



ImmunityBio Reports Sales Momentum & Unit Growth Since Permanent J-code Issuance (J9028) in January 2025 and Financial Results for Year End 2024

March 3, 2025

- With a permanent J-code (J9028) awarded in January 2025, ImmunityBio's February 2025 ANKTIVA® unit sales volume grew 97% over unit sales volume in December 2024
- ANKTIVA sales momentum continues to trend upward quarter to date 2025, with sales volume in February representing a 67% increase month-over-month from January
- Sales volume in the 2 months in 2025 to date shows a 69% increase over the sales volume in the 2 months prior (November and December 2024) and already exceeds the total units for all of Q4 2024
- For the three-month period ending December 31, 2024 prior to permanent J-code approval, ImmunityBio achieved net product revenue of approximately \$7.2 million, surpassing net product revenue of \$6.0 million in the prior quarter, a 21% quarter over quarter increase
- FDA authorization of expanded access of an alternative source of BCG in February 2025 is expected to address the issue of BCG shortage with over 45,000 doses available
- Over 60 sites are now being activated to receive recombinant BCG (rBCG) under the Expanded Access Program
- Global submission of marketing authorization applications (MAAs) for the treatment of patients with BCG-unresponsive NMIBC with CIS with or without papillary tumors for ANKTIVA in combination with BCG to the Medicines and Healthcare products Regulatory Agency (MHRA) and to the European Medicines Agency (EMA) in the European Union (EU) have been accepted for review in February 2025
- Regenerative Medicine Advanced Therapy (RMAT) designation granted by the FDA in February 2025 for ANKTIVA and CAR-NK (PD-L1 t-haNK) in combination with standard-of-care chemotherapy/radiotherapy indicated for:
 - the reversal of lymphopenia and
 - treatment of multiply relapsed locally advanced or metastatic pancreatic cancer
- Over 100 participants have now received ANKTIVA in cancer prevention trial with goal to prevent colon cancer in subjects with Lynch Syndrome
- Analyst Investor Day Conference planned for April 2025 (invitations to follow)

CULVER CITY, Calif.--(BUSINESS WIRE)--Mar. 3, 2025-- ImmunityBio, Inc. ([NASDAQ:IBRX](#)), a leading immunotherapy company, today announced certain operational results following approval of the permanent J-code (J9028) in January 2025, as well as its financial results for the fourth-quarter and full year ended December 31, 2024.

With the issuance of the permanent J-code in January 2025, ImmunityBio has seen increased sales momentum supporting a trend of increases month-over-month as well as quarter-over-quarter, with February unit sales volume increasing 67% over January, and February and January unit sales combined exceeding unit sales achieved for all of Q4 2024. ImmunityBio earned net product revenue of approximately \$7.2 million during the three-month period ending December 31, 2024, which represented an increase of 21% over the \$6.0 million of net revenue earned during the third quarter of 2024.

The TICE BCG shortage was addressed with the FDA authorization to ImmunityBio of Expanded Access of the recombinant BCG (rBCG) supplied by the Serum Institute of India (SII). With the authorization in February 2025, over 60 sites in the United States are being activated to receive rBCG. The first patient dosed with rBCG in the United States is anticipated in March 2025. ImmunityBio anticipates that over 45,000 vials of rBCG will be available for the United States in 2025 to address the overall BCG shortage.

Global submission of marketing authorization applications (MAAs) for the treatment of patients with BCG-unresponsive NMIBC with CIS with or without papillary tumors for ANKTIVA in combination with BCG to the Medicines and Healthcare products Regulatory Agency (MHRA) and to the European Medicines Agency (EMA) in the European Union (EU) have been accepted for review in February 2025.

In January 2025, the Company announced a collaboration and supply agreement with BeiGene, Ltd. (to be renamed to BeOne Medicines, Ltd.), a global oncology company, to conduct a confirmatory randomized Phase 3 clinical trial (ResQ201A-NSCLC), combining BeOne's tislelizumab, a PD-1 checkpoint inhibitor (CPI), and our ANKTIVA (nogapendekin alfa inbakicept-pmln) product. The Phase 3 ResQ201A-NSCLC study aims to confirm the efficacy and safety of combination ANKTIVA plus CPI therapy previously demonstrated in the QUILT 3.055 trial and provide evidence of the potential for these two immunotherapeutic agents to improve overall survival in patients with advanced or metastatic non-small cell lung cancer who have acquired resistance to immune CPI therapy.

In February 2025, ImmunityBio received an important authorization from the FDA designating ANKTIVA plus PD-L1 t-haNK as Regenerative Medicine Advanced Therapies (RMAT). The significance of a RMAT designation, which was established under the 21st Century Cures Act, is to expedite the development and review of promising therapeutic candidates, including cell therapies, that are intended to treat, modify, reverse or cure a serious or life-threatening disease. RMAT designation includes benefits, such as early interactions with the FDA, including discussions on surrogate or intermediate endpoints that could potentially support accelerated approval and satisfy post-approval requirements, and potential priority review of a

product's biologics license application (BLA). The RMAT designation was granted for ANKTIVA and CAR-NK (PD-L1 t-haNK) in combination with standard-of-care chemotherapy/radiotherapy indicated for:

- the reversal of lymphopenia and
- the treatment of multiply relapsed locally advanced or metastatic pancreatic cancer

"The first quarter of 2025 has been an inflection point for the Company with multiple milestones achieved. The approval of ANKTIVA and the permanent J-code, the trajectory of adoption of ANKTIVA by urologists for BCG unresponsive non-muscle invasive bladder cancer CIS, the authorization of expanded access of recombinant BCG to address the TICE BCG shortage, the acceptance of our global marketing submission to EMA and MHRA, the collaboration with BeOne for checkpoint inhibitor supply, and most importantly the potentially transformative RMAT designation by the FDA of ANKTIVA + PD-L1 t-haNK for the reversal of lymphopenia, all occurring at a rapid pace and demonstrating excellent execution are a testament to the strength of the organization and its ability to continue to execute on its ambitious growth plans for this year," said Dr. Patrick Soon-Shiong, Founder, Executive Chairman, Global Chief Scientific & Medical Officer of ImmunityBio. Dr. Soon-Shiong continued, "The RMAT designation positions ANKTIVA to be the backbone of our strategy for Immunotherapy 2.0 beyond checkpoints and the potential foundation of this first-in-class IL-15 receptor superagonist as a therapeutic cancer vaccine with over 100 participants enrolled in the Lynch Syndrome trial to evaluate cancer prevention in this high-risk population."

Fourth-Quarter Ended December 31, 2024 Financial Summary and Comparison to Prior Year Quarter

Product Revenue, Net

Product revenue, net increased \$7.2 million during the three months ended December 31, 2024, as compared to the three months ended December 31, 2023. The increase was driven by sales of ANKTIVA after FDA approval in April 2024.

Research and Development Expenses

Research and development (R&D) expenses decreased \$16.3 million to \$35.2 million during the three months ended December 31, 2024, as compared to \$51.5 million during the three months ended December 31, 2023. The decrease was primarily driven by lower research agreement expenses, inventory capitalization, less contract manufacturing organization activities, and lower consulting costs.

Selling, General and Administrative Expenses

Selling, general and administrative expense increased \$8.6 million to \$41.7 million during the three months ended December 31, 2024, as compared to \$33.1 million during the three months ended December 31, 2023. The increase was due to higher costs related to post-commercialization activities and a litigation settlement.

Net Loss Attributable to ImmunityBio Common Stockholders

Net loss attributable to ImmunityBio common stockholders was \$59.2 million during the three months ended December 31, 2024, compared to \$233.4 million during the three months ended December 31, 2023. The reduction of loss was primarily driven by product revenue and changes in the fair value of related-party convertible notes and warrant liabilities.

Fiscal Year Ended December 31, 2024 Financial Summary and Comparison to Prior Year

Cash and Marketable Securities Position

As of December 31, 2024, the Company had consolidated cash and cash equivalents, and marketable securities of \$149.8 million.

Product Revenue, Net

Product revenue, net increased \$14.1 million during the year ended December 31, 2024, as compared to the year ended December 31, 2023. The increase was driven by sales of ANKTIVA after FDA approval in April 2024.

Research and Development Expenses

R&D expenses decreased \$42.2 million to \$190.1 million during the year ended December 31, 2024, as compared to \$232.3 million during the year ended December 31, 2023. The decrease was mainly due to less contract manufacturing organization activities, inventory capitalization, lower research agreement expenses, and lower consulting costs.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased \$39.2 million to \$168.8 million during the year ended December 31, 2024, as compared to \$129.6 million during the year ended December 31, 2023. The increase was primarily driven by higher legal expenses, higher consulting fees and other operating costs related to post-commercialization marketing activities and higher salary and benefits expenses, partially offset by lower stock-based compensation expenses.

Net Loss Attributable to ImmunityBio Common Stockholders

Net loss attributable to ImmunityBio common stockholders was \$413.6 million during the year ended December 31, 2024, compared to \$583.2 million during the year ended December 31, 2023. This reduction of loss was primarily driven by product revenue and changes in the fair value of related-party convertible notes and warrant liabilities.

ImmunityBio, Inc.

Condensed Consolidated Statements of Operations

	Three Months Ended December 31,		Year Ended December 31,	
	2024	2023	2024	2023
<i>(in thousands, except per share amounts)</i>				
Revenue				
Product revenue, net	\$ 7,206	\$ —	\$ 14,150	\$ —
Other revenues	346	139	595	622
Total revenue	7,552	139	14,745	622
Operating costs and expenses				
Cost of product revenue	—	—	—	—
Research and development (including amounts with related parties)	35,221	51,532	190,144	232,366
Selling, general and administrative (including amounts with related parties)	41,731	33,110	168,783	129,620
Impairment of intangible assets	—	886	—	886
Total operating costs and expenses	76,952	85,528	358,927	362,872
Loss from operations	(69,400)	(85,389)	(344,182)	(362,250)
Other income (expense), net:				
Interest and investment income, net	1,187	484	7,975	1,131
Change in fair value of warrant and derivative liabilities, and related-party convertible notes	46,598	(116,352)	76,904	(83,803)
Interest expense (including amounts with related parties)	(26,071)	(31,862)	(114,670)	(128,934)
Interest expense related to revenue interest liability	(11,503)	(264)	(39,657)	(264)
Other income (expense), net (including amounts with related parties) and loss on equity method investment	10	(71)	(15)	(9,772)
Total other income (expense), net	10,221	(148,065)	(69,463)	(221,642)
Loss before income taxes and noncontrolling interests	(59,179)	(233,454)	(413,645)	(583,892)
Income tax expense	—	40	—	40
Net loss	(59,179)	(233,414)	(413,645)	(583,852)
Net loss attributable to noncontrolling interests, net of tax	(17)	(22)	(81)	(656)

Net loss attributable to ImmunityBio common stockholders	\$ (59,162)	\$ (233,392)	\$ (413,564)	\$ (583,196)
Net loss per ImmunityBio common share – basic	\$ (0.08)	\$ (0.35)	\$ (0.59)	\$ (1.15)
Net loss per ImmunityBio common share – diluted	\$ (0.09)	\$ (0.35)	\$ (0.62)	\$ (1.15)
Weighted-average number of common shares used in computing net loss per share – basic	733,204	667,811	697,312	508,636
Weighted-average number of common shares used in computing net loss per share – diluted	734,542	667,811	700,443	508,636

ImmunityBio, Inc.

Selected Balance Sheet Data

	As of December 31,	
(in thousands)	2024	2023
Cash and cash equivalents, and marketable securities	\$ 149,809	\$ 267,353
Total assets	382,933	504,452
Total related-party debt	461,877	681,537
Revenue interest liability	284,404	155,415
Total liabilities	871,062	1,090,389
Total ImmunityBio stockholders' deficit	(489,098)	(586,987)
Total liabilities and stockholders' deficit	382,933	504,452

ImmunityBio, Inc.

Summary Reconciliations of Cash Flows

	Three Months Ended December 31,		Year Ended December 31,	
(in thousands)	2024	2023	2024	2023
Cash (used in) provided by:				
Net cash used in operating activities	\$ (85,144)	\$ (115,271)	\$ (391,236)	\$ (366,757)
Net cash provided by (used in) investing activities	9,834	2,249	(12,246)	(30,470)

Net cash provided by financing activities	106,929	200,539	281,630	558,341
Effect of exchange rate changes on cash and cash equivalents, and restricted cash	(7)	(27)	(23)	(292)
Net change in cash and cash equivalents, and restricted cash	31,612	87,490	(121,875)	160,822
Cash and cash equivalents, and restricted cash, beginning of period	112,300	178,297	265,787	104,965
Cash and cash equivalents, and restricted cash, end of period	\$ 143,912	\$ 265,787	\$ 143,912	\$ 265,787

About ANKTIVA

Cytokine fusion proteins, such as ANKTIVA, represent a novel class of biologics that improve immune responses by enhancing the therapeutic potential of cytokines and promoting lymphocyte infiltration at a site of disease. 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.

ANKTIVA is a first-in-class IL-15 receptor superagonist IgG1 fusion complex, consisting of an IL-15 mutant (IL-15N72D) fused with an IL-15R α , which binds with high affinity to IL-15 receptors on NK, CD4+, and CD8+ T cells. This fusion complex of ANKTIVA, which confers stability and longer half-life than recombinant or native IL-15, mimics the natural biological properties of the membrane-bound IL-15R α , 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. By activating NK cells, ANKTIVA overcomes the tumor escape phase of clones resistant to T cells without stimulating immunosuppressive T-reg cells and restores memory T cell activity with resultant prolonged duration of complete response. Further, by stimulating the release of interferon- γ , ANKTIVA restores MHC-I expression, making more tumor cells targets for T-cell killing. As evidenced by its ability to increase lymphocyte counts in healthy adults in Phase 1 testing, ANKTIVA also has the potential to rescue lymphopenia, which is associated with poor prognosis in cancer before treatment or as a consequence of chemo- or radiation therapy.

[ANKTIVA was approved by the FDA in 2024](#) for use in the United States with BCG for the treatment of adult patients with BCG-unresponsive non-muscle invasive bladder cancer with CIS with or without papillary tumors. For more information, visit [ImmunityBio.com](#) (Founder's Vision) and [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 platforms, alone and together, act to drive an immune response with the goal of creating durable immune memory generating safe protection against disease. We are applying our 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 future operating results and prospects, commercialization activities, momentum and market data, market access initiatives and coverage under medical reimbursement policies, the timing of shipments under the rBCG EAP, expected available doses of rBCG supply, anticipated patient enrollment and timing of dosing, the expectation that the rBCG EAP will enable ImmunityBio to reliably bring an alternative source of BCG to patients in the U.S., the utility of rBCG to improve immunogenicity and safety in comparison to earlier strains and formulations of BCG, the RMAT designation referenced herein and potential results therefrom, the related anticipated EAP submission and timing thereof, the related anticipated BLA submission and timing thereof, global expansion efforts and anticipated timeline of regulatory review of our pending MAAs by the MHRA and EMA, clinical trial enrollment, data and potential results to be drawn 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 for the reversal of lymphopenia and use in combination with checkpoint inhibitors or in cancer vaccines and across multiple tumor types, 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 commercial launch execution, success and timing, (ii) risks and uncertainties related to the regulatory submission, filing and review process and the timing thereof with respect to the FDA, EMA, MHRA and other regulatory agencies, (iii) risks and uncertainties regarding the timing of shipments under the rBCG EAP and ImmunityBio's ability to establish and maintain a reliable source of BCG under the EAP, (iv) whether the RMAT designation will lead to an accelerated review or approval, of which there can be no assurance, (v) ImmunityBio's ability to submit the regulatory submissions referenced herein on the anticipated timeline or at all, (vi) the ability of ImmunityBio to fund its ongoing and anticipated clinical trials, (vii) whether clinical trials will result in registrational pathways, (viii) whether

clinical trial data will be accepted by regulatory agencies, (ix) 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, (x) potential delays in product availability and regulatory approvals, (xi) the risks and uncertainties associated with third-party collaborations and agreements, including that with Serum Institute of India, (xii) ImmunityBio's ability to retain and hire key personnel, (xiii) ImmunityBio's ability to obtain additional financing to fund its operations and complete the development and commercialization of its various product candidates, (xiv) potential product shortages or manufacturing disruptions that may impact the availability and timing of product, (xv) ImmunityBio's ability to successfully commercialize its approved product and product candidates, (xvi) ImmunityBio's ability to scale its manufacturing and commercial supply operations for its approved product and future approved products, and (xvii) 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 19, 2024 and the Company's Form 10-Q filed with the SEC on November 12, 2024, 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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