Adicet Reports Third Quarter 2024 Financial Results and Provides Business Updates

November 6, 2024

ADI-001 Phase 1 clinical trial expanded to include a total of six autoimmune disease indications; preliminary clinical data in lupus nephritis (LN) anticipated in 1H25

Strong balance sheet with $202.1 million in cash, cash equivalents and short-term investments as of September 30, 2024

REDWOOD CITY, Calif. & BOSTON--(BUSINESS WIRE)--Nov. 6, 2024-- Adicet Bio, Inc. (Nasdaq: ACET), a clinical stage biotechnology company discovering and developing allogeneic gamma delta T cell therapies for autoimmune diseases and cancer, today reported financial results and operational highlights for the third quarter ended September 30, 2024.

“Our commitment to delivering best-in-class gamma delta 1 T cell therapies for patients battling autoimmune diseases and cancer is reflected in the expansion of our clinical pipeline in the third quarter. We are now investigating ADI-001 across six autoimmune indications to provide potentially transformative curative therapies for these debilitating diseases. Additionally, in the fourth quarter we plan to open enrollment for our Phase 1 trial of ADI-270 in patients with metastatic/advanced clear cell renal cell carcinoma (ccRCC), our first gamma delta 1 CAR T cell therapy for solid tumors. This progress highlights the broad and important potential applications of our gamma delta platform,” said Chen Schor, President and Chief Executive Officer. “Looking ahead, we anticipate advancing enrollment in these trials and expect to share preliminary clinical data from both lupus nephritis with ADI-001 and metastatic/advanced ccRCC with ADI-270 in the first half of 2025.”

Third Quarter 2024 and Recent Operational Highlights:

Autoimmune diseases

- ***Activated clinical sites in ADI-001 Phase 1 trial in autoimmune diseases.*** In September 2024, Adicet activated sites for its Phase 1 clinical trial of ADI-001 in autoimmune diseases. The company is exploring the potential of ADI-001 across six indications including LN, systemic lupus erythematosus (SLE), systemic sclerosis (SSc), idiopathic inflammatory myopathy (IIM), stiff person syndrome (SPS) and anti-neutrophil cytoplasmic autoantibody (ANCA) associated vasculitis (AAV). The Company opened enrollment for patients with LN in 4Q24 and expects to initiate enrollment for patients with SLE, SSc, IIM, and SPS in 1Q25, and for patients with AAV in 2H25. The Company plans to report preliminary clinical data from the Phase 1 clinical study of ADI-001 in LN in 1H25, and for other autoimmune diseases in 2H25, subject to study site initiation and patient enrollment.
- ***FDA clearance of IND amendment to evaluate ADI-001 in IIM and SPS.*** In October 2024, Adicet announced that the U.S. Food and Drug Administration (FDA) cleared the Company’s Investigational New Drug (IND) amendment application to evaluate ADI-001 in IIM and SPS as part of the Phase 1 clinical trial in autoimmune diseases.
- ***Presented ADI-001 clinical biomarker data demonstrating robust tissue trafficking and complete B cell depletion in secondary lymphoid tissue.*** In September 2024, Adicet presented clinical biomarker data from the Phase 1 GLEAN trial of ADI-001 at the 9th Annual CAR-TCR Summit. The data demonstrated robust tissue trafficking resulting in high levels of ADI-001, significant chimeric antigen receptor (CAR) T cell activation, and complete CD19+ B cell depletion in secondary lymphoid tissue. These findings further reinforce ADI-001's potential as a best-in-class allogeneic cell therapy for autoimmune diseases.
- ***Presentation of ADI-001 clinical data at the American College of Rheumatology (ACR) Convergence 2024.*** In November 2024, Adicet will present an oral abstract highlighting previously presented ADI-001 clinical biomarker data at ACR Convergence 2024 taking place November 14-19 in Washington, D.C.

Hematologic malignancies and solid tumor indications

- ***ADI-270 Fast Track Designation in metastatic/ advanced ccRCC.*** In July 2024, Adicet announced that the FDA granted ADI-270 Fast Track Designation for the potential treatment of patients with metastatic/advanced ccRCC who have been treated with an immune checkpoint inhibitor and a vascular endothelial growth factor inhibitor.
- ***Presented ADI-270 data at the American Society of Gene & Cell Therapy’s (ASGCT) 2024 Advancing Gene + Cell Therapies for Cancer conference.*** In October 2024, Adicet presented ADI-270 data in an oral presentation at the ASGCT 2024 Advancing Gene and Cell Therapies for Cancer conference.

Corporate Updates

- ***Appointed Lloyd Klickstein, M.D., Ph.D. to Board of Directors.*** In August 2024, Adicet appointed Dr. Lloyd Klickstein to its Board of Directors. Dr. Klickstein brings over two decades of leadership experience in the biopharmaceutical industry and biomedical research, and expertise in rheumatology and immunology to Adicet. Dr. Klickstein currently serves as President and Chief Executive Officer of Koslapp Therapeutics, Inc. and is the Board Chair of the Lupus Foundation of

New England.

Financial Results for Third Quarter 2024:

- **Research and Development (R&D) Expenses:** R&D expenses were $26.3 million for the three months ended September 30, 2024, compared to $26.2 million during the same period in 2023. The increase in R&D expenses was primarily due to a $0.9 million increase in laboratory expenses, a $0.8 million increase in payroll and personnel expenses as well as a less than $0.1 million increase in professional fees for the period. This increase was partially offset by a $1.3 million decrease in expenses related to contract development manufacturing organizations and other externally conducted research and development and a $0.4 million decrease in allocated facility expenses.
- **General and Administrative (G&A) Expenses:** G&A expenses were $6.9 million for the three months ended September 30, 2024, compared to $6.6 million during the same period in 2023. The increase in general and administrative expenses was primarily due to a $0.3 million increase in payroll and personnel expenses.
- **Net Loss:** Net loss for the three months ended September 30, 2024 was $30.5 million, or a net loss of $0.34 per basic and diluted share, including non-cash stock-based compensation expense of $6.8 million, as compared to a net loss of $49.9 million, or a net loss of $1.16 per basic and diluted share, including non-cash goodwill impairment expense of $19.5 million and non-cash stock-based compensation expense of $5.6 million during the same period in 2023.
- **Cash Position:** Cash, cash equivalents and short-term investments in treasury securities were $202.1 million as of September 30, 2024, compared to $159.7 million as of December 31, 2023. The Company expects that current cash, cash equivalents and short-term investments as of September 30, 2024, will be sufficient to fund its operating expenses into the second half of 2026.

About Adicet Bio, Inc.

Adicet Bio, Inc. is a clinical stage biotechnology company discovering and developing allogeneic gamma delta T cell therapies for autoimmune diseases and cancer. Adicet is advancing a pipeline of “off-the-shelf” gamma delta T cells, engineered with chimeric antigen receptors (CARs), to facilitate durable activity in patients. For more information, please visit our website at https://www.adicetbio.com.

Forward-Looking Statements

This press release contains "forward-looking statements" of Adicet within the meaning of the Private Securities Litigation Reform Act of 1995 relating to the business and operations of Adicet. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, but are not limited to, express or implied statements regarding: the expansion of Adicet’s clinical pipeline and the preclinical and clinical development of Adicet’s product candidates, including future plans or expectations for ADI-001 and ADI-270, including the potential safety, durability, tolerability and efficacy of these product candidates as well as their potential promising profiles; the progress, timing and success of the Company’s ongoing and planned Phase 1 clinical trials of ADI-001 in autoimmune diseases, including expectations for site activation, enrollment and data readouts; the Company’s clinical trial of ADI-270 in metastatic/advanced ccRCC, including expectations for site enrollment and data readouts; and expectations regarding the Company’s uses of capital, expenses and financial results, including the expected cash runway.

Any forward-looking statements in this press release are based on management’s current expectations and beliefs of future events, and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements, including without limitation, the effect of global economic conditions and public health emergencies on Adicet’s business and financial results, including with respect to disruptions to our preclinical and clinical studies, business operations, employee hiring and retention, and ability to raise additional capital; Adicet’s ability to execute on its strategy including obtaining the requisite regulatory approvals on the expected timeline, if at all; that positive results, including interim results, from a preclinical or clinical study may not necessarily be predictive of the results of future or ongoing studies; clinical studies may fail to demonstrate adequate safety and efficacy of Adicet’s product candidates, which would prevent, delay, or limit the scope of regulatory approval and commercialization; and regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming, and inherently unpredictable; and Adicet’s ability to meet production and product release expectations. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause Adicet’s actual results to differ from those contained in the forward-looking statements, see the section entitled “Risk Factors” in Adicet’s most recent quarterly report on Form 10-Q and subsequent filings with the U.S. Securities and Exchange Commission (SEC), as well as discussions of potential risks, uncertainties, and other important factors in Adicet’s other filings with the SEC. All information in this press release is as of the date of the release, and Adicet undertakes no duty to update this information unless required by law.

ADICET BIO, INC.
Consolidated Statements of Operations and Comprehensive Income
(in thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	26,253	26,167	76,050	81,284
General and administrative	6,900	6,633	20,822	19,726

Goodwill impairment	—	19,462	—	19,462
Total operating expenses	33,153	52,262	96,872	120,472
Loss from operations	(33,153)	(52,262)	(96,872)	(120,472)
Interest income	2,730	2,520	8,647	7,800
Interest expense	(1)	(1)	(3)	(25)
Other expense, net	(54)	(142)	(167)	(472)
Loss before income tax provision	(30,478)	(49,885)	(88,395)	(113,169)
Income tax provision	—	—	—	—
Net loss	$ (30,478)	$ (49,885)	$ (88,395)	$ (113,169)
Net loss per share, basic and diluted	$ (0.34)	$ (1.16)	$ (1.02)	$ (2.63)
Weighted-average common shares used in computing net loss per share, basic and diluted	90,846,293	42,980,641	86,865,285	43,001,901
Other comprehensive income				
Unrealized gain on treasury securities, net of tax	121	—	121	—
Total other comprehensive income	121	—	121	—
Comprehensive loss	$ (30,357)	$ (49,885)	$ (88,274)	$ (113,169)

ADICET BIO, INC.
Consolidated Balance Sheets Information
(in thousands)
(Unaudited)

	September 30, 2024	December 31, 2023
Cash, cash equivalents, and short term investments in treasury securities	$ 202,065	$ 159,711
Working capital	186,922	142,985
Total assets	245,962	207,295
Accumulated deficit	(469,167)	(380,772)
Total stockholders' equity	211,531	170,175

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