NexImmune Reports Second Quarter 2022 Financial Results and Highlights FDA Clearance of IND for NEXI-003 for the Treatment of HPV-Related Cancers

August 15, 2022

- *Received U.S. Food and Drug Administration (FDA) clearance of Investigational New Drug (IND) submission for NEXI-003, the Company's first solid tumor product candidate for the treatment of HPV-related cancers*
- *Plans to report additional preclinical and IND enabling data for the AIM Injectable platform in 2H22*
- *Clinical updates for the Company's two lead product candidates in Phase 1/2 clinical trials expected in 4Q22*
- *Company is prioritizing resources to support Company's lead product candidates, NEXI-001 and NEXI-003*

GAITHERSBURG, Md., Aug. 15, 2022 (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 for liquid and solid malignancies, today reported financial results for the second quarter of 2022.

"We are encouraged by the increase in enrollment in our NEXI-001 trial and look forward to providing a clinical update in fourth quarter," said Kristi Jones, Chief Executive Officer. "The FDA has recently cleared the NEXI-003 IND, enabling us to advance our first solid tumor program in HPV-related malignancies and we plan to initiate the study before year end. Due to resource prioritization, and the evolving treatment landscape in relapsed refractory multiple myeloma, we plan to pause enrollment of NEXI-002 and provide an update on patients currently being treated. In parallel, we continue to make progress on our IND-enabling work for the AIM injectable modality, an 'off-the-shelf' multi-antigen specific approach to treating malignancies and autoimmune diseases, which we believe has the potential to be disruptive. We will provide an update on these early programs through the end of year. We continue to focus on generating data and demonstrating the potential of our 'IND engine' to enable a rapid path to clinical development and look forward to providing updates on our progress and upcoming catalysts."

Second Quarter 2022 Clinical and Business Highlights

Clinical and Preclinical Updates

NEXI-001

- Currently enrolling patients in cohort 3, dose level 4, the final safety cohort, prior to expansion
- Updated clinical results, including patients at the highest dose level, are expected to be announced in the 4Q22
- Robust immune responses with signs of clinical activity and potential dose response have been observed
- Due to the favorable emerging clinical profile, the protocol has been amended to include patients with haplo-identical donors
- NEXI-001 continues to be well tolerated across all dose levels administered to date, with no Grade ≥3 treatment-related adverse events, including infusion reactions, GVHD, CRS or neurotoxicity (ICANS), reported

NEXI-003

- Received IND clearance by the FDA for the treatment of HPV-related cancers
- Finalized antigen selection for NEXI-003 and manufactured nanoparticles for clinical trials
- Trial expected to be initiated by YE22

NEXI-002

- Due to recent product approvals and the competitive environment in the relapsed refractory multiple myeloma space, the Company will pause enrollment to prioritize resources
- Company will consider shifting enrollment to earlier disease at a future date
- In this heavily pre-treated population, evidence of immune response and signs of clinical activity have been observed. NEXI-002 continues to be well tolerated with no Grade ≥3 treatment-related adverse events, including infusion reactions, GVHD, CRS or neurotoxicity (ICANS), reported
- Manufacturing achieved higher final cell count yield in recent products by adjusting prior treatment washout period, updating cell collection guidance and other process adjustments
- Further clinical data from existing patients are expected later this year

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

- Advanced *in vivo* and preclinical work to support the development of injectable nanoparticles, as a therapeutic, in oncology and autoimmune diseases
- Advanced work with Yale University Professor Kevan Herold to evaluate NEXI's injectable nanoparticles for the treatment of type 1 diabetes. A JDRF-funded grant award supports the collaboration

Select Second Quarter 2022 Financial Highlights

Cash, cash equivalents and marketable securities for the Company as of June 30, 2022 were $53.1 million compared to $65.0 million for the quarter ending March 31, 2022. Based on 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 second quarter of 2023.

Research and development expenses were $11.8 million in the second quarter of 2022, compared to $8.1 million for the same period in the prior year. The increase in research and development expenses was mainly attributable to costs for the two ongoing clinical trials, as well as personnel-related expenses driven by increased headcount.

General and administrative expenses were $4.1 million, compared to $4.0 million for the same period in the prior year. The slight increase was primarily due to increased fees related to professional and consulting services offset by reductions in personnel-related expenses.

Net loss, according to generally accepted accounting principles in the U.S. (GAAP), was $15.9 million for the quarter, or a basic and diluted GAAP loss per share of $0.69. This compares to a net loss of $12.2 million, or a basic and diluted GAAP loss per share of $0.54, 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.

NexImmune's lead programs, NEXI-001, NEXI-002 and NEXI-003, are in Phase 1/2 clinical trials for the treatment of relapsed AML after allogeneic stem cell transplantation, multiple myeloma refractory to 3 or more prior lines of therapy and HPV-related cancers, respectively. NexImmune is also developing AIM nanoparticle constructs and modalities for potential clinical evaluation in oncology and in disease areas outside of oncology, including autoimmune disorders and infectious disease.

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.

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 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; the timing, progress and release of preclinical data from our AIM injectable 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, 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.

Contacts

Investors:
Chad Rubin, SVP Corporate Affairs
NexImmune, Inc.
crubin@neximmune.com

NEXIMMUNE, INC.

BALANCE SHEETS

	June 30, 2022	December 31, 2021
	(unaudited)	
ASSETS		

Current assets:		
Cash and cash equivalents	$ 40,644,227	$ 30,326,352
Marketable securities	12,484,305	51,491,942
Restricted cash	105,000	67,500
Prepaid expenses and other current assets	6,355,781	4,394,916
Total current assets	59,589,313	86,280,710
Property and equipment, net	4,709,036	4,427,307
Operating lease right-of-use assets	1,221,668	—
Other non-current assets	146,013	324,099
Total assets	$ 65,666,030	$ 91,032,116
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,652,435	$ 1,045,159
Accrued expenses	6,871,039	6,170,709
Operating lease liabilities, current	590,313	—
Total current liabilities	9,113,787	7,215,868
Operating lease liabilities, net of current portion	699,562	—
Deferred rent, net of current portion	—	55,581
Total liabilities	9,813,349	7,271,449
Commitments and contingencies		
Stockholders' equity		
Common Stock, $0.0001 par value, 250,000,000 shares authorized as of June 30, 2022 and December 31, 2021; 22,893,551 and 22,828,904 issued and outstanding as of June 30, 2022 and December 31, 2021	2,289	2,283
Additional paid-in-capital	214,486,976	211,498,827
Accumulated other comprehensive income	(9,335)	3,012
Accumulated deficit	(158,627,249)	(127,743,455)
Total stockholders' equity	55,852,681	83,760,667
Total liabilities and stockholders' equity	$ 65,666,030	$ 91,032,116

NEXIMMUNE, INC.

STATEMENTS OF OPERATIONS
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	**2021**	**2022**	**2021**
Revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	11,837,519	8,124,973	22,286,362	14,137,581
General and administrative	4,088,445	4,038,050	8,693,124	8,095,642
Total operating expenses	15,925,964	12,163,023	30,979,486	22,233,223
Loss from operations	(15,925,964)	(12,163,023)	(30,979,486)	(22,233,223)
Other (expense) income:				
Interest income	84,221	6,851	117,314	10,464
Change in fair value of derivative liability	—	—	—	2,424,877
Interest expense	—	(101)	—	(904,220)
Other expense	(19,046)	(25,974)	(21,622)	(26,696)
Other income (expense)	65,175	(19,224)	95,692	1,504,425
Net Loss	$ (15,860,789)	$ (12,182,247)	$ (30,883,794)	$ (20,728,798)
Accumulated dividends on Redeemable Convertible Preferred Stock	—	—	—	(377,562)
Net loss attributable to common stockholders	$ (15,860,789)	$ (12,182,247)	$ (30,883,794)	$ (21,106,360)
Basic and diluted net loss attributable to common stockholders per common share	$ (0.69)	$ (0.54)	$ (1.35)	$ (1.20)
Basic and diluted weighted-average number of common shares outstanding	22,871,369	22,608,866	22,854,311	17,648,551

STATEMENTS OF COMPREHENSIVE LOSS
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	**2021**	**2022**	**2021**
Net loss	$ (15,860,789)	$ (12,182,247)	$ (30,883,794)	$ (20,728,798)

Other comprehensive loss:				
Unrealized gain (loss) on available-for-sale marketable securities, net of tax	11,243	(2,917)	(12,347)	(2,917)
Comprehensive loss	$ (15,849,546)	$ (12,185,164)	$ (30,896,141)	$ (20,731,715)