NexImmune Reports Third Quarter 2022 Financial Results and Announces Strategic Update

November 14, 2022

- *Company announces a strategic shift to focus on advancing its AIM Direct Injection (AIM INJ) platform and potential product candidates in oncology and autoimmune diseases*
- *Initiating a corporate resource reallocation to advance the AIM INJ platform, reduce operating expenses and extend cash runway through the third quarter of 2023*
- *Pausing enrollment and initiation for the NEXI-001 and NEXI-003 trials, respectively, and pursuing external clinical development through potential academic and corporate partners*

GAITHERSBURG, Md., Nov. 14, 2022 (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 third quarter of 2022 and announced a change in corporate strategy.

"While we remain confident in the potential therapeutic benefit of our AIM ACT cell therapy programs, following a strategic review of our pipeline, indications, timelines and cash position, we have decided that the best path forward for NexImmune is to realign internal resources to focus on advancing our AIM INJ 'off-the-shelf' platform," said Kristi Jones, Chief Executive Officer. "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. We believe there is a high level of excitement and momentum around our AIM INJ platform and its 'off-the-shelf' applications. Internally and externally generated evidence show encouraging signals of preclinical activity in models of oncology and autoimmune disorders. We will provide an update on these programs and continue to focus our resources to demonstrate the potential of our AIM INJ 'IND engine' to enable a rapid path to clinical development."

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 we will be pausing our cell therapy clinical trials, we are exploring external opportunities with academic centers and corporate collaborators with the potential to continue advancing our clinical and preclinical programs. Importantly, we have demonstrated unique capabilities to successfully transfer our platform manufacturing process, rapidly validate targets and deliver IND-ready products in months. We will retain the internal expertise and core capabilities which will be fully leveraged, provide utility and drive value, regardless of modality."

Business and Strategy Update

The Company's realignment of R&D resources to focus on the AIM INJ platform will extend its cash runway and enable greater focus on generating data and advancing the AIM INJ preclinical programs. The Company will pause development of its current adoptive cell therapy (AIM ACT) products in the NEXI-001 trial in relapsed refractory AML following hematopoietic stem cell transplantation (HSCT). The Company will not initiate the NEXI-003 trial in HPV-mediated tumors at this time and, as previously disclosed, the NEXI-002 trial in multiple myeloma will also remain paused. As part of this strategic realignment, the Company intends to:

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

- Maintain development capabilities and expand collaborations necessary to continue to generate data and information needed to advance preclinical programs to Investigational New Drug (IND) application submission.
- Continue multiple ongoing preclinical studies in oncology and autoimmune disorders and initiate several additional studies. Initial preclinical evidence demonstrates the potential to modify the course of autoimmune diseases using nanoparticles designed to treat and ultimately to induce tolerance.

NEXI-001 Relapsed Refractory AML Post Allo-HSCT

- Continue to dose and follow patients currently enrolled in the trial.
- Announce data for currently enrolled patients, which is expected in the first quarter of 2023.

NEXI-003 HPV-Related Cancers

- 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.
- Pause current ongoing activities required to initiate the NEXI-003 cell therapy trial and focus on developing a potential product candidate using the AIM INJ platform.

Operational Changes

- Implement a strategic realignment initiative, which is designed to reduce costs and reallocate resources towards our AIM INJ preclinical development programs. As part of this strategy, the Company will initiate a workforce reduction plan to

reduce headcount by approximately 30%, primarily affecting the clinical development, manufacturing and administrative staff that had been needed to support the AIM ACT clinical programs.

- The Company estimates that it will incur approximately $0.7 million of costs in connection with the reduction in workforce related to severance pay and other related termination benefits and expects the majority of the costs associated with the restructuring to be incurred during the fourth quarter ending December 31, 2022.

Select Third Quarter 2022 Financial Highlights

Cash, cash equivalents, and marketable securities for the Company as of September 30, 2022 were $45.9 million compared to $53.1 million for the quarter ending June 30, 2022. Based on current operating plans, including the impact of the ongoing restructuring, NexImmune expects that its existing cash and cash equivalents will enable the Company to fund its operating and capital expenditure requirements through the third quarter of 2023.

Research and development expenses were $11.1 million in the third quarter of 2022, compared to $11.3 million for the same period in the prior year.

General and administrative expenses were $3.7 million, compared to $4.2 million for the same period in the prior year. The decrease was primarily due to decreased personnel-related expenses partially offset by increased professional fees.

Net loss, according to generally accepted accounting principles in the U.S. GAAP, was $14.7 million for the quarter, or a basic and diluted GAAP loss per share of $0.60. This compares to a net loss of $14.6 million, or a basic and diluted GAAP loss per share of $0.65, 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 planned change in corporate strategy and realignment, including the pausing of the Company's current clinical trials and the focusing on development of the AIM INJ platform; the enrollment, timing, progress, release of data from and results of the 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 utility of prior preclinical and clinical data in determining future clinical results; and the expectation that existing cash and cash equivalents will enable the Company to fund its operating and capital expenditure requirements through the third quarter of 2023. 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, 2021 filed with the Securities and Exchange Commission ("SEC") on March 9, 2022, 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

	September 30, 2022 (unaudited)	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 45,860,454	$ 30,326,352
Marketable securities	—	51,491,942

Restricted cash	105,000	67,500
Prepaid expenses and other current assets	6,034,874	4,394,916
Total current assets	52,000,328	86,280,710
Property and equipment, net	4,506,566	4,427,307
Operating lease right-of-use assets	1,095,475	—
Other non-current assets	72,079	324,099
Total assets	$ 57,674,448	$ 91,032,116
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,260,511	$ 1,045,159
Accrued expenses	7,539,235	6,170,709
Operating lease liabilities, current	594,664	—
Total current liabilities	9,394,410	7,215,868
Operating lease liabilities, net of current portion	564,505	—
Deferred rent, net of current portion	—	55,581
Total liabilities	9,958,915	7,271,449
Commitments and contingencies		
Stockholders' equity		
Common Stock, $0.0001 par value, 250,000,000 shares authorized as of September 30, 2022 and December 31, 2021; 26,078,451 and 22,828,904 issued and outstanding as of September 30, 2022 and December 31, 2021	2,608	2,283
Additional paid-in-capital	221,069,554	211,498,827
Accumulated other comprehensive income	—	3,012
Accumulated deficit	(173,356,629)	(127,743,455)
Total stockholders' equity	47,715,533	83,760,667
Total liabilities and stockholders' equity	$ 57,674,448	$ 91,032,116

NEXIMMUNE, INC.
STATEMENTS OF OPERATIONS
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	11,136,500	11,331,189	33,422,862	25,468,770
General and administrative	3,719,601	4,159,196	12,412,725	12,254,838
Total operating expenses	14,856,101	15,490,385	45,835,587	37,723,608
Loss from operations	(14,856,101)	(15,490,385)	(45,835,587)	(37,723,608)
Other (expense) income:				
Interest income	226,752	19,855	344,066	30,319
Change in fair value of derivative liability	—	—	—	2,424,877
Interest expense	—	(1,106)	—	(905,326)
Other expense	(100,031)	(19,095)	(121,653)	(45,791)
Other income (expense)	126,721	843,273	222,413	2,347,698
Net Loss	$ (14,729,380)	$ (14,647,112)	$ (45,613,174)	$ (35,375,910)
Accumulated dividends on Redeemable Convertible Preferred Stock	—	—	—	(377,562)
Net loss attributable to common stockholders	$ (14,729,380)	$ (14,647,112)	$ (45,613,174)	$ (35,753,472)
Basic and diluted net loss attributable to common stockholders per common share	$ (0.60)	$ (0.65)	$ (1.95)	$ (1.85)
Basic and diluted weighted-average number of common shares outstanding	24,410,334	22,653,410	23,380,613	19,335,170

STATEMENTS OF COMPREHENSIVE LOSS
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Net loss	$ (14,729,380)	$ (14,647,112)	$ (45,613,174)	$ (35,375,910)

Other comprehensive loss:				
Unrealized gain (loss) on available-for-sale marketable securities, net of tax	9,335	3,619	(3,012)	702
Comprehensive loss	$ (14,720,045)	$ (14,643,493)	$ (45,616,186)	$ (35,375,208)