



NextCure Provides Business Update and Reports Fourth Quarter and Full Year 2021 Financial Results

March 3, 2022

- *Multiple data readouts expected in 2022, including updates for all three clinical programs*
- *Ends 2021 with cash position of \$219.6 million that is expected to fund operations into first quarter of 2024*

BELTSVILLE, Md., March 03, 2022 (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 fourth quarter and full year 2021 financial results and provided a business update.

"In 2021, NextCure set the stage for multiple data readouts in 2022. This year, we intend to have important updates on NC318, NC410, and NC762," said Michael Richman, NextCure's president and chief executive officer. "Additionally, we expect our year-end cash position of \$219.6 million to fund us into the first quarter of 2024."

Business Highlights

- **NC318**
 - Combined Phase 1 and 2 data presented at the Society for Immunotherapy of Cancer (SITC) Annual Meeting showed early evidence of potential clinical benefit in patients with lung cancer, squamous cell carcinoma of the head and neck, breast cancer and other advanced/metastatic solid tumors.
 - Preclinical data presented at the American Society of Hematology (ASH) Annual Meeting suggest that Siglec-15 (S15) may be targeted therapeutically with compounds such as NC318 to activate T lymphocytes against leukemia cells. Knock-out of S15 in a murine model resulted in leukemia clearance in immunocompetent recipients and 100% survival across all recipients.
- **NC410**
 - Interim Phase 1 data presented at the SITC Annual Meeting showed that NC410 appears to be safe and well-tolerated in patients with advanced tumors and demonstrated evidence of immune modulation.
 - Preclinical data published in the online journal *Frontiers in Immunology* indicated that collagen fragments in the tumor microenvironment (TME) can mediate T cell suppression through LAIR-1, and this suppression could subsequently be reversed by a LAIR-2 fusion protein like NC410.
- **NC762**
 - Continued to enroll patients and advance the program to report initial Phase 1 clinical data in the second half of 2022.
- **NC525**
 - Introduced our fourth program, which targets LAIR-1 expression with a novel mechanism of action that kills acute myeloid leukemia (AML) blasts and leukemia stem cells with minimal effect on hematopoietic stem and progenitor cells.
 - Preclinical data presented at the ASH Annual Meeting appear to show that NC525 could preferentially target and kill LAIR-1 expressing AML stem cells with minimal effect on healthy hematopoietic stem and progenitor cells.
- Appointed Ellen G. Feigal, M.D., a Partner and Head of the Biologics Practice at NDA Partners LLC, and Anne Borgman, M.D., former Vice President and Global Therapeutic Area Lead, Hematology-Oncology, at Jazz Pharmaceuticals, to the Board of Directors.
- Appointed Elizabeth Jaffee, M.D., Ursula Matulonis, M.D., and Weiping Zou, M.D., Ph.D., to the NextCure Scientific Advisory Board.

Expected Upcoming Milestones

The widespread impact of the COVID-19 pandemic, including the emergence of the Omicron variant, has impacted enrollment and operations at certain clinical trial sites involved in NextCure's ongoing trials. As a result, some milestones have been delayed. NextCure has taken multiple steps intended to drive enrollment and will continue to institute measures designed to mitigate the impact of the pandemic.

- NC318 Phase 2 update: fourth quarter of 2022 (Amended Phase 2: S15+ selection with CLIA assay, 800 mg dosed Q1W).
- NC318 anti-PD-1 Combo (Yale University Investigator-Initiated trial): second half of 2022.

- NC410 Phase 1 update: second half of 2022.
- NC762 initial Phase 1 data: second half of 2022.
- NC525 Investigational New Drug Application (IND) filing: fourth quarter of 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 expenditures into the first quarter of 2024.

Financial Results for Fourth Quarter and Full Year Ended December 31, 2021

- Cash, cash equivalents, and marketable securities, excluding restricted cash as of December 31, 2021, were \$219.6 million as compared with \$283.4 million as of December 31, 2020. The decrease of \$63.8 million as of December 31, 2021, as compared to December 31, 2020, primarily reflects cash used to fund operations of \$57.2 million.
- Research and development expenses were \$50.2 million and \$12.3 million for the year and quarter ended December 31, 2021, respectively, as compared with \$46.6 million and \$12.1 million for the year and quarter ended December 31, 2020, respectively. The increase was driven primarily by clinical-related and personnel-related costs, partially offset by timing of research and manufacturing supply costs.
- General and administrative expenses were \$20.6 million and \$4.8 million for the year and quarter ended December 31, 2021, respectively, as compared with \$17.0 million and \$4.1 million for the year and quarter ended December 31, 2020, respectively. The increase was primarily related to personnel-related costs.
- Revenue was not recognized for the year ended December 31, 2021, as compared with \$22.4 million for the year ended December 31, 2020. Revenue generated in 2020 was from our former research and development agreement with Eli Lilly.
- Net loss was \$69.4 million and \$16.9 million for the year and quarter ended December 31, 2021, respectively, as compared with \$36.6 million and \$15.5 million for the year and quarter ended December 31, 2020, respectively. The changes in net loss for the year and quarter were primarily due to increased research and development expenses and increased general and administrative expenses from an increase in headcount, offset by the recognition for the year ended 2020 of the remaining deferred revenue under the former research and development agreement with Eli Lilly.

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. <http://www.nextcure.com>

Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements, including statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements are based on current expectations, forecasts, assumptions and other information available to NextCure as of the date hereof. Forward-looking statements include statements regarding NextCure's expectations, beliefs, intentions or strategies regarding the future and can be identified by forward-looking words such as "may," "will," "potential," "expects," "believes," "intends," "hope," "towards," "forward," "later" and similar expressions. Examples of forward-looking statements in this press release include, among others, statements about the development plans for our immunomedicines, statements about the progress and evaluation and expected timing of results of NextCure's ongoing clinical trial of NC318, expectations regarding the potential benefits, activity, effectiveness and safety of NC318, expectations regarding the investigator initiated trial conducted by Yale, the expected timing of results of NextCure's ongoing clinical trial of NC410, the development plans for NC762, NextCure's financial guidance, expected upcoming milestones, and NextCure's plans, objectives and intentions with respect to the discovery and development of immunomedicines. 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 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 in NextCure's filings with the Securities and Exchange Commission (the "SEC"), including in Item 1A of NextCure's most recent Form 10-K and elsewhere in the Company's filings with the SEC. 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, except as required by law, even if expectations change.

Investor Inquiries

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Selected Financial Information

Selected Statement of Operations Items:

	Year Ended December 31,	
	2021	2020
<i>(in thousands, except share and per share amounts)</i>		
Revenue:		
Revenue from former research and development arrangement	\$	\$ 22,378
Operating expenses:		
Research and development	50,192	46,554
General and administrative	20,573	17,049
Loss from operations	(70,765)	(41,225)
Other income, net	1,376	4,622
Net loss	\$ (69,389)	\$ (36,603)
Net loss per common share - basic and diluted	\$ (2.51)	\$ (1.33)
Weighted-average shares outstanding - basic and diluted	27,615,977	27,532,177

Selected Balance Sheet Items:

	Year Ended December 31,	
	2021	2020
<i>(in thousands)</i>		
Cash, cash equivalents, and marketable securities	\$ 219,591	\$ 283,448
Total assets	242,386	306,644
Accounts payable and accrued expenses	6,391	8,528
Total stockholder's equity	233,386	293,721



Source: NextCure