ImmunityBio Reports 60% Increase in Revenue in Q2 2025, with Year-to-Date Sales of $43 Million and 246% Unit Growth Since J-Code with Regulatory Updates

July 25, 2025

CULVER CITY, Calif.--(BUSINESS WIRE)--Jul. 25, 2025-- ImmunityBio, Inc. (NASDAQ: IBRX), a leading immunotherapy company, today announced preliminary financial results for the fiscal quarter ended June 30, 2025, and clinical progress across its pipeline.

Key Highlights

- **Q2 2025 Revenue Growth with Continued Strong Sales Momentum**: $26.4 million, up 60% from Q1 2025, with year-to-date sales of ~$43 million.
- **ANKTIVA® Unit Growth Since J-Code:** 246% unit sales volume growth in 1H 2025 compared to 2H 2024.
- **Cash Position**: $153.7 million in cash, cash equivalents and marketable securities as of June 30, 2025.
- **NSCLC**: Initiated randomized clinical trial (RCT) ResQ201A with N-803 + tislelizumab in 2nd line lung cancer; US sites initiated, submitted clinical trial applications in EU, UK; Canada and Asia filings planned.
- **Lymphopenia**: FDA supportive of new data; reaffirmed RMAT/EAP; collaborative discussion outlining regulatory endpoints, trial design and registrational pathways to full approval for the treatment of lymphopenia with randomized trial design in progress.
- Full Enrollment Reached in the Randomized NCI Cancer Prevention Clinical Trial Using ANKTIVA + Adenovirus Vaccine in 186 Patients with Lynch Syndrome.
- United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) marketing authorization application of ANKTIVA approved.
- **Papillary NMIBC**: Discussion with FDA regarding filing status of supplemental BLA. ImmunityBio performing ongoing evaluation of next steps to address the Refuse to File decision by the FDA, following June Type A meeting with the Agency. New updated data on Papillary disease provided to the FDA and discussions with Agency to continue. Separately, ImmunityBio has applied to the National Comprehensive Cancer Network (NCCN) to seek expansion of the BCG-unresponsive NMIBC guidelines to include papillary-only disease.

Financial Overview

In the second quarter of 2025, ImmunityBio reported **$26.4 million in revenue**, representing a **60% increase** from $16.5 million in the first quarter of 2025. This growth reflects continued commercial traction of ANKTIVA + BCG in BCG-unresponsive non-muscle invasive bladder cancer with CIS with or without Papillary tumors. The 1H 2025 sales of $42.9 million represents a 246% increase in unit volume during the first two quarters of 2025 since the J-code approval versus the last two quarters of 2024. The Company ended the quarter with **$153.7 million in cash, cash equivalents and marketable securities** as of **June 30, 2025**.

Non-Muscle Invasive Bladder Cancer (Papillary NMIBC)

ImmunityBio conducted a Type A meeting with the FDA in June to discuss its program targeting papillary-only NMIBC and the Agency's response to the supplemental BLA filing. Contrary to the advice the FDA gave the Company in January 2025 to submit the supplemental BLA, the FDA responded with a Refuse-to-File (RTF) notice in May on the basis of requiring a randomized controlled trial (RCT) against chemotherapy. At the June meeting, ImmunityBio provided new data regarding the updated results since the initial BLA filing of papillary only data as well as real-world data of chemotherapy just published in this indication. In the papillary only NMIBC new data based on 26 of the 100 subjects in Cohort A and 80 subjects in Cohort B (Papillary Alone) of our QUILT-3.032 trial, demonstrated long-term (36-month) progression free survival and bladder sparing with ANKTIVA + BCG. ImmunityBio presented the newly published real-world data which demonstrates that compared to chemotherapy, ANKTIVA + BCG led to improved outcomes of progression free survival and cystectomy avoidance at 36-months. To our knowledge, the results to date of ANKTIVA + BCG represent the longest duration of follow-up with the longest duration of bladder sparing in these subjects. The Company indicated at the meeting that it would seek a new meeting request with this new data and withdraw the prior supplemental BLA filing; however, the Company is re-evaluating this approach in consultation with its regulatory counsel and may seek to amend the initial filing with the new data rather than withdrawing it, with a commitment to initiate a randomized controlled trial of chemotherapy free ANKTIVA + BCG versus chemotherapy in the papillary alone indication.

Separately, ImmunityBio has applied to the National Comprehensive Cancer Network (NCCN) to seek expansion of the BCG-unresponsive NMIBC guidelines to include papillary-only disease, in addition to the currently recognized CIS with or without papillary disease. The NCCN is expected to review the submission at its August 2025 meeting.

Non-Small Cell Lung Cancer (NSCLC)

ImmunityBio has launched ResQ201A, a randomized controlled trial, in the United States, evaluating its IL-15 superagonist N-803 in combination with tislelizumab, a PD-1 checkpoint inhibitor from BeOne Medicines in patients with 2nd line lung cancer who were progressing on checkpoint inhibitors. The Company has also submitted clinical trial applications for ResQ201A in the European Union and the United Kingdom, with Canada expected to be

submitted in early Q3 2025, and with plans underway to submit in Asia.

Lymphopenia

The Company also met with the Division of Non-Malignant Hematology at the FDA in June to present updated data from its lymphopenia program. The Division was supportive of the findings including the underlying science of stimulating lymphocytes with ANKTIVA and expressed a desire to support an efficient path to approval, noting that additional time will be required to finalize the appropriate development plan. Expanded Access Program (EAP) authorization has been activated for the indication for all solid tumors in patients who have failed first-line treatment on chemotherapy, radiotherapy or immunotherapy and exhibit low Absolute Lymphocyte Counts (ALC < 1,000/μL).

Disclaimer Regarding Financial Overview

The information and amounts presented above, including under the caption “Financial Overview,” reflects the Company’s preliminary estimates based solely upon information available to it as of the date of this press release, and the amounts reported are not a comprehensive statement of its financial results or position as of June 30, 2025. Any actual amount that the Company reports in its Quarterly Report on Form 10-Q for the period ended June 30, 2025 will be subject to its financial closing procedures and any final adjustments that may be made prior to the time its financial results for the period ended June 30, 2025 are finalized. As a result, these preliminary estimates may differ materially from the actual results that will be reflected in the Company’s condensed consolidated financial statements for the quarter when they are completed and publicly disclosed.

About ANKTIVA

The cytokine interleukin-15 (IL-15) 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 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 by dendritic cells and drives the activation and proliferation of NK cells with the generation of memory killer T cells that have retained immune memory against these tumor clones. The proliferation of the trifecta of these immune killing cells and the activation of trained immune memory results in immunogenic cell death, inducing a state of equilibrium with durable complete responses. ANKTIVA has improved pharmacokinetic properties, longer persistence in lymphoid tissues, and enhanced anti-tumor activity compared to native, non-complexed IL-15 in-vivo.

ANKTIVA was approved by the FDA in 2024 and by UK MHRA in 2025 for BCG-unresponsive non-muscle invasive bladder cancer CIS with or without papillary tumors. For more information, visit 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 natural killer 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 discussions and meetings with the U.S. FDA, including with respect to the previously reported RTF letter received by the Company and potential implications thereof, potential next steps, decisions and timeline related to the Company’s regulatory submissions and strategy, financial results anticipated to be reported in future SEC filings, clinical trial data and potential results and implications to be drawn therefrom, the expectation that the EAP described herein will enable patients to have access to ANKTIVA for the indication described, the RMAT designation as previously reported and potential results therefrom and regulatory submissions in connection therewith, the belief that ALC levels and NLR levels obtained from a CBC are predictors of clinical benefit and outcomes relating to overall survival, clinical trial and expanded access program enrollment, timing, data and potential results to be drawn therefrom, anticipated components of ImmunityBio’s Cancer BioShield ™ platform, anticipated review timeline for the Company’s NCCN guidelines submission in NMIBC papillary only and potential implications therefrom, 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, potential future uses and applications of ANKTIVA alone or in combination with other therapeutic agents for the prevention or reversal of lymphopenia, potential future uses and applications of ANKTIVA alone or in combination with other therapeutic agents across multiple tumor types and indications and for potential applications beyond oncology, potential regulatory pathways and the regulatory review process and timing thereof, the application of the Company’s science and platforms to treat cancers or develop cancer vaccines, immunotherapies and cell therapies that have the potential to change the paradigm in cancer care, 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 the FDA regulatory submission, filing and review process and the timing thereof, (ii) whether the RMAT designation will lead to an accelerated review or approval, of which there can be no assurance, (iii) risks and uncertainties regarding commercial launch execution, success and timing, (iv) risks and uncertainties regarding participation and enrollment and potential results from the expanded access clinical investigation program described herein, (v) whether clinical trials will result in registrational pathways and the risks, (vi) whether clinical trial data will be accepted by regulatory agencies, (vii) 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, (viii) potential delays in product availability and regulatory approvals, (ix) ImmunityBio's ability to retain and hire key personnel, (x) ImmunityBio's ability to obtain additional financing to fund its operations and complete the development and commercialization of its various product candidates, (xi) potential product shortages or manufacturing disruptions that may impact the availability and timing of product, (xii) ImmunityBio's ability to successfully commercialize its approved product and product candidates, (xiii) ImmunityBio's ability to scale its manufacturing and commercial supply operations for its approved product and future approved products, (xiv) whether the NCCN will review and/or approve the Company's submission described herein on the anticipated timeline or at all, and (xv) 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 May 12, 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.

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