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): November 30, 2022

ONCORUS, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-39575**	**47-3779757**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
4 Corporate Drive Andover, Massachusetts		**01810**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (857) 320-6400

(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:

☐ 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, $0.0001 par value per share	ONCR	The NASDAQ Stock Market LLC

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.

On November 30, 2022, Oncorus, Inc. (the "***Company***") issued a press release announcing the reprioritization of its product pipeline to focus on its lead self-amplifying viral RNA ("***vRNA***") immunotherapy product candidate, ONCR-021, along with the discontinuation of its Phase 1 clinical trial of ONCR-177 in patients with advanced disease. The Company also announced it will host a live conference and webcast beginning at 8:00 a.m. Eastern Time on the same date, during which the Company will discuss these and other business updates. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

On November 30, 2022, the Company posted an updated corporate presentation to its website. The corporate presentation is available under the "Events & Presentations" tab in the "Investors & Media" section of the Company's website, located at www.oncorus.com.

The information in this Item 7.01 and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "***Exchange Act***") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any incorporation by reference language in such a filing, except as expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

On November 30, 2022, the Company announced that it is reprioritizing its product pipeline to focus on its lead self-amplifying vRNA immunotherapy product candidate, ONCR-021. The Company plans to submit an investigation new drug application ("***IND***") to the U.S. Food and Drug Administration in mid-2023 to evaluate ONCR-021 in patients with non-small cell lung cancer, renal cell carcinoma, melanoma and hepatocellular carcinoma.

In October 2022, the Company published preclinical data in the journal *Nature Communications* highlighting the potential of its self-amplifying RNA platform as a novel approach to treating cancer by enabling repeat intravenous ("***IV***") administration. The data demonstrated that delivery of RNA encoding for the genome of a replication-competent virus encapsulated within a lipid nanoparticle ("***LNP***") enabled selective replication, virus assembly, viral spread and lysis of tumor cells, leading to potent anti-tumor efficacy even in the presence of virus-neutralizing antibodies in the bloodstream. These RNA constructs were well tolerated in preclinical models and resulted in tumor-specific *in situ* production of oncolytic virions, broad immune cell recruitment and tumor destruction. Efficacy was observed across multiple cancer models, including xenografts, PDX, GEMM and syngeneic models, with survival benefit observed in an orthotopic small cell lung cancer tumor model. Overall, these constructs were well tolerated after single or multiple IV doses in both mice and non-human primates. The Company believes these preclinical results support the potential of this modality to safely and effectively kill tumor cells and stimulate multiple arms of the immune system to better fight cancer.

The Company also announced that it is discontinuing its Phase 1 clinical trial of ONCR-177 in patients with advanced disease. The Company plans to present the results of the Phase 1 clinical trial in conjunction with a scientific congress in 2023. Further development of ONCR-788, the Company's second self-amplifying vRNA immunotherapy product candidate, which encodes for a modified version of the Seneca Valley Virus for the treatment of small cell lung cancer, neuroendocrine prostate cancer and other neuroendocrine tumors, and ONCR-719, an armed HSV-1 engineered for viral entry via the EGFR receptor for the treatment of glioblastoma multiforme, is dependent on the Company's ability to obtain additional financing.

The Company also announced that it is reducing its workforce by 20% with the remaining workforce solely focused on the clinical development of ONCR-021. In addition, the Company reiterated its previously announced guidance that its current cash and cash equivalents and investments are expected to be sufficient to fund its operating expenses and capital expenditure requirements into early 2024.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, implied and express statements regarding the Company's plans to reprioritize its product pipeline to focus on ONCR-021 and its plans to submit an IND in mid-2023 to evaluate ONCR-021 in patients with non-small cell lung cancer, renal cell carcinoma, melanoma and hepatocellular carcinoma; the Company's belief that preclinical results for ONCR-021 support the potential of such a modality to safely and effectively kill tumor cells and stimulate multiple arms of the immune system to fight cancer; the Company's plans to discontinue its Phase 1 clinical trial of ONCR-0177 in advanced disease settings and its plans to present results from the trial in 2023; and the Company's belief that its cash and cash equivalents and

investments will be sufficient to fund its operating expenses and capital expenditure requirements into early 2024. The words "may," "might," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "expect," "estimate," "seek," "predict," "future," "project," "potential," "continue," "target" and similar words or expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this Current Report on Form 8-K are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this Current Report on Form 8-K, including, without limitation: the Company's ability to successfully demonstrate the safety, tolerability and efficacy of ONCR-021, or any future product candidates, and obtain regulatory approval thereof; the risk that the results of preclinical studies and early results from clinical trials may not be predictive of future clinical trial results; the Company's ability to obtain or manufacture the requisite components for its product candidates manufactured in accordance with regulatory requirements; the adequacy of the Company's cash resources and availability of financing on commercially reasonable terms; and the Company's ability to obtain, maintain and protect its intellectual property. These and other risks and uncertainties are described in greater detail in the section entitled "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2021, filed with the Securities and Exchange Commission on March 9, 2022, along with the Company's subsequent Quarterly Reports on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in the other filings that the Company makes with the Securities and Exchange Commission from time to time. Any forward-looking statements represent the Company's views only as of the date of this Current Report on Form 8-K and should not be relied upon as representing its views as of any subsequent date. The Company explicitly disclaims any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release issued by Oncorus, Inc. on November 30, 2022
104	Cover Page Interactive Data File (embedded within the inline XBRL document)

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.

ONCORUS, INC.

Date: November 30, 2022

By: /s/ Richard Wanstall

Richard Wanstall
Chief Financial Officer

Exhibit 99.1

Oncorus Announces Portfolio Reprioritization to Focus on IV-Administered, Self-Amplifying RNA Medicines for Patients with Cancer

- *Company now focused on the development of ONCR-021, Oncorus' lead self-amplifying RNA product candidate for non-small cell lung and other cancers; program remains on track for IND submission in mid-2023 --*
- *Phase 1 clinical trial of ONCR-177 in patients with advanced disease is being discontinued --*
- *Prioritization of ONCR-021 and reduction in workforce reduces company's cash burn rate; Oncorus reiterates guidance of cash runway into early 2024 --*

ANDOVER, Mass., November 30, 2022 – Oncorus, Inc. (Nasdaq: ONCR), an RNA medicines company focused on developing IV administered, self-amplifying RNA to transform outcomes for cancer patients, today announced that it is reprioritizing its pipeline to focus on its lead viral RNA (vRNA) immunotherapy product candidate, ONCR-021. In addition, the company is discontinuing the development of ONCR-177, reducing its workforce and burn rate and reiterating guidance for its cash runway into early 2024.

"Oncorus' mission is now focused on realizing the full promise of IV-administered, self-amplifying RNA medicines to transform outcomes for cancer patients through our lead program, ONCR-021, which we plan to evaluate in patients with non-small cell lung and other cancers," said Theodore (Ted) Ashburn, M.D., Ph.D., President, and Chief Executive Officer of Oncorus. "As part of this reprioritization, we are discontinuing the Phase 1 trial of ONCR-177 to focus our resources on ONCR-021. We would like to express our deep gratitude to all the patients and their families, investigators and collaborators who participated in the ONCR-177 study. We believe that we are now well positioned to execute on our goals and progress our novel, first-of-its-kind self-amplifying vRNA immunotherapy candidate, ONCR-021, into the clinic for cancer patients."

Oncorus will present the results of the Phase 1 study of ONCR-177 in patients with advanced disease in conjunction with a scientific congress in 2023. In addition, Oncorus has reduced its workforce by 20%, with its remaining workforce solely focused on the clinical development of ONCR-021, its first self-amplifying RNA product candidate. With this re-prioritization and workforce realignment, Oncorus has reduced its burn rate and continues to expect its current cash, cash equivalents and investments will be sufficient to fund its operating expenses into early 2024.

ONCR-021 Program Highlights and Upcoming Milestones

ONCR-021 is Oncorus' lead candidate from its self-amplifying RNA platform intended to allow for intravenous (IV) administration. ONCR-021 is comprised of vRNA encoding for the genome of an optimized strain of the Coxsackievirus A21 (CVA21) formulated in a proprietary lipid nanoparticle (LNP). This technology enables RNA self-amplification via multiple transcription cycles in tumor cells and further amplification via viral spread to neighboring tumor cells. The company is planning to submit an investigational new drug application (IND) for this program in mid-2023 to evaluate ONCR-021 in patients with non-small cell lung cancer (NSCLC), renal cell carcinoma (RCC), melanoma and hepatocellular carcinoma (HCC).

In October 2022, Oncorus published preclinical data in *Nature Communications* highlighting the potential of its self-amplifying RNA platform as a novel approach to treating cancer by enabling repeat IV administration. The data demonstrate that the delivery of RNA encoding for the genome of a replication competent virus encapsulated in an LNP enables selective replication, virus assembly, spread and lysis of tumor cells, leading to potent anti-tumor efficacy even in the presence of virus neutralizing antibodies in the bloodstream. These RNA constructs were well-tolerated in preclinical models and elicited tumor-specific *in situ* production of oncolytic virions, broad immune cell recruitment and tumor destruction. Efficacy was observed across multiple cancer models, including xenografts, PDX, GEMM and syngeneic models, with survival benefit observed in an orthotopic small cell lung cancer (SCLC) tumor model. Overall, these constructs were well-tolerated after a single or multiple IV doses in both mice and non-human primates. These results support the potential of this modality to safely and effectively kill tumor cells while stimulating multiple arms of the immune system to better fight cancer.

Additional Development Programs

Further development of ONCR-788, the company's second self-amplifying RNA product candidate, which encodes for a modified genome of the Seneca Valley Virus (SVV) for the treatment of small cell lung cancer (SCLC), neuroendocrine prostate cancer and other neuroendocrine tumors, and ONCR-719, an armed HSV-1 engineered for viral entry via the EGFR receptor for the treatment of glioblastoma multiforme, is dependent on additional financing.

Conference Call and Webcast Information

Oncorus will host a live conference and webcast today, November 30, 2022, at 8:00 a.m. ET to discuss these company updates. To access the conference call, please register here. The live webcast can be accessed under the "Events & Presentations" section of Oncorus' website at www.oncorus.com. A webcast replay will also be available on the corporate website at the conclusion of the call.

About Oncorus

At Oncorus, we are focused on driving innovation in RNA medicines by developing next-generation immunotherapies to stimulate the immune system and transform outcomes for cancer patients. Our self-amplifying RNA immunotherapy platform improves upon key characteristics of this therapeutic class to enhance systemic activity. ONCR-021, our lead product candidate for non-small cell lung and other cancers, is an IV-administered RNA encoding an optimized Coxsackievirus 21A (CVA21) genome, encapsulated within an LNP.

Please visit www.oncorus.com to learn more.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, implied and express statements regarding Oncorus' plans to focus its efforts and resources on the development of ONCR-021 and its self-amplifying RNA platform along with ONCR-021's ability to improve outcomes for cancer

patients; Oncorus' plans to submit an IND for ONCR-021 by mid-2023; Oncorus' plans to evaluate ONCR-021 in patients with non-small cell lung and other cancers; Oncorus' belief that, following reprioritization, it will be better positioned to deliver on its strategic goals; Oncorus' plans to discontinue the further clinical development of ONCR-177 and its plans to present full data in 2023; and Oncorus' expectations that its cash and cash equivalents will be sufficient to fund its operations into early 2024.. The words "may," "might," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "expect," "estimate," "seek," "predict," "future," "project," "potential," "continue," "target" and similar words or expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, risks associated with: Oncorus' ability to successfully demonstrate the safety, tolerability and efficacy of its product candidates and obtain regulatory approval thereof; the adequacy of Oncorus' existing capital resources and availability of financing on commercially reasonable terms; Oncorus' ability to obtain the requisite components for its product candidates manufactured in accordance with regulatory requirements; the expansion of Oncorus' in-house manufacturing capabilities; the impact of COVID-19 on Oncorus' operations and the timing and anticipated results of its ongoing and planned clinical trials; the accuracy of the Oncorus' estimates regarding expenses, future revenue, capital requirements and needs for additional financing; and Oncorus' ability to obtain, maintain and protect its intellectual property. These and other risks and uncertainties are described in greater detail in the section entitled "Risk Factors" in Oncorus' Annual Report on Form 10-K for the year ended December 31, 2021, filed with the Securities and Exchange Commission ("SEC") on March 9, 2022, and Oncorus' Quarterly Reports on Form 10-Q for the quarters ended March 31, 2022, June 30, 2022 and September 30, 2022, filed with the SEC on May 4, 2022, August 4, 2022 and November 2, 2022, respectively, as well as discussions of potential risks, uncertainties, and other important factors in the other filings that Oncorus makes with the SEC from time to time. These documents are available under the "SEC filings" page of the Investors section of Oncorus' website at http://investors.oncorus.com. Any forward-looking statements represent Oncorus' views only as of the date of this press release and should not be relied upon as representing its views as of any subsequent date. Oncorus explicitly disclaims any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

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