NexImmune Reports Third Quarter 2021 Financial Results and Provides Business Updates

November 12, 2021

- *Advancing two lead product candidates in Phase 1/2 clinical trials*
- *Additional clinical and preclinical data anticipated by year end 2021 and first half 2022*
- *Announced collaboration with Yale University Department of Immunobiology to explore use of AIM INJ in regard to regulation of Type 1 Diabetes*

GAITHERSBURG, Md., Nov. 12, 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 third quarter of 2021.

“We had another strong quarter as characterized by our continued progress developing the AIM technology platform,” said Scott Carmer, Chief Executive Officer. “Our primary focus remains on completing enrollment in our Phase I/II clinical trials for NEXI-001 and NEXI-002. We plan to provide clinical updates for the NEXI-001 trial in AML during the first half of 2022 and will update the NEXI-002 trial in relapsed / refractory multiple myeloma at the upcoming ASH conference. Additionally, we are presenting the antigen peptide targets to be included in our first solid tumor IND application for HPV-associated malignancies at the SITC Annual Meeting. Finally, we’re very excited with the progress of our research collaboration with the lab of Professor Kevan Herold at Yale University, which explores the effects of our AIM injectable nanoparticle as a therapeutic for Type 1 Diabetes. Our team looks forward to providing future updates on these and other important projects as we continue to progress the development of our AIM technology across a range of therapy areas and with multiple modalities.”

Select 3Q 2021 Clinical and Business Highlights

Clinical and Preclinical Updates

NEXI-001

- Robust immune responses across all dose levels with signs of increased clinical activity associated with higher doses
- 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
- Due to the favorable emerging clinical profile, plans are underway to expand the addressable population with an additional study arm to include patients with haplo-identical donors
- Ongoing enrollment in the Phase I/II trial has been affected by higher than anticipated patient replacements between the enrollment and 28-day DLT clearance period due to non-treatment-related events; updated clinical results expected to be announced in the first half of 2022

NEXI-002

- Safety cohort completed and expansion phase continues to enroll and dose
- NEXI-002 continues to be well tolerated with no Grade ≥3 treatment-related adverse events, including infusion reactions, GVHD, CRS or neurotoxicity (ICANS), reported
- Further clinical data from the Phase I/II trial is expected to be announced at the American Society of Hematology (ASH) Annual Meeting in December 2021

NEXI-003

- Preclinical data supporting the selection of multiple immunogenic antigen peptides commonly expressed on HPV-associated tumors is being presented during the Society for Immunotherapy of Cancer’s Annual Meeting (SITC 2021) in November 2021
- Investigational New Drug (IND) submission planned for mid-year 2022

Other R&D

- First collaboration in autoimmune diseases announced with Yale University Professor Kevan Herold to evaluate AIM INJ nanoparticles as a therapeutic in Type 1 diabetes

Business Updates

- Announced the appointments of Dr. Jack Ragheb as SVP, Translational Medicine, and Matthew Schiller as Head of Business Development

Select 3Q 2021 Financial Highlights

Cash, cash equivalents and marketable securities for the company as of September 30, 2021 were $93.2M compared to $102.8M for quarter ending June 30, 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 4Q22.

Research and development expenses were $11.3M in the third quarter of 2021, compared to $4.9M 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 $4.2M, compared to $2.8M 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 $14.6M for the quarter, or a basic and diluted GAAP loss per share of $0.65. This compared to a net loss of $8.6M, or a basic and diluted GAAP loss per share of $7.52, 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 nine months ended September 30, 2021; the sufficiency of the Company's current cash, cash equivalents and marketable securities to fund its planned operations through the fourth quarter of 2022; our planned and ongoing clinical trials 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 trials and preclinical 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.

Contacts

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NEXIMMUNE, INC.

BALANCE SHEETS

	September 30, 2021	December 31, 2020
	(unaudited)	
ASSETS		
Current assets:		

Cash and cash equivalents	$ 37,256,427	$ 5,031,079
Marketable securities	55,986,355	—
Restricted cash	67,500	67,500
Prepaid expenses and other current assets	5,416,575	3,293,858
Total current assets	98,726,857	8,392,437
Property and equipment, net	4,287,254	2,885,260
Other non-current assets	1,527,596	23,373
Total assets	$ 104,541,707	$ 11,301,070
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 3,501,098	$ 2,760,129
Accrued expenses	3,931,449	2,603,027
Derivative liability	—	1,702,359
Other current liabilities	—	843,619
Convertible notes issued to related parties	—	7,324,267
Convertible notes	—	11,793,397
Total current liabilities	7,432,547	27,026,798
Deferred rent, net of current portion	—	23,529
Other non-current liabilities	—	4,935
Total liabilities	7,432,547	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 September 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 September 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 September 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, 22,711,247 issued and outstanding as of September 30, 2021 and 1,256,609 shares issued and outstanding as of December 31, 2020.	2,271	126
Additional paid-in-capital	209,324,044	8,206,938
Accumulated other comprehensive income	702	—
Accumulated deficit	(112,217,857)	(77,582,005)
Total stockholders' equity (deficit)	97,109,160	(69,374,941)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 104,541,707	$ 11,301,070

NEXIMMUNE, INC.

STATEMENTS OF OPERATIONS
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	11,331,189	4,913,055	25,468,770	13,394,483
General and administrative	4,159,196	2,752,251	12,254,838	7,406,054
Total operating expenses	15,490,385	7,665,306	37,723,608	20,800,537
Loss from operations	(15,490,385)	(7,665,306)	(37,723,608)	(20,800,537)
Other (expense) income:				
Interest income	19,855	812	30,319	20,680
Change in fair value of derivative liability	—	(397,244)	2,424,877	(397,244)
Gain on extinguishment of debt	843,619	—	843,619	—
Interest expense	(1,106)	(559,325)	(905,326)	(743,996)

Other (expense) income	(19,095)	12,328	(45,791)	66,329
Other (expense) income	843,273	(943,429)	2,347,698	(1,054,231)
Net Loss	$ (14,647,112)	$ (8,608,735)	$ (35,375,910)	$ (21,854,768)
Accumulated dividends on Redeemable Convertible Preferred Stock	—	(824,781)	(377,562)	(2,456,413)
Net loss attributable to common stockholders	$ (14,647,112)	$ (9,433,516)	$ (35,753,472)	$ (24,311,181)
Basic and diluted net loss attributable to common stockholders per common share	$ (0.65)	$ (7.52)	$ (1.85)	$ (19.38)
Basic and diluted weighted-average number of common shares outstanding	22,653,410	1,254,808	19,335,170	1,254,724

STATEMENTS OF COMPREHENSIVE LOSS
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
Net loss	$ (14,647,112)	$ (8,608,735)	$ (35,375,910)	$ (21,854,768)
Other comprehensive loss:				
Unrealized (loss) gain on available-for-sale marketable securities, net of tax	3,619	—	702	(506)
Comprehensive loss	$ (14,643,493)	$ (8,608,735)	$ (35,375,208)	$ (21,855,274)