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

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**FORM 8-K**

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

**Date of Report (Date of earliest event reported): May 15, 2023**

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

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**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**

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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
<b>Common Stock, \$0.0001 par value per share</b>	<b>NEXI</b>	<b>The Nasdaq Stock Market LLC</b>

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.

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**Item 2.02 Results of Operations and Financial Condition.**

On May 15, 2023, NexImmune, Inc. (the “Company”) issued a press release announcing a strategic update and its financial results for the third quarter ended March 31, 2023 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 Item 2.02 of Current Report on Form 8-K (including Exhibit 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

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press release announcing the Company’s strategic update and financial results for the first quarter ended March 31, 2023, dated May 15, 2023.</a>
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: May 15, 2023



# NexImmune Reports First Quarter 2023 Financial Results and Provides Business Updates

- *Company has initiated pre-IND discussions with the FDA for its first AIM INJ indication*
- *NEXI-001 Phase I data to be presented at ASCO 2023 in June*

GAITHERSBURG, Md., May 15, 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 in oncology, autoimmune and infectious diseases, today reported financial results for the first quarter 2023.

“This is an exciting time for NexImmune, as we remain focused on progressing the development of novel approaches in the field of immunotherapy,” said Kristi Jones, NexImmune’s CEO. “Interest in antigen specific approaches for oncology, autoimmune disorders and infectious diseases has never been higher. We believe our AIM INJ direct injectable nanoparticle platform offers a unique and powerful solution to direct a multi-antigen specific T cell response in a scalable “off the shelf” approach across these disease areas. We continue to move our INJ “off the shelf” lead program forward in oncology and are encouraged by our conversations with the FDA.”

“I am also pleased that our NEXI-001 phase 1 clinical data in cell therapy has been accepted for presentation at ASCO and I look forward to reviewing this data, as well as the preclinical data across oncology, autoimmune and infectious disease areas for our “off the shelf” injectable this year.”

“We remain confident in the potential therapeutic benefit of our AIM platform-based product candidates and their ability to significantly impact the emerging, rapidly moving field of antigen specific immuno-oncology therapies, novel IO/IO combinations, autoimmune disorders and virally-driven diseases.”

## **Select First Quarter 2023 Clinical and Business Highlights**

### **Clinical and Preclinical Updates**

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

- Initiated multiple preclinical studies to evaluate as a monotherapy and in combination with a checkpoint inhibitor to support the Company’s oncology program
- Continue to evaluate AIM INJ nanoparticles as a therapeutic for type 1 diabetes as well as other autoimmune diseases with Yale University Professor Kevan Herold 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* highlighted the potential ability of NexImmune’s AIM platform to treat viral diseases
- Announced research collaboration with the National Institute of Neurological Disorders and Stroke of the National Institutes of Health, with an initial focus on multiple sclerosis
- Announced neo-antigen melanoma research collaboration with NYU Langone’s Perlmutter Cancer Center
- Continued work in other areas of autoimmune diseases; including vitiligo, multiple sclerosis, pemphigus, HTLV-1-associated myelopathy and others.

#### *NEXI-001 Relapsed Refractory AML Post Allo-HSCT*

- Full enrollment and dosing of the final safety cohort of NEXI-001 completed
- Plan to announce data at ASCO 2023
- Continued to explore opportunities to advance NEXI-001 with potential collaborators and investigators

#### *NEXI-003 HPV-Related Cancers*

- Continued 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 First Quarter 2023 Financial Highlights**

Cash and cash equivalents for the Company as of March 31, 2023 were \$22.3 million compared to \$34.6 million at December 31, 2022. Based upon current operating plans, NexImmune expects that its existing cash and cash equivalents will enable the Company to fund its operating and capital expenditure requirements into the fourth quarter of 2023.

Research and development expenses were \$6.1 million in the first quarter of 2023, compared to \$10.4 million for the same period in the prior year. The decrease of \$4.3 million was due primarily to the completion of preclinical manufacturing work and the pausing of the clinical trials.

General and administrative expenses were \$3.7 million, compared to \$4.6 million for the same period in the prior year. The decrease was primarily due to decreases in personnel-related expenses and in legal and other administrative fees expenses.

Net loss, according to generally accepted accounting principles in the U.S. GAAP, was \$9.6 million for the quarter, or a basic and diluted GAAP net loss per share of \$0.37. This compares to a net loss of \$15.0 million, or a basic and diluted GAAP net loss per share of \$0.66, for the same period in 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](http://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 three months ended March 31, 2023; the sufficiency of the Company's current cash and cash equivalents 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

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NEXIMMUNE, INC.

BALANCE SHEETS

	March 31, 2023 (unaudited)	December 31, 2022
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 22,315,215	\$ 34,642,340
Restricted cash	55,000	55,000
Prepaid expenses and other current assets	3,034,485	2,671,411
<b>Total current assets</b>	<b>25,404,700</b>	<b>37,368,751</b>
Property and equipment, net	4,232,655	4,459,071
Operating lease right-of-use assets	836,292	967,032
Other non-current assets	190,583	264,970
<b>Total assets</b>	<b>\$ 30,664,230</b>	<b>\$ 43,059,824</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 650,568	\$ 2,377,374
Accrued expenses	5,547,648	7,357,153
Operating lease liabilities, current	587,944	599,047
<b>Total current liabilities</b>	<b>6,786,160</b>	<b>10,333,574</b>
Operating lease liabilities, net of current portion	300,217	425,766
<b>Total liabilities</b>	<b>7,086,377</b>	<b>10,759,340</b>
<b>Commitments and contingencies</b>		
<b>Stockholders' equity</b>		
Common Stock, \$0.0001 par value, 250,000,000 shares authorized as of March 31, 2023 and December 31, 2022; 26,078,451 shares issued and outstanding as of March 31, 2023 and December 31, 2022	2,608	2,608
Additional paid-in-capital	223,389,976	222,547,530
Accumulated deficit	(199,814,731)	(190,249,654)
<b>Total stockholders' equity</b>	<b>23,577,853</b>	<b>32,300,484</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 30,664,230</b>	<b>\$ 43,059,824</b>

NEXIMMUNE, INC.

STATEMENTS OF OPERATIONS  
(unaudited)

	Three Months Ended March 31,	
	2023	2022
<b>Operating expenses:</b>		
Research and development	6,124,044	10,448,843
General and administrative	3,701,365	4,604,679
Total operating expenses	9,825,409	15,053,522
<b>Loss from operations</b>	<b>(9,825,409)</b>	<b>(15,053,522)</b>
<b>Other income (expense):</b>		
Interest income	274,738	33,093
Other expense	(14,406)	(2,576)
Other income, net	260,332	30,517
<b>Net Loss</b>	<b>\$ (9,565,077)</b>	<b>\$ (15,023,005)</b>
Basic and diluted net loss attributable to common stockholders per common share	<b>\$ (0.37)</b>	<b>\$ (0.66)</b>
Basic and diluted weighted-average number of common shares outstanding	26,078,451	22,836,781

STATEMENTS OF COMPREHENSIVE LOSS  
(unaudited)

	Three Months Ended March 31,	
	2023	2022
<b>Net loss</b>	<b>\$ (9,565,077)</b>	<b>\$ (15,023,005)</b>
Other comprehensive loss:		
Unrealized gain (loss) on available-for-sale marketable securities, net of tax	—	(23,590)
<b>Comprehensive loss</b>	<b>\$ (9,565,077)</b>	<b>\$ (15,046,595)</b>