NextCure Provides Business Update and Reports Third Quarter 2024 Financial Results

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- *Prioritize and focus resources on LNCB74 (B7-H4 ADC) with a planned IND submission by year-end*
- *Cash of approximately $75 million expected to fund operations into second half of 2026*

BELTSVILLE, Md., Nov. 07, 2024 (GLOBE NEWSWIRE) -- NextCure, Inc. (Nasdaq: NXTC), a clinical-stage biopharmaceutical company committed to discovering and developing novel, first-in-class, and best-in-class therapies to treat cancer, today provided a business update and reported third-quarter 2024 financial results.

"The November SITC presentation of LNCB74 preclinical data will highlight the differentiation of our B7-H4 ADC from other ADC's that also target B7-H4. We plan to file an IND in the fourth quarter of this year and advance into Phase 1, shortly following receipt of an FDA safe-to-proceed letter," said Michael Richman, NextCure's president and CEO. "Additionally, while the NC410 combo has shown encouraging Phase 1b clinical activity in both ovarian cancer and CRC patients, we plan to conclude the current trial and seek a partner to advance the program, allowing us to focus our resources on advancing the development of LNCB74."

Business Highlights and Near-Term Milestones

LNCB74 (B7-H4 ADC)

- Leveraging LigaChem Biosciences, Inc. glucuronidase cleavable site-specific linkage as part of a collaboration agreement that includes a 50-50 cost sharing of external development expenses and certain internal cost sharing associated with the development of the antibody- drug conjugate (ADC) program.
- Preclinical data from LNCB74 (B7-H4 ADC) will be presented at the Society of Immunotherapy of Cancer (SITC) annual meeting in November.
- Planned submission of an Investigational New Drug (IND) application in the fourth quarter of this year.

NC410 (LAIR-2 fusion)

- Additional colorectal cancer (CRC) patient Phase 1b clinical data along with biomarker data supporting mechanism of action to be presented at SITC annual meeting in November.
- As of October 14, 2024 (the cut-off date), 11 patients (4 with ovarian cancer and 7 with CRC) remain in the Phase 1b study evaluating NC410 in combination with pembrolizumab and will continue to be monitored while the study concludes.
- As of the cut-off date, the response rate for the ovarian cancer patients that were immune checkpoint inhibitor (ICI) naïve was 25% based on 5 out of 20 patients, which consisted of 2 partial responses (PRs) at 200 mg, and 3 PRs at 100mg in ICI naïve.
- As of the cut-off date, the 100 mg cohort CRC response rate was 8.3% based on 3 out of 36 patients, which consisted of 3 PRs in ICI naïve, MSS/microsatellite instability-low with a disease control rate (DCR) of 47% (17/36), median disease control (mDC) duration of 8.5 months, and median duration of response of 15.2 months. A 200 mg CRC cohort of 7 showed no clinical responses with a DCR of 86% (6/7) and a mDC duration of 8.3 months.
- Will seek a partner or pursue third party financing to advance NC410 in further clinical trials.

Preclinical Non-Oncology Programs Seeking Third Party Financing

- NC181 (ApoE4), a humanized antibody for the treatment of Alzheimer's disease (AD). In preclinical AD animal models, NC181 has demonstrated amyloid clearance, prevention of amyloid deposition, plaque clearance and reduced neuroinflammation.
- NC605 (Siglec-15), a humanized antibody for the treatment of osteogenesis Imperfecta (OI). Preclinical data reported that NC605 treatment reduced bone loss and enhanced bone quality in mice with OI.
- Both programs could lead to IND filings within 12 to 18 months if financial support from third parties is secured.

Financial Results for Quarter Ended September 30, 2024

- Cash, cash equivalents, and marketable securities as of September 30, 2024 were $75.3 million as compared to $108.3 million as of December 31, 2023. The decrease of $33.0 million was primarily due to cash used to fund operations. NextCure expects financial resources to fund operating expenses and capital expenditures into the second half of 2026.

- Research and development expenses were $8.8 million for the three months ended September 30, 2024, as compared to $11.0 million for the three months ended September 30, 2023. Net costs on the LNCB74 program were more than offset by lower costs on other programs and preclinical development and lower personnel-related costs.
- General and administrative expenses were $3.7 million for the three months ended September 30, 2024, as compared to $4.6 million for the three months ended September 30, 2023. The decrease of $0.9 million was primarily related to lower payroll, lower stock compensation expense and lower insurance costs.
- Net loss was $11.5 million for the three months ended September 30, 2024, as compared to a net loss of $14.3 million for the three months ended September 30, 2023.

About NextCure, Inc.

NextCure is a clinical-stage biopharmaceutical company that is focused on advancing innovative medicines that treat cancer patients that do not respond to, or have disease progression on, current therapies, through the use of differentiated mechanisms of actions including antibody-drug conjugates, antibodies and proteins. We focus on advancing therapies that leverage our core strengths in understanding biological pathways and biomarkers, the interactions of cells, including in the tumor microenvironment, and the role each interaction plays in a biologic response. 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 funding for our operations, objectives and expectations for our business, operations and financial performance and condition, including the progress and results of clinical trials, development plans and upcoming milestones regarding our therapies. 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: positive results in preclinical studies may not be predictive of the results of clinical trials; NextCure’s limited operating history and not having any products approved for commercial sale; NextCure’s history of significant losses; NextCure’s need and ability to obtain additional financing on acceptable terms or at all; risks related to clinical development, marketing approval and commercialization; and NextCure’s 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 NextCure’s other filings 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.

Selected Financial Information

Selected Statement of Operations Items:	**Three Months Ended September 30,**		**Nine Months Ended September 30,**	
(in thousands, except share and per share amounts)	**2024**	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 8,770	$ 11,010	$ 32,586	$ 36,104
General and administrative	3,725	4,608	12,165	15,743
Restructuring and asset impairment	—	—	2,542	—
Loss from operations	(12,495)	(15,618)	(47,293)	(51,847)
Other income, net	955	1,317	3,242	3,591
Net loss	$ (11,540)	$ (14,301)	$ (44,051)	$ (48,256)
Net loss per common share - basic and diluted	$ (0.41)	$ (0.51)	$ (1.58)	$ (1.73)
Weighted-average shares outstanding - basic and diluted	27,975,840	27,839,968	27,950,634	27,814,655

Selected Balance Sheet Items:

(in thousands)	**September 30, 2024**	**December 31, 2023**
Cash, cash equivalents, and marketable securities	$ 75,308	$ 108,299
Total assets	$ 90,345	$ 128,038
Accounts payable and accrued liabilities	$ 8,672	$ 6,883
Total stockholders' equity	$ 75,592	$ 114,421

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Source: NextCure