et al. Contemporary data on incidence, treatments and outcomes of high-grade NMIBC in the US. Presented at: New England AUA Annual Meeting; 2019.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. All statements contained in this press release other than statements of historical fact, including statements regarding the potential benefits, commercial opportunities, market potential, and anticipated impact of the U. S. Food and Drug Administration's approval of the expanded indication for ANKTIVA® (nogapendekin alfa inbakicept-pmln) are forward-looking statements.

Forward-looking statements include, without limitation, statements regarding the Company's expectations, beliefs, plans, objectives, strategies, prospects, and future performance relating to: the potential clinical benefits, safety, effectiveness, utility, and therapeutic value of ANKTIVA® for patients within the newly approved indication; the potential for ANKTIVA® to address unmet medical needs, improve patient outcomes, or become an important treatment option or standard of care; the size and characteristics of the patient population eligible for treatment; the potential market opportunity and commercial potential associated with the expanded indication; the anticipated timing, scope, effectiveness, and success of the Company's commercialization, promotional, marketing, medical affairs, market access, and product launch activities; the anticipated adoption, utilization, prescribing patterns, and acceptance of ANKTIVA® by physicians, patients, healthcare providers, payors, and other stakeholders; the Company's ability to obtain, maintain, or expand adequate coverage, reimbursement, formulary access, and favorable pricing for ANKTIVA®; the anticipated effect of the expanded indication on product demand, sales, revenue, profitability, cash flows, financial condition, and future operating results; the Company's ability to manufacture, supply, distribute, and commercialize sufficient quantities of ANKTIVA® to meet anticipated demand; the potential competitive positioning of ANKTIVA® relative to existing and future treatment alternatives; and the Company's plans and expectations concerning additional clinical development, regulatory submissions, label expansions, lifecycle management, and other potential opportunities for ANKTIVA®.

These statements may be identified by words such as "aim," "anticipate," "believe," "contemplate," "could," "estimate," "expect," "forecast," "goal," "intend," "may," "plan," "possible," "potential," "predict," "project," "seek," "should," "strive," "target," "will," "would," and similar expressions.

These forward-looking statements are based on the Company's current expectations, estimates, forecasts, assumptions, and beliefs as of the date of this press release and involve known and unknown risks, uncertainties, assumptions, and other factors, many of which are outside the Company's control, that could cause actual results, developments, performance, or achievements to differ materially from those expressed, implied, or anticipated by such statements. Such risks and uncertainties include, among others: the possibility that the expanded indication for ANKTIVA® will not

result in the anticipated levels of physician adoption, patient utilization, market penetration, product demand, or commercial success; that the actual number of patients eligible for or receiving treatment may be smaller than anticipated; that physicians, patients, treatment guidelines, healthcare institutions, or payors may not adopt or support use of ANKTIVA® to the extent or within the time frames anticipated; that clinical experience following approval may differ from results observed in clinical trials; that additional safety, tolerability, efficacy, or other product-related information, including adverse events or previously unidentified risks, may emerge through post-marketing surveillance, real-world use, or additional studies; and that the Company may encounter unexpected challenges in complying with ongoing regulatory requirements, including those governing manufacturing, product quality, pharmacovigilance, advertising, promotion, and commercialization. Additional risks and uncertainties include: the Company's ability to successfully execute its commercial strategy for the expanded indication; the effectiveness of its sales force, marketing initiatives, medical education efforts, distribution arrangements, and other commercialization activities; limitations on the Company's ability to promote ANKTIVA® outside its approved labeling; the availability, scope, timing, and adequacy of coverage and reimbursement from Medicare, Medicaid, commercial insurers, and other third-party payors; pricing pressures, rebates, discounts, utilization management restrictions, prior authorization requirements, and changes in healthcare laws, regulations, and reimbursement policies; the impact of federal and state drug pricing initiatives and other healthcare cost-containment measures; competition from currently marketed products, newly approved therapies, generic products, biosimilars, and other existing or emerging treatment modalities; changes in clinical practice guidelines or treatment paradigms; the ability of the Company and its third-party manufacturers and suppliers to maintain adequate manufacturing capacity, product quality, inventory levels, and reliable supply chains; manufacturing deviations, quality-control issues, product shortages, recalls, or disruptions in distribution; and the Company's ability to protect, maintain, and enforce intellectual property rights, regulatory exclusivities, and other proprietary rights relating to ANKTIVA®.

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 February 23, 2026, Quarterly Report on Form 10-Q filed with the SEC on August 4, 2026, 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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