
**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): March 28, 2023

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

Delaware
(State or other jurisdiction
of incorporation)

001-40045
(Commission
File Number)

45-2518457
(IRS Employer
Identification No.)

9119 Gaither Road
Gaithersburg, Maryland
(Address of principal executive offices)

20877
(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 2.02 Results of Operations and Financial Condition.

On March 28, 2023, NexImmune, Inc. (the “Company”) issued a press release announcing its financial results for the fourth quarter and full year ended December 31, 2022 and providing business highlights. The full text of the press release is incorporated by reference herein and furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K (including Exhibits 99.1) shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

| Exhibit No. | Description |
|--------------------|--|
| 99.1 | Press release announcing the Company’s financial results for the fourth quarter and full year ended December 31, 2022, dated March 28, 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: March 28, 2023



NexImmune Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Business Updates

- *Company has initiated Pre-IND discussions with the FDA for its first AIM INJ indication*
- *NEXI-001 completed enrollment in its final safety cohorts and all patients have been dosed, Company continues to follow patients and will announce data at or around an upcoming scientific conference*
- *Company announces executive management changes as part of resource reallocation*

GAITHERSBURG, Md., March 28, 2023 (GLOBE NEWSWIRE) -- 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 reported financial results for the fourth quarter and full year 2022.

“We remain confident in the potential therapeutic benefit of our AIM platform-based products and their ability to significantly impact the emerging field of antigen specific immune-oncology therapies, novel IO combinations, autoimmune treatments and potential approaches for viral-driven diseases. While we are still observing patients in our ongoing cell therapy program, we are focused on advancing our AIM INJ ‘off-the-shelf’ modality,” said Kristi Jones, Chief Executive Officer. “The combined data from our clinical cell therapy programs and INJ pre-clinical experiments are consistent, and we believe validate the AIM nanoparticles MOA regardless of modality. In addition, recent pre-clinical data combining AIM nanoparticle expanded multi-antigen specific T cells with a T cell bispecific engager demonstrated superior potency as well as enhanced persistence and durability supporting novel antigen specific IO combinations.”

We believe that the AIM INJ therapeutic modality offers the most disruptive potential to benefit patients, as well as the greatest potential to create long-term value for our shareholders. The unique benefits of our “off the shelf” T cell targeted therapies include scalability and access to broader patient populations to address unmet need. We will provide an update on these programs over the coming months.”

Jones continued, “Our AIM ACT cell therapy product candidates currently in clinical trials continue to show clinical activity in early dose escalation and are well-tolerated in patients. While paused, these clinical programs have demonstrated evidence of activity such as reduction in tumor burden, and a tolerability profile to support potential novel IO combinations and to shift into patients with lower tumor burden. We are exploring external opportunities, including with academic centers and corporate collaborators, to advance these programs.”

Select Fourth Quarter and Full Year 2022 Clinical and Business Highlights

Business and Strategy Update

Jerry Zeldis, MD, PhD, will retire from his position of Executive Vice President, R&D, effective March 31, 2023. Also, as part of the Company’s previous announced realignment of resources to focus on the AIM INJ platform and pause our cell therapy clinical programs, Bob Knight, MD, will step down from the position of Chief Medical Officer. Dr. Knight and Dr. Zeldis will transition to advisory roles and continue to provide both strategic counsel and fulfill operating responsibilities at NexImmune. Dr. Zeldis will also continue to be an active member on NexImmune’s Scientific Advisory Board.

“On behalf of the BOD, I want to thank Jerry and Bob for their leadership and contribution in bringing NexImmune’s revolutionary technology to the clinic and into patients. We are grateful for the continued support we will receive as both will remain involved with NexImmune in an active advisory capacity,” said Sol Barer, NexImmune’s Chairman of the Board.

Clinical and Preclinical Updates

AIM INJ, Injectable “Off-the-shelf” Antigen-Specific Immunotherapy, and Other Preclinical Research

- Initiated multiple pre-clinical studies to evaluate monotherapy and in combination with a checkpoint inhibitor to support our oncology program
- Continued to evaluate AIM INJ nanoparticles as a therapeutic for type 1 diabetes as well as other autoimmune diseases with Yale University Professor Kevan Harold in partnership with JDRF
- Poster presented at 2023 Tandem Meetings: Transplantation & Cellular Therapy Meetings of ASTCT and CIBMTR demonstrated evidence that AIM multi-antigen specific cells combined with a BCMA bispecific results in superior potency, enhanced persistence and durability in multiple myeloma models
- Publication in *Frontiers in Medicine* highlighting the ability of NexImmune’s AIM Platform to treat viral diseases
- Announced research collaboration with National Institute of Neurological Disorders and Stroke of the National Institutes of Health with initial focus on multiple sclerosis
- Announced neo-antigen melanoma research collaboration with NYU Langone’s Perlmutter Cancer Center

NEXI-001 Relapsed Refractory AML Post Allo-HSCT

- Full enrollment and dosing in the final safety cohort of NEXI-001 completed
- Plan to announce data for currently enrolled patients at or around an upcoming conference in mid-2023
- Continue to explore opportunities to advance NEXI-001 with potential collaborators and investigators

NEXI-003 HPV-Related Cancers

- Announced clearance of IND by the FDA for NEXI-003 for treatment of HPV-related cancers
- Continue to explore opportunities to develop this adoptive cell therapy with external partners and collaborators and develop a corporate HPV strategy that utilizes the AIM INJ modality.

Select 4Q and Full 2022 Financial Highlights

Cash, cash equivalents and marketable securities for the company as of December 31, 2022 were \$34.6 million compared to \$81.8 million at December 31, 2021. Based upon current operating plans, NexImmune expects that its existing cash, cash equivalents and marketable securities will enable the company to fund its operating and capital expenditure requirements into the fourth quarter of 2023.

Research and development expenses were \$13.7 million in the fourth quarter ended December 31, 2022, compared to \$12.0 million for the same period in the prior year. Research and development expenses were \$47.1 million for the full year period ended December 31, 2022, an increase of \$9.6 million compared to \$37.5 million for the full year ended December 31, 2021. The increase in R&D expenses was mainly attributable to costs for research related to preclinical manufacturing and the two clinical trials, as well as personnel-related expenses driven by increased headcount.

General and administrative expenses were \$3.5 million for the fourth quarter ended December 31, 2022, which represent effectively no change for the same period in the prior year. General and administrative expenses were \$15.9 million for the full year period ended December 31, 2022, an increase of \$0.1 million compared to \$15.8 million for the full year ended December 31, 2021. The increase was due primarily to an increase in fees related to professional and consulting services offset by decrease in headcount and stock compensation expense.

Net loss, according to generally accepted accounting principles in the U.S. (GAAP), was \$16.9 million for the quarter and \$62.5 million for the full year 2022, or a basic and diluted GAAP loss per share of \$0.65 and \$2.60 respectively. This compared to a net loss of \$50.9 million, or a basic and diluted GAAP loss per share of \$2.54, for the same period the prior year.

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 results of operations for the full year ended December 31, 2022; the sufficiency of the Company’s current cash, cash equivalents and marketable securities to fund its planned operations into the fourth quarter of 2023; the enrollment, timing, progress, release of data from and results of the Company’s paused clinical trials and the expectations with respect to potential AIM INJ product candidates; the timing, progress and release of preclinical data from our AIM INJ platform programs and other preclinical research programs; 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

Investors and Media:

Chad Rubin, SVP Corporate Affairs and Investor Relations

NexImmune, Inc.

crubin@neximmune.com

NEXIMMUNE, INC.
BALANCE SHEETS

| | December 31, 2022 | December 31, 2021 |
|---|----------------------|----------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 34,642,340 | \$ 30,326,352 |
| Available-for-sale marketable securities | — | 51,491,942 |
| Restricted cash | 55,000 | 67,500 |
| Prepaid expenses and other current assets | 2,671,411 | 4,394,916 |
| Total current assets | 37,368,751 | 86,280,710 |
| Property and equipment, net | 4,459,071 | 4,427,307 |
| Operating lease right-of-use assets, net | 967,032 | — |
| Other non-current assets | 264,970 | 324,099 |
| Total assets | \$ 43,059,824 | \$ 91,032,116 |
| LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 2,377,374 | \$ 1,045,159 |
| Accrued expenses | 7,357,153 | 6,170,709 |
| Operating lease liabilities, current | 599,047 | — |
| Total current liabilities | 10,333,574 | 7,215,868 |
| Operating lease liabilities, non-current | 425,766 | — |
| Deferred rent, net of current portion | — | 55,581 |
| Total liabilities | 10,759,340 | 7,271,449 |
| Commitments and contingencies | | |
| Stockholders' equity | | |
| Common Stock, \$0.0001 par value, 250,000,000 shares authorized as of December 31, 2022 and 2021, 26,078,451 and 22,828,904 issued and outstanding as of December 31, 2022 and 2021 | 2,608 | 2,283 |
| Additional paid-in-capital | 222,547,530 | 211,498,827 |
| Accumulated deficit | (190,249,654) | (127,743,455) |
| Accumulated other comprehensive income | — | 3,012 |
| Total stockholders' equity | 32,300,484 | 83,760,667 |
| Total liabilities, redeemable convertible preferred stock and stockholders' equity | \$ 43,059,824 | \$ 91,032,116 |

NEXIMMUNE, INC.
STATEMENTS OF OPERATIONS

| | Year Ended December 31, | |
|---|-------------------------|------------------------|
| | 2022 | 2021 |
| Operating expenses: | | |
| Research and development | \$ 47,148,450 | \$ 37,456,350 |
| General and administrative | 15,934,439 | 15,799,432 |
| Total operating expenses | 63,082,889 | 53,255,782 |
| Loss from operations | (63,082,889) | (53,255,782) |
| Other (expense) income: | | |
| Interest income | 664,372 | 52,511 |
| Change in fair value of derivative liability | — | 2,424,877 |
| Gain on extinguishment of debt | — | 843,619 |
| Interest expense | — | (905,326) |
| Other (expense) income | (87,682) | (61,407) |
| Other (expense) income | 576,690 | 2,354,274 |
| Net Loss | (62,506,199) | (50,901,508) |
| Accumulated dividends on Redeemable Convertible Preferred Stock | — | (377,562) |
| Net loss attributable to common stockholders | <u>\$ (62,506,199)</u> | <u>\$ (51,279,070)</u> |
| Basic and diluted net loss attributable to common stockholders per common share | <u>\$ (2.60)</u> | <u>\$ (2.54)</u> |
| Basic and diluted weighted-average number of common shares outstanding | 24,059,104 | 20,186,127 |

STATEMENTS OF COMPREHENSIVE LOSS

| | Year Ended December 31, | |
|--|-------------------------|------------------------|
| | 2022 | 2021 |
| Net loss | <u>\$ (62,506,199)</u> | <u>\$ (50,901,508)</u> |
| Other comprehensive loss: | | |
| Unrealized (loss) gain on available-for-sale marketable securities, net of tax | (3,012) | 3,012 |
| Comprehensive loss | <u>(62,509,211)</u> | <u>(50,898,496)</u> |

