

**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 02, 2022

ONCORUS, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-39575
(Commission File Number)

47-3779757
(IRS Employer
Identification No.)

4 Corporate Drive

Andover, Massachusetts
(Address of Principal Executive Offices)

01810
(Zip Code)

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

**50 Hampshire Street, Suite 401
Cambridge, Massachusetts 02139**
(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 2.02 Results of Operations and Financial Condition.

On November 2, 2022, Oncorus, Inc. (the "**Company**") issued a press release announcing its financial results for the quarter ended September 30, 2022. 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.

The information in this Current Report on Form 8-K 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 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press release issued by Oncorus, Inc. on November 2, 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 2, 2022

By: _____
/s/ Richard Wanstall
Richard Wanstall
Chief Financial Officer

Oncorus Reports Third Quarter 2022 Financial Results and Provides Business Updates

- Additional clinical data from ONCR-177 surface lesion monotherapy and combination expansion cohorts expected in the fourth quarter of 2022
- On track to submit IND for ONCR-021 in mid-2023
- Completed construction phase of GMP-compliant manufacturing facility in Andover, MA
- Ended the quarter with \$81.5 million in cash and cash equivalents to support next-generation viral immunotherapy pipeline

CAMBRIDGE, Mass., November 2, 2022 – Oncorus, Inc. (Nasdaq: ONCR), a viral immunotherapies company focused on driving innovation to transform outcomes for cancer patients, today reported financial results for the third quarter of 2022 and highlighted recent achievements and developments.

"We continue to focus on our differentiated portfolio of intratumorally and intravenously administered viral immunotherapies across our two platforms. We've been tracking well against our set milestones for this year and are well positioned for further advancement across our portfolio," said Theodore (Ted) Ashburn, M.D., Ph.D., President and Chief Executive Officer of Oncorus. "We've bolstered our position within the viral immunotherapy landscape with the recent relocation of our company to our facility in Andover, Massachusetts, bringing research, process development and GMP-compliant manufacturing under one roof. With the completion of Andover, we are realizing our goal of becoming a fully integrated viral immunotherapies company. We are preparing to announce further data from our ongoing clinical trial of ONCR-177 in the fourth quarter of this year. In parallel, we are rapidly progressing our vRNA/LNP immunotherapy platform, further supported by the recent publication of promising preclinical results in *Nature Communications*. We expect an IND submission for our lead vRNA/LNP product candidate, ONCR-021, in mid-2023."

Third Quarter 2022 and Recent Business Highlights

- **On track to report combination data and additional monotherapy data for ONCR-177 in the fourth quarter of 2022.** Oncorus continues to dose patients in its Phase 1 open-label, multi-center clinical trial in patients with advanced and/or refractory cutaneous, subcutaneous or metastatic nodal solid tumors or with liver metastases of solid tumors. The company expects to report initial surface lesion combination expansion data for ONCR-177 administered with Merck's KEYTRUDA and additional surface lesion monotherapy expansion data in the fourth quarter of 2022.
 - **Preclinical results featured in *Nature Communications* supporting intravenously administered self-amplifying viral RNA (vRNA)/lipid nanoparticle (LNP) immunotherapy platform.** In October 2022, Oncorus published preclinical data in *Nature Communications* highlighting the potential of its vRNA/LNP immunotherapy platform as a novel approach to treating cancer through repeat intravenous (IV) administration. The data demonstrate vRNA/LNP delivery and 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. Oncorus remains on track to submit an investigational new drug application (IND) for the company's lead product candidate from this platform, ONCR-021, in mid-2023.
 - **Completed construction phase of Good Manufacturing Practice (GMP) -compliant manufacturing facility in Andover, Massachusetts.** Oncorus built its state-of-the-art, 105,000 square foot process development and GMP-compliant clinical manufacturing facility as a comprehensive solution for its Chemistry, Manufacturing and Controls (CMC) development needs, allowing for the manufacture, quality control and supply of clinical-grade viral immunotherapies for its IND-enabling and clinical studies. The company also relocated all
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personnel and corporate activities to the facility, enabling collaboration among company personnel and enhanced efficiency.

Third Quarter 2022 Financial Results

- Cash and cash equivalents and investments totaled \$81.5 million as of September 30, 2022 compared to \$123.9 million as of December 31, 2021.
- Research and development expenses for the quarter ended September 30, 2022 were \$14.1 million compared to \$11.3 million for the corresponding quarter in 2021. The increase was primarily attributable to increased headcount, which drove higher employee compensation and stock-based compensation, increased development costs related to the company's nominated candidates, as well as increased rent expense related to the company's manufacturing facility.
- General and administrative expenses for the quarter ended September 30, 2022 were \$5.2 million compared to \$5.4 million for the corresponding quarter in 2021. The slight decrease was primarily attributable to lower recruiting and consulting costs.
- Net loss for the quarter ended September 30, 2022 was \$19.6 million, or \$0.76 per share, as compared to a net loss of \$16.7 million, or \$0.65 per share for the corresponding quarter in 2021.

Financial Guidance

Oncorus expects its cash, cash equivalents and investments to fund its capital expenditures and operating expenses into early 2024.

About Oncorus

At Oncorus, we are focused on driving innovation to deliver next-generation viral immunotherapies to stimulate the immune system and transform outcomes for cancer patients. We are advancing a portfolio of intratumorally (iT_u) and intravenously (IV) administered viral immunotherapies for multiple indications with significant unmet need based on our Herpes Simplex Virus (HSV) and self-amplifying viral RNA/LNP Immunotherapy Platforms.

Our HSV Platform is designed to improve upon key characteristics of viral immunotherapies to enhance systemic activity. Our lead HSV program, ONCR-177, which is currently in the clinic, is designed to be directly administered into a tumor, resulting in high local concentrations of the therapeutic agent and its five encoded transgenes, as well as low systemic exposure to the therapy, which could limit systemic toxicities. Our pioneering self-amplifying vRNA/LNP Immunotherapy Platform, highlighted by our product candidates ONCR-021 and ONCR-788, involves a highly innovative, novel combination of RNA and LNP-based modalities designed to realize the potential of RNA medicines for cancer.

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 the clinical development of ONCR-177, including expectations regarding enrollment, dosing and timing for reporting additional data from the monotherapy and combination arms of the ongoing Phase 1 clinical trial, as well as the product candidate's therapeutic potential and clinical benefits and the utility and potential of Oncorus' HSV Platform; the preclinical and

clinical development of ONCR-021 and ONCR-788, including expectations regarding timing for submitting an IND for ONCR-021, as well as the product candidates' therapeutic potential and clinical benefits and the utility and potential of Oncorus' self-amplifying vRNA Immunotherapy Platform; and Oncorus' belief that its current cash and investment resources will be sufficient to fund its operations 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 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, Oncorus' Quarterly Reports on Form 10-Q for the quarters ended March 31, 2022 and June 30, 2022, filed with the SEC on May 4, 2022 and August 4, 2022, respectively, and Oncorus' Quarterly Report on Form 10-Q for the quarter ended September 30, 2022, to be filed with the SEC on or about November 2, 2022, 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.

Investor Contact:

Stern Investor Relations

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Oncorus, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	\$ 14,087	\$ 11,299	\$ 39,036	\$ 30,406
General and administrative	5,211	5,440	16,721	14,550
Total operating expenses	<u>19,298</u>	<u>16,739</u>	<u>55,757</u>	<u>44,956</u>
Loss from operations	(19,298)	(16,739)	(55,757)	(44,956)
Other income (expense):				
Other expense	8	-	(63)	(1)
Interest expense	(670)	-	(1,261)	-
Interest income	340	11	590	38
Total other income (expense), net	<u>(322)</u>	<u>11</u>	<u>(734)</u>	<u>37</u>
Net loss	<u>\$ (19,620)</u>	<u>\$ (16,728)</u>	<u>\$ (56,491)</u>	<u>\$ (44,919)</u>
Comprehensive loss:				
Net unrealized loss on investments	(32)	-	(73)	-
Comprehensive loss	<u>\$ (19,652)</u>	<u>\$ (16,728)</u>	<u>\$ (56,564)</u>	<u>\$ (44,919)</u>
Net loss per share - basic and diluted	<u>\$ (0.76)</u>	<u>\$ (0.65)</u>	<u>\$ (2.18)</u>	<u>\$ (1.79)</u>
Weighted-average number of common shares	<u>25,972</u>	<u>25,748</u>	<u>25,907</u>	<u>25,153</u>

Oncorus, Inc.
Selected Condensed Consolidated Balance Sheet Data
(in thousands)
(Unaudited)

	September 30, 2022		December 31, 2021
Cash and cash equivalents	\$ 41,568	\$	100,752
Investments	39,955		23,173
Working capital (1)	66,666		108,136
Property and equipment, net	42,883		23,233
Right-of-use asset	33,997		45,218
Total assets	164,365		201,587
Debt, net of debt discount and issuance fees	19,257		-
Long term lease liability	48,147		50,388
Total liabilities	84,369		71,565
Total stockholders' equity	79,996		130,022

(1) Working capital is defined as current assets less current liabilities
