NexImmune Reports Second Quarter 2023 Financial Results and Provides Business Updates

August 10, 2023

- *NEXI-001 data presented at ASCO 2023 demonstrates proof-of-concept in patients with relapsed AML after allogeneic hematopoietic cell transplantation (HCT) and refractory to additional chemotherapy or salvage treatments; one patient continues to show no evidence of disease at nine months*
- *Preclinical data demonstrates superior potency and durability when combining T cell engager (TCE) bispecific agents with AIM-expanded multi-tumor-antigen-specific T cell at low doses*
- *NIH collaboration demonstrates AIM antigen-target functional validation capability and the potential of CD8+ T cell therapies as future treatments for EBV-related non-malignant diseases, such as multiple sclerosis (MS) and systemic lupus erythematosus (SLE)*
- *The oncology and autoimmune injectable nanoparticles demonstrate the ability to activate and expand or reduce and suppress targeted antigen specific T cells in vivo*

GAITHERSBURG, Md., Aug. 10, 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 in oncology, autoimmune and infectious diseases, today reported financial results for the second quarter of 2023.

“Our previously announced strategic prioritization of our injectable modality (AIM INJ) underscores our commitment to delivering on the significant potential of our artificial antigen-presenting cell (aAPC) nanoparticles to drive antigen-specific T cell function beyond cell therapy approaches and oncology. In our clinical trials with our adoptive cell therapy, we have demonstrated the ability to expand AML tumor-specific T cells with combined memory and effector functions and have observed clinical responses. Furthermore, our collaborations have generated preclinical data that highlights the potential to drive response in solid tumor indications, as well as non-malignant immunology diseases such as MS and SLE,” said Kristi Jones, NexImmune’s CEO.

“Our cells exhibit potential superior potency and durability in preclinical models, combining a low dose of AIM multi-tumor expanded T cells with low doses of T-cell engaging bispecific agents, and showing synergistic tumor killing. We believe that these data support the importance of combining a “fit” multi-tumor specific T cell approach with other T cell immuno-oncology mechanisms and represent a unique opportunity to transform treatment paradigms, especially in solid tumors.”

“We remain excited about advancing the injectable programs to the clinic and we are encouraged by initial dialogue with the FDA. We believe that the ability to bypass the host dendritic cell and directly engage T cells in the body provides the potential for greater specific T cell responses. Preclinical data to date has been consistent across modalities in the ability to selectively activate and expand important tumor specific T cells with cancer cell killing capacity. In autoimmune disease models, our injectable nanoparticles have been shown to selectively reduce and suppress the disease-causing T cells that reside in the lymph node and target organs in diseases such as T1D. Several manufacturing components have already been produced and process transfer plans are underway. We also continue to advance our Class II approach designed to address diseases like rheumatoid arthritis (RA) and celiac disease.”

“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 immunotherapies and novel combinations and look forward to providing updates in the future.”

Select Second Quarter 2023 Clinical and Business Highlights

Clinical and Preclinical Updates

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

- Initiated multiple preclinical studies to evaluate NEXI-100 as a monotherapy and in combination with other cancer immunotherapies to support the Company’s oncology program.
- 2023 FOCIS Annual Meeting poster presentation reported AIM nanoparticle expansion of EBV-specific T-cell from healthy donors and patients with MS revealed a functional defect in the EBV response of MS patients to select antigen peptide targets, which may be a contributing factor in the pathogenesis of MS as well as other EBV related non-malignant diseases such as SLE.
- In partnership with Yale University Professor Kevan Herold and the Juvenile Diabetes Research Fund (JDRF), evaluation of AIM injectable nanoparticles in type 1 diabetes (T1D) confirmed their ability to drive T cell function *in vivo* as evidenced by a significant delay in the onset of spontaneous T1D that is associated with a reduction in T1D inducing memory T cells in pancreatic lymph nodes and the pancreas. Future experiments will be conducted to test the addition of suppressive and apoptotic 2nd signals to the AIM nanoparticles in addition to therapeutic combination approaches with anti-CD3 agents.

- Continued to advance neo-antigen our melanoma research collaboration with NYU Langone's Perlmutter Cancer Center.
- Continued to work in other areas of autoimmune diseases, including vitiligo, MS, HTLV-1-associated myelopathy and others.

NEXI-001 Relapsed Refractory AML Post Allo-HSCT

- A marked increase in antigen-specific cells was observed with increasing dose levels, consistent with a dose response observation. The persistence of antigen-specific T-cells with phenotypes associated with anti-tumor effect and immunologic memory was consistently observed in blood and bone marrow.
- Phase 1 data reported at ASCO 2023 shows NEXI-001 is well tolerated with a favorable safety profile. An immunologic and clinical dose responses were observed. Since ASCO, the clinical response observed in the Cohort 3 patient with poor prognosis extramedullary disease who received the highest cell dose tested (200M x 3, Cycle 1 only) has now been maintained up to nine months. As of the most recent follow-up, the patient remains asymptomatic with no evidence of disease and continues to be monitored.

Manufacturing and Regulatory:

- Transitioning the IND engine capability: Established ACT cell therapy and nanoparticle platform manufacturing to enable IND engine in blood and solid tumor indications. The Company is proactively transitioning this approach to the injectable program.
- Preparing to manufacture clinical material for the planned injectable IND: Completed clinical protein production, selected polymer vendor and the transfer activities to our CDMO are underway to support the planned submission of an IND for NEXI-101 (injectable) in 2H2024.

Select Second Quarter 2023 Financial Highlights

Cash and cash equivalents for the Company as of June 30, 2023 were $16.3 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 $4.9 million in the second quarter of 2023, compared to $11.8 million for the same period in the prior year. The decrease of $6.9 million was due primarily to the completion of preclinical manufacturing work, pausing of clinical trials, and reduction in personnel-related expenses resulting from terminations.

General and administrative expenses were $2.9 million, compared to $4.1 million for the same period in the prior year. The decrease was primarily due to decreases in legal and other administrative fees expenses and in personnel-related expenses.

Net loss, according to U.S. generally accepted accounting principles in the, or GAAP, was $7.6 million for the quarter, or a basic and diluted GAAP net loss per share of $0.29. This compares to a net loss of $15.9 million, or a basic and diluted GAAP net loss per share of $0.69, 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.

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 and six months ended June 30, 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; the expectation of submitting an IND for NEXI-101 (injectable) in 2024; 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.

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NEXIMMUNE, INC.

BALANCE SHEETS

	June 30, 2023	December 31, 2022
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 16,281,020	$ 34,642,340
Restricted cash	55,000	55,000
Prepaid expenses and other current assets	2,163,990	2,671,411
Total current assets	18,500,010	37,368,751
Property and equipment, net	3,970,516	4,459,071
Operating lease right-of-use assets	703,217	967,032
Other non-current assets	300,205	264,970
Total assets	$ 23,473,948	$ 43,059,824
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 582,510	$ 2,377,374
Accrued expenses	5,139,784	7,357,153
Operating lease liabilities, current	545,285	599,047
Total current liabilities	6,267,579	10,333,574
Operating lease liabilities, net of current portion	203,887	425,766
Total liabilities	6,471,466	10,759,340
Commitments and contingencies		
Stockholders' equity		
Common Stock, $0.0001 par value, 250,000,000 shares authorized as of June 30, 2023 and December 31, 2022; 26,078,451 shares issued and outstanding as of June 30, 2023 and December 31, 2022	2,608	2,608
Additional paid-in-capital	224,381,109	222,547,530
Accumulated deficit	(207,381,235)	(190,249,654)
Total stockholders' equity	17,002,482	32,300,484
Total liabilities and stockholders' equity	$ 23,473,948	$ 43,059,824

NEXIMMUNE, INC.

STATEMENTS OF OPERATIONS
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	4,880,338	11,837,519	11,004,382	22,286,362
General and administrative	2,904,321	4,088,445	6,605,686	8,693,124
Total operating expenses	7,784,659	15,925,964	17,610,068	30,979,486
Loss from operations	(7,784,659)	(15,925,964)	(17,610,068)	(30,979,486)
Other income (expense):				
Interest income	223,321	84,221	498,059	117,314
Other expense	(5,166)	(19,046)	(19,572)	(21,622)
Other income, net	218,155	65,175	478,487	95,692
Net Loss	$ (7,566,504)	$ (15,860,789)	$ (17,131,581)	$ (30,883,794)
Basic and diluted net loss attributable to common stockholders per common share	$ (0.29)	$ (0.69)	$ (0.66)	$ (1.35)

Basic and diluted weighted-average number of common shares outstanding	26,078,451	22,871,369	26,078,451	22,854,311

STATEMENTS OF COMPREHENSIVE LOSS
(unaudited)

	Three Months Ended March 31,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Net loss	$ (7,566,504)	$ (15,860,789)	$ (17,131,581)	$ (30,883,794)
Other comprehensive loss:				
Unrealized gain (loss) on available-for-sale marketable securities, net of tax	—	11,243	—	(12,347)
Comprehensive loss	$ (7,566,504)	$ (15,849,546)	$ (17,131,581)	$ (30,896,141)