UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): June 5, 2023

NEXIMMUNE, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-40045**	**45-2518457**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

9119 Gaither Road **Gaithersburg, Maryland**	**20877**
(Address of principal executive offices)	**(zip code)**

Registrant's telephone number, including area code: (301) 825-9810

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	NEXI	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging Growth Company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On June 5, 2023, NexImmune, Inc. issued a press release announcing initial results from its Phase 1/2 clinical trial of NEXI-001 in patients with relapsed/refractory acute myeloid leukemia (AML) post-allogeneic hemopoietic stem cell transplant (allo-HSCT). The press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and incorporated by reference this Item 7.01. The press release may contain hypertext links to information on our website. The information on our website is not incorporated by reference into this Current Report on Form 8-K and does not constitute a part of this Form 8-K.

The information contained in this Item 7.01 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities under that Section, nor shall it be deemed incorporated by reference into any registration statement or other filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

On June 5, 2023, NexImmune, Inc. issued a press release announcing initial results from its Phase 1/2 clinical trial of NEXI-001 in patients with relapsed/refractory acute myeloid leukemia (AML) post-allogeneic hemopoietic stem cell transplant (allo-HSCT). In this clinical trial to date, NEXI-001 is well tolerated with a favorable safety profile while eliciting an immune response to target antigens and a clinical effect in some patients. The data describing two patients from the dose escalation study of NEXI-001 are being presented in a poster session at the American Society of Clinical Oncology (ASCO) 2023 Annual Meeting in Chicago on Monday, June 5, 2023. To date, 11 patients have completed the dose-limiting toxicity (DLT) period and one patient is currently ongoing in the first month of protocol treatment. Through all dose levels to date, NEXI-001 maintains a favorable tolerability profile with no grade 3 or greater treatment related SAEs. Two patients experienced grade 2 CRS which resolved within 24 hours with tocilizumab therapy. No cases of ICANS have occurred as of May 2023. Clinicians observed persistence of antigen-specific T cells in both peripheral blood and bone marrow with evidence of clinical activity including tumor burden reduction, increased chimerism and improved ECOG scores. The antigen-specific T cells maintain less-differentiated immunophenotypes, including stem-cell-like T cells (Tscm) over time in both blood and bone marrow. Additionally, a marked increase in the antigen specificity of CD8+ T cells in the bone marrow resulted with increasing dose levels. Six of 11 patients across all dose levels experienced stable disease for some period, including a stable clinical response (MRD+) in one patient and one CR (MRD-) for up to 9 months in cohort 2 (200 million NEXI-001 T cells, administered once).

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release, issued on June 5, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

NEXIMMUNE, INC.

By: /s/ John Trainer
John Trainer
Chief Financial Officer

Date: June 5, 2023

NexImmune Presents Initial Positive Data in the NEXI-001 Phase 1 Trial for Relapsed/Refractory Post Allo-HSCT AML at the American Society of Clinical Oncology 2023 Annual Meeting

- *Trial includes high risk AML patients that have relapsed post allo-HSCT and are refractory to salvage therapy*
- *NEXI-001 is well tolerated with a favorable safety profile, including no grade $\geq$ 3 treatment related events as of May 2023*
- *Robust immune response with clinical activity at the highest dose level with one patient achieving no evidence of disease 7 months post-infusion with NEXI-001*
- *Antigen-specific T cells persist in blood and bone marrow and maintain important phenotypes that are associated with anti-tumor effect and immunologic memory*

GAITHERSBURG, Md., June 5, 2023 — NexImmune, Inc. (Nasdaq: NEXI), a biotechnology company developing a novel approach to immunotherapy designed to orchestrate a targeted immune response by directing the function of antigen-specific T cells for liquid and solid malignancies, today announced results from its Phase 1/2 clinical trial of NEXI-001 in patients with relapsed/refractory acute myeloid leukemia (AML) post-allogeneic hemopoietic stem cell transplant (allo-HSCT). In this clinical trial to date, NEXI-001 is well tolerated with a favorable safety profile while eliciting an immune response to target antigens and a clinical effect in some patients. The data describing two patients from the dose escalation study of NEXI-001 are being presented in a poster session at the American Society of Clinical Oncology (ASCO) 2023 Annual Meeting in Chicago on Monday, June 5.

“We are pleased that NEXI-001, our donor derived multi-antigen-specific T cell product candidate, is demonstrating evidence of dose response and tolerability in the initial Phase 1 dose escalation portion of this clinical trial,” said Kristi Jones, NexImmune’s Chief Executive Officer. “We have seen a clinical response maintained for seven months, which is an additional update from the data reported in our poster. These data have established the ability of our AIM nanoparticles to expand healthy, multi-antigen-specific T cells with anti-tumor activity. The data also show these T cells persist and maintain their memory phenotype at the site of tumor. We expect to provide an additional update on Cohort 3 later this year with more details from the patients in this study, and plan to apply learnings from this trial to inform future trials for NexImmune products in cancer.

“We believe that NexImmune’s multi-antigen-specific product candidates, alone or in combination with other immunotherapies, offer the potential to benefit patients with challenging cancers such as AML, for which treatment options with meaningful benefit and tolerability has remained elusive. The safety profile of our product candidate to date also presents the potential to investigate trials in patients with lower burden disease where significant unmet need remains,” added Ms. Jones.

Study Design

The goals of the NEXI-001 Phase 1 clinical trial are to evaluate the safety, tolerability, immune response, and clinical activity of the antigen-specific CD8+ NEXI-001 T cells, as well as to inform the range of patient characteristics and to determine the recommended Phase 2 dose. The dose escalation phase of the study included patients who have relapsed acute myeloid leukemia (AML) post allo-HSCT and are refractory to salvage therapy. All patients in the study, except one, relapsed after, or were refractory to, subsequent salvage therapies (one to three prior therapies). A majority of patients had three-to-four adverse risk characteristics linked to poor prognosis in addition to poor prognostic patients with extramedullary disease.

Three dose-ascending cohorts of patients were enrolled in the study, with potential doses ranging from a single dose of 50 million NEXI-001 T cells to multiple doses of up to a total of 1.2 billion NEXI-001 T cells. To date, the maximum dose evaluated has been 600 million NEXI-001 T cells.

The study includes a lymphodepletion chemotherapy (Flu / Cy 30/300) following a baseline bone marrow biopsy. To date, 11 patients have completed the dose-limiting toxicity (DLT) period and one patient is currently ongoing in the first month of protocol treatment.

“I am very encouraged by the responses and the tolerability profile observed in these difficult-to-treat refractory patients,” said Dr. Monzr M. Al Malki, MD, Associate Professor of Hematology, Director of BMT and Transplant, City of Hope and an investigator for NEXI-001. “These patients are frequently fragile and lack effective and tolerable options. Responses for these patients, if any, are typically short-lived and there is an urgent need for better options. As highlighted in the ASCO poster, achieving and maintaining a durable clinical response in extramedullary disease is clinically meaningful and supports the potential of NEXI-001 to provide significant benefit to these patients.”

Key Data Highlights

- Through all dose levels to date, NEXI-001 maintains a favorable tolerability profile with no grade 3 or greater treatment related SAEs. Two patients experienced grade 2 CRS which resolved within 24 hours with tocilizumab therapy. No cases of ICANS have occurred as of May 2023.
- Patients treated with NEXI-001 experienced rapid reconstitution of both CD8+ and CD4+ T-cell subtypes after lymphodepletion chemotherapy.
- Clinicians observed persistence of antigen-specific T cells in both peripheral blood and bone marrow with evidence of clinical activity including tumor burden reduction, increased chimerism and improved ECOG scores.

- The antigen-specific T cells maintain less-differentiated immunophenotypes, including stem-cell-like T cells (T_{scm}) over time in both blood and bone marrow. Additionally, a marked increase in the antigen specificity of CD8+ T cells in the bone marrow resulted with increasing dose levels.
- Six of 11 patients across all dose levels experienced stable disease for some period, including a stable clinical response (MRD+) in one patient and one CR (MRD-) for up to 9 months in cohort 2 (200 million NEXI-001 T cells, administered once), which was reported in the ASCO poster. Data continue to support potential dose response with 600 million total cells infused during Cycle 1 being the maximum dose evaluated as of May 2023. Additional cycles or dose increases are anticipated to offer benefit in the designed expansion phase of the study.
- One patient in Cohort 3 with a poor prognostic extramedullary relapse of AML manifested by pericardial and bilateral pleural effusions (cytology positive for AML blasts) resulting in symptoms of moderate to severe dyspnea was enrolled in the highest dosing cohort (200 million NEXI-001 T cells administered weekly for three weeks). After one cycle of protocol therapy the patient became asymptomatic and repeat PET/CT scans document that the effusions regressed to minimal volumes. This extramedullary clinical response has been maintained for up to 7 months and is updated from the 3 months described in the ASCO poster.
- These data indicating both immunologic and clinical dose responses and observed durability in the patient at the higher dose support further clinical study of NEXI-001.

Poster Presentation:

Title: An Analysis of a First-In-Human Study of NEXI-001 Donor-Derived Antigen-Specific CD8+ T-Cell Treatment of Relapsed AML after Allogeneic Hematopoietic Cell Transplantation (HCT)

Abstract #: 7043 (Poster Board #173)

Session Title: Hematologic Malignancies – Leukemia, Myelodysplastic Syndromes, and Allotransplant

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About NexImmune

NexImmune is a clinical-stage biotechnology company developing a novel approach to immunotherapy designed to employ the body's own T cells to generate a specific, potent, and durable immune response. The backbone of NexImmune's approach is a proprietary Artificial Immune Modulation (AIM™) nanoparticle technology platform. The AIM technology enables NexImmune to construct nanoparticles that function as synthetic dendritic cells capable of directing a specific T cell-mediated immune response. AIM constructed nanoparticles employ natural biology to engage, activate and expand endogenous T cells in ways that combine anti-tumor attributes of antigen-specific precision, potency and long-term persistence with reduced potential for off-target toxicities. NexImmune is focused on developing injectable AIM nanoparticle constructs and modalities for potential clinical evaluation in oncology, autoimmune disorders and infectious diseases.

For more information, visit www.neximmune.com.

Forward Looking Statements

This press release may contain “forward-looking” statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are based on the beliefs and assumptions and on information currently available to management of NexImmune, Inc. (the “Company”). All statements other than statements of historical fact contained in this press release are forward-looking statements, including statements concerning our clinical trials for the Company’s product candidates, including NEXI-001; the initiation, enrollment, timing, progress, release of data from and results of those and other planned clinical trials and preclinical studies; and the utility of prior preclinical and clinical data in determining future clinical results. In some cases, you can identify forward-looking statements by terminology such as “may,” “will,” “should,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “predicts,” “potential” or “continue” or the negative of these terms or other comparable terminology. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the Company’s actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These risks and uncertainties include, but are not limited to, the risks and uncertainties set forth in the “Risk Factors” section of our Annual Report on Form 10-K for the year ended December 31, 2022 filed with the Securities and Exchange Commission (“SEC”) on March 28, 2023, and subsequent reports that we file with the SEC. Forward-looking statements represent the Company’s beliefs and assumptions only as of the date of this press release. Although the Company believes that the expectations reflected in the forward-looking statements are reasonable, it cannot guarantee future results, levels of activity, performance or achievements. Except as required by law, the Company assumes no obligation to publicly update any forward-looking statements for any reason after the date of this press release to conform any of the forward-looking statements to actual results or to changes in its expectations.

Contacts

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