ImmunityBio Reports Third-Quarter 2024 Financial Results

November 12, 2024

CULVER CITY, Calif.--(BUSINESS WIRE)--Nov. 12, 2024-- ImmunityBio, Inc. (NASDAQ: IBRX) today announced its financial results for the third-quarter ended September 30, 2024.

- ANKTIVA® received a J-code (HCPCS Level II Code) in October 2024, effective January 1, 2025.
- ANKTIVA (FDA-approved and commercially available in the U.S. since May 2024) is now widely accessible to patients through commercial and government insurance programs (VA, DoD, Medicare). ImmunityBio has secured coverage for over 200 million medical lives through medical reimbursement policies.
- ImmunityBio achieved a net product revenue of approximately $6.0 million during the three months ended September 30, 2024, surpassing net product revenue of $1.0 million in the prior quarter and analyst estimates.
- ImmunityBio has extended the shelf life of ANKTIVA from two years to three years, with over 125,000 doses, providing ample product for the market and for clinical trials.
- ImmunityBio submitted to the Medicines and Healthcare products Regulatory Agency (MHRA) a Marketing Authorization Application (MAA) for ANKTIVA in the United Kingdom on November 1, 2024.
- ImmunityBio intends to submit to the European Medicines Agency (EMA) an MAA for ANKTIVA in the European Union (EU) in Q4 2024, covering 30 countries, including 27 in the EU and 3 in the European Economic Area (Iceland, Norway, Liechtenstein).

“The U.S. launch of ANKTIVA for NMIBC CIS continues to gain momentum, and we are pleased to see the clinical impact for patients,” said Richard Adcock, President and CEO of ImmunityBio. “Our permanent J-code has been issued by Centers for Medicare and Medicaid Services and will be effective January 1, 2025. Our submission of ANKTIVA for NMIBC CIS to the MHRA in the UK for potential approval demonstrates our plans for global expansion. Further, we anticipate an EU submission this quarter.”

“The response from the urologists and clinical practices with regard to the utility of ANKTIVA in NMIBC CIS has been gratifying. ImmunityBio’s clinical trial in BCG naïve NMIBC is enrolling well, and clinical sites have been expanded from the U.S. to multiple global locations. In the urology space, initial clinical trials of ANKTIVA are being designed for high-risk prostate cancer,” said Dr. Patrick Soon-Shiong, Executive Chairman, Global Chief Scientific & Medical Officer of ImmunityBio. “With the approval of ANKTIVA and the label of activating NK cells, CD4+ CD8+ T cells with memory T cells, ImmunityBio is focusing the regulatory development of ANKTIVA in BCG naïve bladder cancer and non-small cell lung cancer (NSCLC) patients who have failed checkpoint inhibitors.”

Third-Quarter Ended September 30, 2024 Financial Summary

Cash and Marketable Securities Position

As of September 30, 2024, the Company had consolidated cash and cash equivalents, and marketable securities of $130.4 million.

Research and Development Expenses

Research and development (R&D) expenses increased $2.0 million to $50.4 million during the three months ended September 30, 2024, as compared to $48.4 million during the three months ended September 30, 2023. The increase was primarily driven by personnel-related and other R&D costs, partially offset by a decrease in external R&D expense driven by lower CMO fees and material purchases.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased $4.1 million to $35.9 million during the three months ended September 30, 2024, as compared to $31.8 million during the three months ended September 30, 2023. The increase was primarily driven by higher salaries and benefits expense as a result of a reversal of discretionary compensation not paid in the prior period and an increase in consulting costs associated with commercial activities.

Net Loss Attributable to ImmunityBio Common Stockholders

Net loss attributable to ImmunityBio common stockholders was $85.7 million during the three months ended September 30, 2024, compared to $95.6 million during the three months ended September 30, 2023.

ImmunityBio, Inc.

Condensed Consolidated Statements of Operations

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands, except per share amounts; unaudited)	**2024**	**2023**	**2024**	**2023**
Revenue				
Product revenue, net	$ 5,954	$ —	$ 6,944	$ —
Other revenues	152	82	249	483
Total revenue	6,106	82	7,193	483
Operating costs and expenses				
Cost of product revenue	—	—	—	—
Research and development (including amounts with related parties)	50,443	48,402	154,923	180,834
Selling, general and administrative (including amounts with related parties)	35,916	31,816	127,052	96,510
Total operating costs and expenses	86,359	80,218	281,975	277,344
Loss from operations	(80,253)	(80,136)	(274,782)	(276,861)
Other income (expense), net:				
Interest and investment income, net	1,798	35	6,788	647
Change in fair value of warrant and derivative liabilities, and convertible note	32,938	21,782	30,306	32,549
Interest expense (including amounts with related parties)	(29,322)	(35,021)	(88,599)	(97,072)
Interest expense related to revenue interest liability	(10,925)	—	(28,154)	—
Other income (expense), net (including amounts with related parties) and equity method investments	12	(2,302)	(25)	(9,701)
Total other expense, net	(5,499)	(15,506)	(79,684)	(73,577)
Loss before income taxes and noncontrolling interests	(85,752)	(95,642)	(354,466)	(350,438)
Income tax expense	—	—	—	—
Net loss	(85,752)	(95,642)	(354,466)	(350,438)
Net loss attributable to noncontrolling interests, net of tax	(23)	(60)	(64)	(634)
Net loss attributable to ImmunityBio common stockholders	$ (85,729)	$ (95,582)	$ (354,402)	$ (349,804)
Net loss per ImmunityBio common share – basic	$ (0.12)	$ (0.19)	$ (0.52)	$ (0.77)

Net loss per ImmunityBio common share – diluted	$ (0.14)	$ (0.19)	$ (0.53)	$ (0.77)
Weighted-average number of common shares used in computing net loss per share – basic	695,895	498,375	685,261	454,994
Weighted-average number of common shares used in computing net loss per share – diluted	697,961	498,375	688,939	454,994

ImmunityBio, Inc.

Selected Balance Sheet Data

	Sept. 30, 2024	**December 31, 2023**
(in thousands)	**(Unaudited)**	
Cash and cash equivalents, and marketable securities	$ 130,367	$ 267,353
Total assets	364,570	504,452
Total related-party debt	699,118	681,537
Revenue interest liability	273,657	155,415
Total liabilities	1,108,732	1,090,389
Total stockholders' deficit (including noncontrolling interests)	(744,162)	(585,937)
Total liabilities and stockholders' deficit	364,570	504,452

ImmunityBio, Inc.

Summary Reconciliation of Cash Flows

	Three Months Ended September 30,		**Nine Months Ended September 30,**	
(in thousands; unaudited)	**2024**	**2023**	**2024**	**2023**
Cash (used in) provided by:				
Net cash used in operating activities	$ (98,763)	$ (87,403)	$ (306,092)	$ (251,486)
Net cash provided by (used in) investing activities	65,032	(15,631)	(22,080)	(32,719)
Net cash provided by financing activities	15,582	237,502	174,701	357,802
Effect of exchange rate changes on cash and cash equivalents, and restricted cash	11	(1)	(16)	(265)
Net change in cash and cash equivalents, and restricted cash	(18,138)	134,467	(153,487)	73,332

Cash and cash equivalents, and restricted cash, beginning of period	130,438	43,830	265,787	104,965
Cash and cash equivalents, and restricted cash, end of period	$ 112,300	$ 178,297	$ 112,300	$ 178,297

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.

About ImmunityBio

ImmunityBio is a vertically-integrated biotechnology company developing next-generation therapies and vaccines 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 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 anticipated regulatory submissions and timing thereof, market access initiatives and coverage under medical reimbursement policies, shelf life of ANKTIVA and product supply, global expansion efforts, effectiveness of the permanent J-code for ANKTIVA, clinical trial plans and timing, market and prevalence data, the regulatory filing and review process and timing thereof, 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 and use 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 presentation 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, (iii) the ability of ImmunityBio to fund its ongoing and anticipated clinical trials, (iv) whether clinical trials will result in registrational pathways and the risks and uncertainties regarding the regulatory submission, review and approval process, (v) risks and uncertainties associated with third-party collaborations and agreements, (vi) 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, (vii) potential delays in product availability and regulatory approvals, (viii) ImmunityBio's ability to retain and hire key personnel, (ix) ImmunityBio's ability to obtain additional financing to fund its operations and complete the development and commercialization of its various product candidates, (x) potential product shortages or manufacturing disruptions that may impact the availability and timing of product, (xi) ImmunityBio's ability to successfully commercialize its approved product and product candidates, (xii) ImmunityBio's ability to scale its manufacturing and commercial supply operations for its approved product and future approved products, and (xiii) 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 August 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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