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): August 9, 2021

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 2.02 Results of Operations and Financial Condition.

On August 9, 2021, NexImmune, Inc. (the "Company") issued a press release announcing its financial results for the second quarter ended June 30, 2021 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.

Item 7.01 Regulation FD Disclosure.

On August 9, 2021 the Company issued a press release announcing its collaboration with Yale University's Department of Immunobiology, which will focus on the use of the Company's direct injection, artificial antigen presenting cells with regards to the regulation of autoimmune diabetes. The full text of the press release is furnished as Exhibit 99.2 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K (including Exhibits 99.1 and 99.2) 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 second quarter ended June 30, 2021, dated August 9, 2021.
99.2	Press release announcing the Company's collaboration with Yale University's Department of Immunobiology
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: August 9, 2021

NexImmune Reports Second Quarter 2021 Financial Results and Provides Business Updates

- *Announcing first solid tumor indication in HPV associated-malignancies – NEXI-003*
- *Advancing two lead product candidates in Phase 1/2 clinical trials*
- *Additional clinical and preclinical data anticipated in the second half of 2021*

GAITHERSBURG, Md., August 9, 2021 (GLOBE NEWSWIRE) -- NexImmune, Inc. (Nasdaq: NEXI), a clinical-stage biotechnology company developing a novel approach to immunotherapy designed to orchestrate a targeted immune response by directing the function of antigen-specific T cells, today reported its financial results for the second quarter of 2021.

“The first half of the year was a very productive period for the company. We are focused on completing enrollment in our Phase I/II clinical trials for NEXI-001 and NEXI-002 and expect to present additional clinical data for each during scientific conferences toward the end of this year,” said Scott Carmer, Chief Executive Officer. “We are also excited to announce our first indication in solid tumors and expect to submit our IND for HPV-associated malignancies in the second quarter of 2022. Additionally, we’ve initiated IND-enabling pre-clinical experiments that will be the basis for multiple IND submissions in support of our injectable nanoparticle (AIM INJ). This progress highlights the promise of our AIM platform across disease areas and delivery modalities, and we look forward to providing further updates on these important programs later this year.”

Select 2Q 2021 Clinical and Business Highlights

Clinical and Preclinical Updates

NEXI-001

- Abstract presented at the American Society of Clinical Oncology (ASCO) 2021 Annual Meeting in June 2021 highlights safety, tolerability, immune responses and early clinical activity in all patients evaluated
- Dose Level 2 (single infusion of 200M cells/month x two cycles) is fully enrolled
- Dose Level 3 (single infusion of 200M cells/week for three weeks x two cycles) is enrolling
- Treatment-related adverse events, including infusion reactions, GVHD, CRS, and neurotoxicity (ICANS), have not been observed in patients who received NEXI-001 at Dose Level 1 and Dose Level 2, either as single or repeat infusions
- Further data expected to be announced during the American Society of Hematology (ASH) Annual Meeting in December 2021

NEXI-002

- Abstract presented at European Hematology Association Annual Meeting in May 2021 highlights safety, tolerability and immune responses in all patients evaluated
- Safety cohort completed and expansion phase is enrolling
- Treatment-related adverse events, including infusion reactions, CRS, and neurotoxicity (ICANS), have not been observed in patients who received NEXI-002
- Further data expected to be announced during the American Society of Hematology (ASH) Annual Meeting in December 2021

NEXI-003

- First solid tumor clinical trial for multi-antigen autologous AIM ACT product will target HPV-associated malignancies
- Preclinical data validating the selection of multiple immunogenic HPV antigen peptides expected to be announced during the Society for Immunotherapy of Cancer's Annual Meeting (SITC 2021) in November 2021
- Investigational new drug (IND) submission planned for 2Q 2022

Other R&D

- IND enabling preclinical studies for the AIM INJ platform continue; abstract presentations planned for SITC 2021 in November 2021
- First collaboration in autoimmune diseases announced with Yale University to evaluate AIM INJ nanoparticles in Type 1 diabetes

Business Updates

- Announced formation of the company's Scientific Advisory Board
- Announced the appointments of Dr. Jack Ragheb, SVP, Translational Medicine, and Matthew Schiller, Head of Business Development

Select 2Q 2021 Financial Highlights

Cash, cash equivalents and marketable securities for the company as of June 30, 2021 were $102.8M compared to $118.1M for quarter ending March 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 through the third quarter of 2022.

Research and development expenses were $8.1M in the second quarter of 2021, compared to $4.2M for the same period in the prior year. The increase in R&D expenses was mainly attributable to costs for the two clinical trials, as well as personnel-related expenses driven by increased headcount.

General and administrative expenses were $4.0M, compared to $2.6M for the same period the prior year. The increase was due primarily to increases in headcount and fees related to professional and consulting services.

Net loss, according to generally accepted accounting principles in the U.S. (GAAP), was $12.2M for the quarter, or a basic and diluted GAAP loss per share of $0.54. This compared to a net loss of $6.9M, or a basic and diluted GAAP loss per share of $6.17, 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's two lead programs, NEXI-001 and NEXI-002, are in Phase 1/2 clinical trials for the treatment of relapsed AML after allogeneic stem cell transplantation and multiple myeloma refractory to 3 or more prior lines of therapy, respectively. NexImmune is also developing new AIM nanoparticle constructs and modalities for potential clinical evaluation in oncology and in disease areas outside of oncology, including autoimmune disorders and infectious disease.

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 six months ended June 30, 2021; the sufficiency of the Company's current cash, cash equivalents and marketable securities to fund its planned operations through the third quarter of 2022; our planned and ongoing clinical studies for the Company's product candidates, including NEXI-001, NEXI-002 and NEXI-003; the initiation, enrollment, timing, progress, release of data from and results of those planned and ongoing clinical 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, 2020 filed with the Securities and Exchange Commission ("SEC") on March 31, 2021, 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.

NEXIMMUNE, INC.

BALANCE SHEETS

	June 30, 2021 (unaudited)	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 63,816,106	$ 5,031,079
Marketable securities	38,979,670	—
Restricted cash	67,500	67,500
Prepaid expenses and other current assets	8,327,117	3,293,858
Total current assets	111,190,393	8,392,437
Property and equipment, net	4,148,875	2,885,260
Other non-current assets	53,373	23,373
Total assets	$115,392,641	$ 11,301,070
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 2,169,660	$ 2,760,129
Accrued expenses	2,469,942	2,603,027
Derivative liability	—	1,702,359
Other current liabilities	843,619	843,619
Convertible notes issued to related parties	—	7,324,267
Convertible notes	—	11,793,397
Total current liabilities	5,483,221	27,026,798
Deferred rent, net of current portion		23,529
Other non-current liabilities	—	4,935
Total liabilities	5,483,221	27,055,262
Commitments and contingencies		
Redeemable convertible preferred stock		
Series A Redeemable Convertible Preferred Stock, $0.0001 par value, no shares outstanding as of June 30, 2021 and 121,735,303 shares authorized, issued and outstanding as of December 31, 2020. Liquidation value of $42,314,789 as of December 31, 2020.	—	35,047,435
Series A-2 Redeemable Convertible Preferred Stock, $0.0001 par value, no shares outstanding as of June 30, 2021 and 28,384,899 shares authorized, 22,047,361 shares issued and outstanding as of December 31, 2020. Liquidation value of $8,683,746 as of December 31, 2020.	—	7,685,865
Series A-3 Redeemable Convertible Preferred Stock, $0.0001 par value, no shares outstanding as of June 30, 2021 and 34,061,879 shares authorized, 31,209,734 shares issued and outstanding as of December 31, 2020. Liquidation value of $11,699,176 as of December 31, 2020.	—	10,887,449
Total redeemable convertible preferred stock	—	53,620,749
Stockholders' equity (deficit)		
Common Stock, $0.0001 par value, 250,000,000 shares authorized, 22,628,007 issued and outstanding as of June 30, 2021 and 1,256,609 shares issued and outstanding as of December 31, 2020.	2,263	126
Additional paid-in-capital	207,480,819	8,206,938
Accumulated other comprehensive loss	(2,917)	—
Accumulated deficit	(97,570,745)	(77,582,005)
Total stockholders' equity (deficit)	109,909,420	(69,374,941)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$115,392,641	$ 11,301,070

NEXIMMUNE, INC.

STATEMENTS OF OPERATIONS
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	8,124,973	4,209,261	14,137,581	8,481,428
General and administrative	4,038,050	2,565,402	8,095,642	4,653,803
Total operating expenses	12,163,023	6,774,663	22,233,223	13,135,231
Loss from operations	(12,163,023)	(6,774,663)	(22,233,223)	(13,135,231)
Other (expense) income:				
Interest income	6,851	1,184	10,464	19,868
Interest expense	(101)	(183,682)	(904,220)	(184,671)
Change in fair value of derivative liability	—	—	2,424,877	—
Other (expense) income	(25,974)	26,636	(26,696)	54,001
Other (expense) income	(19,224)	(155,862)	1,504,425	(110,802)
Net Loss	$(12,182,247)	$(6,930,525)	$(20,728,798)	$(13,246,033)
Accumulated dividends on Redeemable Convertible Preferred Stock	—	(815,816)	(377,562)	$ (1,631,632)
Net loss attributable to common stockholders	$(12,182,247)	$(7,746,341)	$(21,106,360)	$(14,877,665)
Basic and diluted net loss attributable to common stockholders per common share	$ (0.54)	$ (6.17)	$ (1.20)	$ (11.86)
Basic and diluted weighted-average number of common shares outstanding	22,608,866	1,254,681	17,648,551	1,254,681

STATEMENTS OF COMPREHENSIVE LOSS
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Net loss	$(12,182,247)	$(6,930,525)	$(20,728,798)	$(13,246,033)
Other comprehensive loss:				
Unrealized (loss) gain on available-for-sale marketable securities, net of tax	(2,917)	—	(2,917)	(506)
Comprehensive loss	$(12,185,164)	$(6,930,525)	$(20,731,715)	$(13,246,539)

Contacts

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NexImmune to Explore the Use of AIM™ Direct Injection Technology in Type 1 Diabetes

GAITHERSBURG, MD – August 9, 2021 – NexImmune, Inc. (Nasdaq: NEXI), a clinical-stage biotechnology company developing a novel approach to immunotherapy designed to orchestrate a targeted immune response by directing the function of antigen-specific T cells, today announced a collaboration with Yale University's Department of Immunobiology. The collaboration will focus on the use of NexImmune's direct injection, artificial antigen presenting cells (AIM INJ) with regards to the regulation of autoimmune diabetes (Type 1 diabetes). Dr. Kevan Herold, Deputy Director of Yale Center for Clinical Investigation and Co-Director of the Yale Diabetes Center will be the principal investigator.

"We are excited to enter into this collaboration that will explore our next-generation, direct-injectable artificial antigen presenting cell platform for autoimmune diseases," said Dr. Jerry Zeldis, Executive Vice President, R&D of NexImmune. "Our goal with Dr. Herold is to advance novel treatments that could potentially reverse the course and prevent type 1 diabetes by targeting the auto-reactive T cells that cause this disease."

"By directly targeting the auto-reactive T cells that are known to be a mediator of pancreatic beta cell destruction, we can potentially develop a transformative therapy for patients suffering with autoimmune diabetes. Working with NexImmune allows us to explore a very compelling technology to impact this life-long and difficult to control disease" stated Dr. Herold.

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Contacts

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