

NextCure Reports Second Quarter 2021 Financial Results

August 5, 2021

BELTSVILLE, Md., Aug. 05, 2021 (GLOBE NEWSWIRE) -- NextCure, Inc. (Nasdaq: NXTC), a clinical-stage biopharmaceutical company committed to discovering and developing novel, first-in-class immunomedicines to treat cancer and other immune-related diseases, today reported second quarter 2021 financial results and provided a business update.

"We have made notable progress across all of our clinical programs including several enhancements to the ongoing NC318 Phase 2 monotherapy trial. Clinical sites can now select for S15+ patients, through screening biopsies in a CLIA certified laboratory. In addition, we have resumed enrolling non-small cell lung cancer (NSCLC) adenocarcinoma patients in the ongoing NC318 monotherapy trial and have revised the NC318 dosing regimen to increase overall drug exposure to NC318," said Michael Richman, NextCure's president and chief executive officer. "We expect to provide a data update from our ongoing Phase 2 monotherapy trial of NC318, as well as to report Phase 1 data for NC410 by year-end. We have initiated clinical development of our third program, NC762 targeting B7-H4, with anticipated initial Phase 1 data mid-2022."

Business Highlights and Upcoming Milestones

- NC318
 - Clinical Laboratory Improvement Amendments (CLIA) validated assay available for S15+ patient selection to
 effectively evaluate NC318 activity in patients with S15+ tumors.
 - Resumed enrollment of a non-small cell lung cancer (NSCLC) adenocarcinoma cohort in the ongoing Phase 2 monotherapy trial.
 - Revised dosing regimen to 800 mg weekly to increase overall drug exposure.
 - o On track to report Phase 2 monotherapy update in the fourth guarter of 2021.
 - In the second quarter of 2021, Yale University commenced a Phase 2 investigator-initiated clinical trial of NC318 in combination with pembrolizumab in patients with advanced NSCLC with anticipated initial data in the first half of 2022
- NC410
 - Presented trial in progress poster at the 2021 American Society of Clinical Oncology (ASCO) Virtual Annual Meeting.
 - Published preclinical data demonstrating that NC410 promoted T cell mediated anti-tumor immunity, enhanced infiltration and increased localized activity of T cells in the tumor microenvironment.
 - On track to report initial clinical data in the fourth quarter of 2021.
- NC762
 - o Started the Phase 1 portion of a Phase 1/2 clinical trial in patients with advanced or metastatic solid tumors.
 - Initial data anticipated to be available in mid-2022.

Financial Guidance

Based on its current research and development plans, NextCure expects its existing cash, cash equivalents and marketable securities will enable it to fund operating expenses and capital expenditure requirements into the second half of 2023.

Financial Results for Quarter Ended June 30, 2021

- Cash, cash equivalents and marketable securities as of June 30, 2021 were \$249.5 million, compared to \$283.4 million as of December 31, 2020. The decrease of \$33.9 million primarily reflects cash used to fund operations, cash used to purchase fixed assets, and repayments on a term loan.
- Research and development expenses were \$11.9 million for the quarter ended June 30, 2021, as compared to \$11.1 million for the quarter ended June 30, 2020. The increase was driven primarily by clinical-related costs, partially offset by timing of clinical supply costs.
- General and administrative expenses were \$6.0 million for the quarter ended June 30, 2021, as compared to \$4.7 million for the quarter ended June 30, 2020. The increase was driven primarily by personnel-related costs.
- Net loss was \$18.0 million for the quarter ended June 30, 2021, as compared to \$14.5 million for the quarter ended June 30, 2020. The increase in net loss for the quarter was primarily due to increased research and development expenses and increased general and administrative expenses from an increase in headcount.

NC318 is a first-in-class immunomedicine against S15, a novel immunomodulatory target found on highly immunosuppressive cells called M2 macrophages in the tumor microenvironment and on certain tumor types including lung, ovarian and head and neck cancers. In preclinical research, it was observed that S15 promoted the survival and differentiation of suppressive myeloid cells and negatively regulated T cell function, allowing cancer to avoid immune destruction. In preclinical studies, NC318 blocked the negative effects of S15. NextCure believes NC318 has the potential to treat multiple cancer types.

About NC410

NC410 is a first-in-class immunomedicine designed to block immune suppression mediated by LAIR-1, an immunomodulatory receptor expressed on T cells and dendritic cells, a type of antigen presenting cell. In preclinical research, it was observed that LAIR-1 inhibited T cell function and dendritic cell activity allowing tumor cells to grow. In preclinical studies, NC410 blocked the negative effects of LAIR-1 and promoted T cell function and dendritic cell activity. NextCure believes NC410 has the potential to treat multiple cancer types.

About NC762

NC762 is a monoclonal antibody that binds specifically to B7-H4, a protein expressed on multiple tumor types. NextCure believes NC762 acts by inhibiting tumor cell growth and killing tumor cells, including by enhancing immune response. The company has observed in preclinical studies that NC762 inhibits the growth of human melanoma tumors in mice and believes that NC762 has the potential to treat multiple tumor types. NextCure's research indicates that NC762 inhibits tumor cell growth independently of immune cell infiltration in the tumor microenvironment.

About NextCure, Inc.

NextCure is a clinical-stage biopharmaceutical company committed to discovering and developing novel, first-in-class immunomedicines to treat cancer and other immune-related diseases. Through our proprietary FIND-IO™ platform, we study various immune cells to discover and understand targets and structural components of immune cells and their functional impact in order to develop immunomedicines. Our initial focus is to bring hope and new treatments to patients who do not respond to current cancer therapies, patients whose cancer progresses despite treatment and patients with cancer types not adequately addressed by available therapies. www.nextcure.com

Forward-Looking Statements

Some of the statements contained in this press release are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including with respect to our plans, objectives and expectations for our business, operations and financial performance and condition, including the progress and results of clinical trials, development plans regarding our immunomedicines and upcoming milestones. Any statements contained herein that are not statements of historical fact may be deemed to be forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "aim," "anticipate," "assume," "believe," "continue," "could," "should," "due," "estimate," "expect," "intend," "hope," "may," "objective," "plan," "predict," "potential," "positioned," "seek," "target," "towards," "forward," "later," "will," "would" and other similar expressions that are predictions of or indicate future events and future trends, or the negative of these terms or similar language.

Forward-looking statements involve substantial risks and uncertainties that could cause actual results to differ materially from those projected in any forward-looking statement. Such risks and uncertainties include, among others: the impacts of the COVID-19 pandemic (including the emergence of variant strains) on NextCure's business, including NextCure's clinical trials, third parties on which NextCure relies and NextCure's operations; positive results in preclinical studies may not be predictive of the results of clinical trials; NextCure's limited operating history and no products approved for commercial sale; NextCure's history of significant losses; NextCure's need to obtain additional financing; risks related to clinical development, marketing approval and commercialization; the unproven approach to the discovery and development of product candidates based on NextCure's FIND-IO platform; and dependence on key personnel. More detailed information on these and additional factors that could affect NextCure's actual results are described under the heading "Risk Factors" in NextCure's most recent Annual Report on Form 10-K and in the Company's other fillings with the Securities and Exchange Commission. You should not place undue reliance on any forward-looking statements. Forward-looking statements speak only as of the date of this press release, and NextCure assumes no obligation to update any forward-looking statements, even if expectations change.

NEXTCURE, INC. CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (unaudited, in thousands, except share and per share amounts)

	Three Months Ended June 30,			Six Months Ended June 30,			
		2021		2020	2021		2020
Revenue:							
Revenue from former research and development arrangement	\$	_	\$	_	\$ _	\$	22,378
Operating expenses:							
Research and development		11,945		11,130	24,331		21,708
General and administrative		6,007		4,671	 10,855		8,259
Total operating expenses		17,952		15,801	 35,186		29,967
Loss from operations		(17,952)		(15,801)	(35,186)		(7,589)
Other income (expense), net		(35)		1,293	 666		2,814
Net loss	\$	(17,987)	\$	(14,508)	\$ (34,520)	\$	(4,775)
Loss per share - basic and diluted	\$	(0.65)	\$	(0.53)	\$ (1.25)	\$	(0.17)
Weighted-average shares outstanding - basic and diluted		27,610,398		27,518,129	27,603,948		27,512,528
Comprehensive loss: Net loss	\$	(17,987)	\$	(14,508)	\$ (34,520)	\$	(4,775)

NEXTCURE, INC. CONDENSED BALANCE SHEETS (unaudited, in thousands, except share and per share amounts)

	June 30, 2021		December 31, 2020		
Assets					
Current assets:					
Cash and cash equivalents	\$	34,903	\$	32,772	
Marketable securities		214,617		250,676	
Restricted cash		1,706		1,706	
Prepaid expenses and other current assets		7,406		2,824	
Total current assets		258,632		287,978	
Property and equipment, net		14,709		15,809	
Other assets		2,018		2,857	
Total assets	\$	275,359	\$	306,644	
Liabilities and Stockholders' Equity					
Current liabilities:					
Accounts payable	\$	1,351	\$	3,901	
Accrued liabilities		5,344		4,627	
Deferred rent, current portion		203		130	
Term loan, current portion		1,667		1,667	
Total current liabilities		8,565		10,325	
Deferred rent, net of current portion		2,224		792	
Term loan, net of current portion		972		1,806	
Total liabilities		11,761		12,923	
Stockholders' equity:					
Preferred stock, par value of \$0.001 per share; 10,000,000 shares authorized at June 30, 2021 and December 31, 2020; no shares issued and outstanding at June 30, 2021 and December 31, 2020 Common stock, par value of \$0.001 per share; 100,000,000 shares authorized at June 30, 2021 and		_		_	
December 31, 2020; 27,611,555 and 27,568,802 shares issued and outstanding at June 30, 2021 and					
December 31, 2020, respectively		28		28	
Additional paid-in capital		415,922		410,551	
Accumulated other comprehensive (loss) income		(195)		779	
Accumulated deficit		(152,157)		(117,637)	
Total stockholders' equity		263,598		293,721	
Total liabilities and stockholders' equity	\$	275,359	\$	306,644	

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