Adicet Bio Provides Corporate Update and Highlights Expected 2026 Milestones

January 7, 2026

Successfully completed meeting with FDA to align on and enable outpatient dosing of systemic lupus erythematosus (SLE) and lupus nephritis (LN) patients with prulacabtagene leucel (prula-cel, formerly ADI-001) in ongoing and future clinical studies

All seven cohorts now actively enrolling in Phase 1 autoimmune clinical program as first anti-neutrophil cytoplasmic autoantibody (ANCA) associated vasculitis (AAV) patient is dosed in study

Next clinical update from Phase 1 study of prula-cel in autoimmune disease expected in 1H/2026; plan to provide additional clinical update from the study in 2H/2026

Exploring potential to reduce need for conditioning with ongoing Phase 1 trial in treatment-refractory rheumatoid arthritis (RA)

Advancing preclinical development of ADI-212 in metastatic castration-resistant prostate cancer (mCPRC); plan to submit regulatory filing in 1H/2026

Underwritten registered direct offering extends cash runway into 2H/2027

REDWOOD CITY, Calif.--(BUSINESS WIRE)--Jan. 7, 2026-- 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 provided corporate updates and highlighted upcoming milestones for 2026.

“Heading into 2026, we are proud of the strong execution across our pipeline. Since reporting data in October from our prula-cel Phase 1 program in autoimmune diseases, enrollment has more than doubled with over 20 patients as of December 31, 2025. We have also reached regulatory alignment with the FDA to enable outpatient dosing of SLE and LN patients receiving prula-cel and are advancing our Phase 1 study in treatment-refractory RA comparing prula-cel following cyclophosphamide alone versus cyclophosphamide/fludarabine conditioning. Taken together, these accomplishments set the stage for a meaningful data readout expected in the first half of 2026,” said Chen Schor, President and Chief Executive Officer of Adicet Bio. “In parallel, we continue to advance our broader pipeline, including ADI-212, our next-generation, gene-edited and armored solid tumor candidate, which is advancing towards a regulatory filing in the first half of 2026. These achievements strongly position us as we prepare for a pivotal study and continue to advance our pipeline.”

Recent Pipeline Progress and Operational Progress:

Autoimmune Diseases Clinical Programs

- The prula-cel Phase 1 program is enrolling patients across seven different autoimmune diseases: LN, SLE, systemic sclerosis (SSc), idiopathic inflammatory myopathy (IIM), stiff person syndrome (SPS), AAV and treatment-refractory RA. Prula-cel has been granted Fast Track Designation by the U.S. Food and Drug Administration (FDA) for the potential treatment of relapsed/refractory class III or class IV LN, refractory SLE with extrarenal involvement, and SSc.
- In November 2025 the Company reached alignment with the FDA to allow LN and SLE patients to be dosed with prula-cel in the outpatient setting in ongoing and future clinical trials.
- In October 2025, Adicet announced the dosing of the first treatment-refractory RA patient in a Phase 1 study. The study will evaluate two conditioning regimens: cyclophosphamide alone and cyclophosphamide with fludarabine. The primary objectives of the study are to evaluate the safety and tolerability of prula-cel. Secondary objectives include measuring cellular kinetics, pharmacodynamics, and disease activity scores.
- In October 2025, the Company reported positive preliminary safety and efficacy data from the Phase 1 clinical trial of prula-cel in patients with LN and SLE. The data highlighted rapid and sustained reductions in Systemic Lupus Erythematosus Disease Activity Index (SLEDAI-2K) score and Physician’s Global Assessment (PGA), improved renal function, and favorable safety and tolerability profile as of the August 31, 2025 data cut-off date.

Solid Tumor Clinical Programs

- Adicet is continuing to advance preclinical development of ADI-212, a next-generation gene-edited and armored clinical candidate designed to target prostate-specific membrane antigen. ADI-212 is engineered to express a novel CAR binder designed to support enhanced tolerability and tumor-specific recognition. It integrates membrane-tethered IL-12 armoring and CRISPR/Cas9 mediated disruption of subunit 12 of the mediator complex (MED12) to enhance potency in solid tumors and deliver multiple anti-tumor mechanisms of action within the tumor microenvironment.
- In October 2025, Adicet presented preclinical data from ADI-212 at the 32nd Annual Prostate Cancer Foundation Scientific Retreat supporting its design elements and functional enhancements in multiple models of disease.

Corporate Updates

- In October 2025, Adicet successfully raised approximately $74.8 million in net proceeds through an underwritten registered direct offering of equity securities, extending its cash runway into the second half of 2027.

Strategic Priorities and Anticipated Key Milestones for 2026

Present new and updated clinical data from the Phase 1 study evaluating prula-cel throughout 2026.

- Adicet remains on track to share a clinical update in LN, SLE, and SSc in the first half of 2026.
- The Company also expects to share another clinical update from the study in the second half of 2026.

Gain alignment with the FDA on a path to registration for prula-cel.

- Adicet plans to request a meeting with the FDA in the second quarter of 2026 to inform potential pivotal trial design. Subject to regulatory clearance to proceed, the Company expects to initiate a pivotal study in LN or LN and SLE patients in the second half of 2026.

Advance innovations designed to enhance patient experience and expand access.

- The Company is actively enrolling patients with treatment-refractory RA in its Phase 1 study of prula-cel evaluating the potential to reduce the need for conditioning.
- Adicet expects to provide a clinical update on the Phase 1 RA study in the second half of 2026.

Initiate clinical development of ADI-212 in mCRPC.

- Adicet expects to submit a regulatory filing for ADI-212 for the treatment of mCRPC in the first half of 2026.
- Subject to regulatory clearance to proceed with a clinical trial, the Company expects to initiate clinical startup activities in the second quarter 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: clinical development of Adicet’s product candidates, including future plans or expectations for prula-cel in autoimmune diseases and the potential safety, tolerability and efficacy for the treatment of autoimmune diseases and cancer; timing and success of the Phase 1 clinical trial of prula-cel in LN, SLE, SSc, AAV, IIM, SPS and RA, including timing and expectations for enrollment and future data releases; expectations regarding regulatory alignment with the FDA to allow LN and SLE patients to be dosed with prula-cel in the outpatient setting; expectations regarding the timing and initiation of a pivotal study for prula-cel in LN or LN and SLE patients; expectations regarding the preclinical and clinical development of ADI-212, including the timing of regulatory filings, clinical startup activities and future data releases; expectations regarding the potential potency of ADI-212; and expectations regarding Adicet’s uses of capital, expenses and financial results, including the expected extension of the 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 U.S. Food and Drug Administration 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 titled “Risk Factors” in Adicet’s most recent annual report on Form 10-K, as well as discussions of potential risks, uncertainties, and other important factors in Adicet’s other filings with the U.S. Securities and Exchange Commission, including its quarterly report on Form 10-Q. 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.

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