

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **March 4, 2021**

NextCure, Inc.

(Exact name of registrant as specified in charter)

Delaware

(State or other jurisdiction
of incorporation)

001-38905

(Commission
File Number)

47-5231247

(IRS Employer
Identification No.)

**9000 Virginia Manor Road, Suite 200
Beltsville, Maryland**

(Address of principal executive offices)

20705

(Zip Code)

(240) 399-4900

Registrant's telephone number, including area code

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.001 par value per share	NXTC	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

Attached as Exhibit 99.1 is a copy of a press release of NextCure, Inc., dated March 4, 2021, reporting its financial results for the quarter and year ended December 31, 2021.

Item 9.01 Financial Statements and Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release of NextCure, Inc. dated March 4, 2021.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: March 4, 2021

NEXTCURE, INC.

/s/ Steven P. Cobourn
Steven P. Cobourn
Chief Financial Officer



NextCure Provides Business Update and Reports Fourth Quarter and Full Year 2020 Financial Results

BELTSVILLE, Md. – March 4, 2021 – 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 2020 financial results and provided a business update.

“Our team has worked diligently throughout 2020 to advance our programs despite the difficult environment created by the COVID-19 pandemic. We are thrilled that Dr. Han Myint has recently joined NextCure as our Chief Medical Officer and we are poised to harness his expertise in oncology product development to further advance our product pipeline. As we enter 2021, we are excited to announce the expansion of our pipeline. We remain encouraged with the potential of NC318 given the evidence of clinical activity seen to date and are now reexploring the treatment of lung cancer through an investigator-initiated trial at Yale University,” said Michael Richman, NextCure’s president and chief executive officer. “In addition, the NC410 Phase 1 trial is advancing and we look forward to reporting initial data in the second half of the year and we are very excited to introduce NC762, a B7-H4 antibody expected to enter the clinic next quarter.”

Business Highlights

- NC318
 - o The two previously announced objective responder patients in the Phase 1 portion of the company’s ongoing Phase 1/2 clinical trial are continuing to receive drug and remain on study at over 118 weeks and over 92 weeks.
 - o The trial continues in head and neck squamous cell carcinoma (HNSCC) and triple-negative breast cancer (TNBC) patients.
 - o The previously announced confirmed partial response (PR) seen in the HNSCC cohort is off study after 40 weeks.
 - o A confirmed PR has been observed in the TNBC cohort and the patient remains on study at over 21 weeks.
 - o Given these responses in the HNSCC and TNBC cohorts, these cohorts met the criteria to advance into the stage 2 portion of the Simon 2-stage trial.
 - o The NC318 Phase 2 monotherapy protocol will be revised to select S15+ patients for enrollment starting in the second quarter of this year.
 - o Yale University plans to initiate in the second quarter of 2021, an investigator-initiated Phase 2 trial of NC318 as a monotherapy and in combination with pembrolizumab in patients with advanced non-small cell lung cancer.
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- NC410
 - o Enrollment is on track and the company expects to announce initial clinical data from the Phase 1 portion of the trial in the second half of 2021.
- NC762
 - o An investigational new drug (IND) application has been filed with the U.S. Food and Drug Administration (FDA) for NC762, a humanized monoclonal antibody targeting B7-H4, which is upregulated in multiple solid tumor types, and which we believe is differentiated from other B7-H4-targeted antibodies.
- Announced the appointment of Dr. Han Myint as Chief Medical Officer.

Expected Upcoming Milestones

- Initiate in the second quarter of 2021, the Yale University Phase 2 investigator-initiated trial of NC318 in NSCLC with anticipated initial data first half of 2022.
- Report NC318 Phase 2 monotherapy data in the fourth quarter of 2021.
- Initiate the NC762 Phase 1 trial in the second quarter of 2021 and report initial data in mid-2022.
- Report NC410 initial Phase 1 data in the second half of 2021.

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 Fourth Quarter and Full Year Ended December 31, 2020

- Cash, cash equivalents, and marketable securities, excluding restricted cash as of December 31, 2020, were \$283.4 million as compared with \$334.6 million as of December 31, 2019. The decrease of \$51.2 million as of December 31, 2020 as compared to December 31, 2019 primarily reflects cash used to fund operations of \$44.9 million and cash used to purchase fixed assets of \$7.2 million, offset by a reduction in restricted cash of \$1.5 million.
 - Research and development expenses were \$46.6 million and \$12.1 million for the year and quarter ended December 31, 2020, respectively, as compared with \$34.2 million and \$11.4 million for the year and quarter ended December 31, 2019, respectively. The increase was primarily related to increase in headcount and clinical research costs related to advancing NC318 and NC410.
 - General and administrative expenses were \$17.0 million and \$4.1 million for the year and quarter ended December 31, 2020, respectively, as compared with \$9.6 million and \$2.6 million for the year and quarter ended December 31, 2019, respectively. The increase in general and administrative expenses for the year and quarter primarily related to increasing infrastructure costs and being a public company for a full year in 2020.
 - Revenue was \$22.4 million for the year ended December 31, 2020. There was no revenue recognized in the quarter ended December 31, 2020, as compared with \$6.3 million and \$2.0 million for the year and quarter ended December 31, 2019, respectively. Revenue generated was from our former research and development agreement with Eli Lilly.
 - Net loss was \$36.6 million and \$15.5 million for the year and quarter ended December 31, 2020, respectively, as compared with \$33.7 million and \$10.9 million for the year and quarter ended December 31, 2019, respectively. The increases 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 of the remaining deferred revenue under the former agreement with Lilly.
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Conference Call

NextCure will host a virtual R&D update event today at 5 pm Eastern time. To participate via telephone, please dial (877) 665-6632 from the U.S. or (602) 563-8471 from outside the U.S., using the conference ID 6773907. To participate via live or replay webcast, a link is available through the Investors section of the company's website at www.nextcure.com.

About NC318

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. We believe NC762 acts by inhibiting tumor cell growth and killing tumor cells, including by enhancing immune response. We have observed in preclinical studies that NC762 inhibits the growth of human melanoma tumors in mice, and we believe that NC762 has the potential to treat multiple tumor types. Our 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

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 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 to be launched 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, even if expectations change.

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

	Year Ended	
	December 31,	December 31,
	2020	2019
Revenue:		
Revenue from former research and development arrangement	\$ 22,378	\$ 6,347
Operating expenses:		
Research and development	46,554	34,216
General and administrative	17,049	9,613
Total operating expenses	63,603	43,829
Loss from operations	(41,225)	(37,482)
Other income, net	4,622	3,745
Net loss	<u>\$ (36,603)</u>	<u>\$ (33,737)</u>
Loss per share:		
Net loss per common share—basic and diluted	<u>\$ (1.33)</u>	<u>\$ (2.15)</u>
Weighted average number of common shares —basic and diluted	<u>27,532,177</u>	<u>15,695,461</u>
Comprehensive loss:		
Net loss	\$ (36,603)	\$ (33,737)
Unrealized gain (loss) on marketable securities	779	(38)
Total comprehensive loss	<u>\$ (35,824)</u>	<u>\$ (33,775)</u>

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

	December 31,	
	2020	2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 32,772	\$ 34,091
Marketable securities	250,676	300,514
Restricted cash	1,706	1,706
Prepaid expenses and other current assets	2,824	3,684
Total current assets	287,978	339,995
Property and equipment, net	15,809	12,090
Other assets	2,857	4,083
Total assets	\$ 306,644	\$ 356,168
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 3,901	\$ 1,861
Accrued liabilities	4,627	4,871
Deferred rent, current portion	130	215
Term loan, current portion	1,667	1,667
Deferred revenue, current portion	—	6,428
Total current liabilities	10,325	15,042
Deferred rent, net of current portion	792	359
Term loan, net of current portion	1,806	3,333
Deferred revenue, net of current portion	—	15,950
Total liabilities	12,923	34,684
Stockholders' equity:		
Preferred stock, par value of \$0.001 per share; 10,000,000 shares authorized at December 31, 2020 and 2019. No shares issued and outstanding at December 31, 2020 and 2019	—	—
Common stock, par value of \$0.001 per share; 100,000,000 shares authorized at December 31, 2020 and 2019, respectively, 27,568,802 and 27,499,260 shares issued and outstanding at December 31, 2020 and 2019, respectively	28	27
Additional paid-in capital	410,551	402,529
Accumulated other comprehensive income (loss)	779	(38)
Accumulated deficit	(117,637)	(81,034)
Total stockholders' equity	293,721	321,484
Total liabilities and stockholders' equity	\$ 306,644	\$ 356,168

Investor Inquiries

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