
**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): **August 8, 2019**

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 communication 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 communication pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communication 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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 7.01 Regulation FD Disclosure.

NextCure provides details on Phase 1 portion of Phase 1/2 clinical trial with NC318

In October 2018, NextCure, Inc. (“NextCure” or the “Company”) initiated a Phase 1/2 clinical trial of NC318 in patients with advanced or metastatic solid tumors. As of March 31, 2019, 21 patients had been dosed, and no dose limiting toxicities had been observed. NC318 has been well tolerated with several patients presenting with Grade 1/2 immune-mediated adverse events (e.g. rash and diarrhea). As of March 31, there was 1 patient with a confirmed partial response, 6 patients with stable disease, and 6 patients with disease progression. To provide investors with additional context, NextCure is providing further details. The patient with the confirmed partial response was a lung cancer patient in the 8mg cohort who had a 40% reduction in the target lesions at 8 weeks, an 80% reduction in the target lesions at 16 weeks, and undetectable target lesions at 24 weeks. At March 31, 2019, a different patient who was in the 80mg cohort and who did not respond to nivolumab as salvage therapy after palliative radiation had a confirmed 20% tumor reduction after 16 weeks on NC318.

As of August 8, 2019, NextCure enrollment in the Phase 1 portion of this trial remains on schedule, and the Company remains on schedule to present topline data from the Phase 1 portion of the Phase 1/2 trial in the fourth quarter of 2019.

The Company does not presently plan to provide a further update on the NC318 Phase 1/2 clinical trial prior to the fourth quarter of 2019.

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 the Phase 1/2 NC318 clinical trial

This first-in-human trial is an open-label Phase 1/2 clinical trial designed to assess the safety and tolerability of NC318, to define the maximal tolerable dose and/or pharmacologically active dose and to assess preliminary efficacy. The trial is being conducted in two phases. The Phase 1 portion, which is designed for dose escalation and safety expansion, is intended to determine the pharmacologically active dose, defined as the dose that provides a maximal biologic effect, such as an increase in biomarkers of immune activation or a reduction of biomarkers associated with immune suppression, and/or the maximal tolerable dose of NC318, including defining the optimal dose administration schedule and the maximum number of tolerated doses. The Phase 2 portion of the trial is intended to detect a relevant efficacy signal, or response rate, for each of the tumor types. In this portion, NextCure will enroll patients with tumor types that have been shown to have elevated S15 expression, including ovarian cancer, non-small cell lung cancer and head and neck squamous cell carcinoma, as well as other malignancies where PD-L1 expression is low. NextCure continues to expect completion of the Phase 1 portion of this trial in the fourth quarter of 2019 and completion of the Phase 2 portion in the fourth quarter of 2020.

Forward Looking Statements

This current report 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,” “plan” and similar expressions. Examples of forward-looking statements in this press release include, among others, statements about the progress and expected timing of NextCure’s ongoing clinical study of NC318. 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: that preliminary results are not predictive of future results; 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; and the unproven approach to the discovery and development of product candidates based on NextCure's FIND-IO platform. 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 NextCure's Form 10-Q filed with the SEC on June 10, 2019. 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.

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: August 8, 2019

NEXTCURE, INC.

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