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 03, 2021

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.)**

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

On November 3, 2021, Oncorus, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2021. 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 3, 2021
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 thereunto duly authorized.

ONCORUS, INC.

Date: November 3, 2021

By: /s/ John McCabe

John McCabe
Chief Financial Officer

Exhibit 99.1

Oncorus Reports Third Quarter 2021 Financial Results and Provides Business Updates

- To report initial data from ongoing Phase 1 clinical trial of lead oncolytic Herpes Simplex Virus (oHSV) viral immunotherapy candidate, ONCR-177, in multiple solid tumor indications at the upcoming Society for Immunotherapy of Cancer's (SITC) 36th Annual Meeting on November 12th
- Completed Pre-IND meeting and initiating GLP IND-enabling safety and tolerability studies for lead intravenously (IV) administered Synthetic viral RNA (vRNA) immunotherapy candidate, ONCR-021 (Synthetic CVA21); plans to submit an IND for ONCR-021 in the first half of 2023
- Continues non-GLP safety and tolerability studies for second Synthetic vRNA immunotherapy candidate ONCR-788 (Synthetic SVV)
- First phase of GMP clinical manufacturing facility completed, with process development activities now underway; anticipates being fully operational in the first half of 2023
- $145.6 million in cash and cash equivalents as September 30, 2021

CAMBRIDGE, Mass., November 3, 2021 – Oncorus, Inc. (Nasdaq: ONCR), a viral immunotherapies company focused on driving innovation to transform outcomes for cancer patients, today reported third quarter 2021 financial results and highlighted recent achievements and developments.

"We continue to make important progress advancing our broad portfolio of next-generation viral immunotherapies and creating a state-of-the-art process development and manufacturing infrastructure to support our planned future development activities and growth," said Theodore (Ted) Ashburn, M.D., Ph.D., President and Chief Executive Officer at Oncorus. "Our Phase 1 clinical trial of ONCR-177 continues to enroll patients, and we are excited to begin sharing data from this trial at SITC next week during a poster presentation beginning on November 12th. Across our oHSV and Synthetic vRNA Immunotherapy platforms we have multiple preclinical efforts underway as we advance our next programs toward the clinic. In addition, we are thrilled to report that the first phase of our manufacturing facility has been completed, with Oncorus team members now working onsite, overseeing process development activities."

Dr. Ashburn continued, "The breadth of activities we have underway is a testament to the tremendous competence and capabilities of our team. We continue to execute on our goal of building the leading viral immunotherapies company, based on world-class science, pipeline breadth, and an unwavering commitment to cancer patients."

Third Quarter 2021 and Recent Highlights

- **Initial data to be presented for ongoing Phase 1 clinical trial of ONCR-177 at SITC 2021, taking place November 12 – 14 in Washington, DC and virtually.** Oncorus continues to enroll patients across 11 sites in the United States and Canada in a Phase 1 clinical trial of ONCR-177, an intratumorally (iTu) administered oHSV viral immunotherapy, being developed for multiple solid tumor indications. The Phase 1 open-label, dose escalation and expansion clinical trial is designed to evaluate the safety and tolerability of ONCR-177 alone and in combination with Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), in patients with advanced and/or refractory cutaneous, subcutaneous or metastatic nodal solid tumors or with liver metastases of

solid tumors. This presentation at SITC will mark Oncorus' first reporting of human data from its oHSV platform.

- **Continued to progress first Synthetic vRNA immunotherapy clinical candidates, ONCR-021 and ONCR-788.** As disclosed earlier this year, ONCR-021 and ONCR-788 employ Oncorus' pioneering IV-administered approach of encapsulating the genomes of RNA viruses known to kill cancer cells (i.e., oncolytic viruses, or OVs) in lipid nanoparticles (LNPs), creating, to the company's knowledge, the first-ever Synthetic vRNA immunotherapy. ONCR-021 encodes an optimized strain of CVA21 (Coxsackievirus A21); ONCR-788 encodes a modified version of SVV (Seneca Valley Virus, or SVV). CVA21 and SVV both have extensive clinical experience and favorable safety profiles when administered intravenously. Oncorus' novel Synthetic vRNA approach holds the potential for IV administration while avoiding the challenge of neutralizing antibodies seen in previous approaches with IV-administered OVs. (Learn more about Oncorus' novel Synthetic vRNA Immunotherapy approach.)

  Oncorus is currently initiating GLP safety and tolerability studies for ONCR-021 and anticipates submitting an IND for this program in the first half of 2023. The company is also conducting preliminary non-GLP safety and tolerability studies for ONCR-788 and is not yet providing guidance on timing of an IND submission for this program. Oncorus plans to investigate its novel Synthetic vRNA immunotherapies in multiple histologies, including cancers of the lung, both as monotherapy and in combination with immune checkpoint inhibitors and possibly other cancer treatments.

- **Upcoming preclinical presentation on ONCR-GBM at the International Oncolytic Virus Conference (IOVC) 2021.** Leveraging its oHSV platform, Oncorus is pursuing ONCR-GBM to specifically target brain cancer, including glioblastoma multiforme (GBM). The company is utilizing its knowledge of microRNA expression to engineer a microRNA attenuation strategy to protect healthy brain tissue and to select a rational combination of payloads intended to address both the cancer itself and the specific drivers of immune suppression in the brain. Oncorus plans to submit an IND for ONCR-GBM in the second half of 2023.

  Oncorus will present a poster titled, "ONCR-GBM: A Novel, Armed Oncolytic HSV-1 Vector Engineered for Efficacy and Safety in Glioblastoma" (Poster #10226), at IOVC 2021, which will take place November 5 – 7 in Sedona, Arizona and virtually. Part of the conference's Virtual Poster Session, Oncorus' e-poster will describe the design and evaluation of multiple features that will be incorporated into the ONCR-GBM program, including robust anti-tumor activity observed with IL-12 and a proprietary PD-1 antagonist nanobody. Link to the meeting website here.

- **Completed first phase of Process Development and Good Manufacturing Practice (GMP) viral immunotherapy clinical manufacturing facility buildout.** Oncorus has completed the first phase of its state-of-the-art, 88,000 square foot process development and GMP viral immunotherapy clinical manufacturing facility in Andover, Mass. Oncorus is building out the expansive facility to provide a comprehensive solution for its Chemistry, Manufacturing and Controls (CMC) development needs, enabling the manufacture, quality control and supply of clinical-grade viral immunotherapies for IND-enabling and clinical studies. Process development and GMP readiness activities are now underway at the site. Oncorus anticipates the buildout to be

completed and the site to be fully operational, including GMP multi-product manufacturing capabilities, in the first half of 2023.

Third Quarter Financial Results

- Cash and cash equivalents were $145.6 million as of September 30, 2021 compared to $130.3 million as of December 31, 2020.
- Research and development expenses for the quarter ended September 30, 2021 were $11.3 million compared to $6.9 million for the corresponding quarter in 2020. The increase in research and development expenses was mainly attributable to increased employee compensation costs, which was driven by increased headcount and increased stock-based compensation, increased rent expense related to the company's new manufacturing facility and increased development costs related to the company's nominated candidates.
- General and administrative expenses for the quarter ended September 30, 2021 were $5.4 million compared to $2.0 million for the corresponding quarter in 2020. The increase in general and administrative expenses was primarily attributable to increases in employee compensation costs, including higher stock-based compensation, increased headcount and increased salary and related expenses. General and administrative expenses also increased due to higher insurance expense and professional and consultant expenses related to operating as a public company.
- Other income (expense), net, for the quarter ended September 30, 2021 was income of $0.01 million compared to an expense of $10.6 million for the quarter ended September 30, 2020. The expense for the quarter ended September 30, 2020 included a non-cash charge of $10.6 million related to an increase in the fair market value of the company's Series B preferred stock tranche rights liability that was settled in September 2020.
- Net loss attributable to common stockholders for the quarter ended September 30, 2021 was $16.7 million, or $0.65 per share, as compared to a net loss attributable to common stockholders of $22.4 million, or $21.73 per share for the same quarter in 2020. The share and net loss per share amounts in the third quarter of 2021 include the impact of Oncorus' IPO, which closed in October 2020, including the conversion of outstanding preferred stock into approximately 15.0 million shares of common stock.

Financial Guidance

Based upon its current operating plans and cash and cash equivalents, Oncorus expects to have sufficient capital to fund its operating expenses and capital expenditure requirements into late 2023.

About Oncorus

At Oncorus, we are focused on driving innovation to deliver next-generation viral immunotherapies to transform outcomes for cancer patients. We are advancing a portfolio of intratumorally (iTu) and intravenously (IV) administered viral immunotherapies for multiple indications with significant unmet need based on our oncolytic Herpes Simplex Virus (oHSV) Platform and Synthetic viral RNA (vRNA) Immunotherapy Platform.

Designed to deliver next-generation viral immunotherapy impact, our oHSV Platform improves upon key characteristics of this therapeutic class to enhance systemic activity. Our lead oHSV program, ONCR-177, 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 Synthetic vRNA Immunotherapy Platform involves a highly innovative, novel combination of RNA- and oncolytic virus-based modalities designed to realize the potential of RNA medicines for cancer. Our lead IV-administered Synthetic vRNA Immunotherapy clinical candidates, ONCR-021 and ONCR-788, are both currently in IND-enabling studies.

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 timing for reporting data from 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' oHSV Platform; Oncorus' expectations regarding its other potential product candidates, including the timing of the submission of an IND for its second oHSV Platform program, ONCR-GBM, and the design thereof; the preclinical and clinical development of ONCR-021 and ONCR-788, including expectations regarding timing for submitting INDs, as well as the product candidates' therapeutic potential and clinical benefits and the utility and potential of Oncorus' Synthetic vRNA Immunotherapy Platform; Oncorus' belief that it is creating the first-ever Synthetic vRNA immunotherapy; expectations regarding manufacturing capabilities including the buildout timeline of Oncorus' viral immunotherapy clinical manufacturing facility and readiness for GMP production; and Oncorus' belief that its current cash resources will be sufficient to fund its operations and capital expenditure requirements into late 2023. 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: the impact of COVID-19 on Oncorus' operations and the timing and anticipated results of its ongoing and planned clinical trials; the risk that the results of preclinical studies and clinical trials may not be predictive of future results in connection with future clinical trials; Oncorus' ability to successfully demonstrate the safety, tolerability and efficacy of ONCR-177, ONCR-021 and ONCR-788 and obtain regulatory approval thereof; 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 adequacy of Oncorus' existing capital resources and availability of financing on commercially reasonable terms; 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, 2020, filed with the Securities and Exchange

Commission on March 10, 2021, as well as discussions of potential risks, uncertainties, and other important factors in the other filings that Oncorus makes with the Securities and Exchange Commission 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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Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except per share data)
Unaudited

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
Operating expenses:				
Research and development	$ 11,299	$ 6,927	$ 30,406	$ 19,560
General and administrative	5,440	1,973	14,550	6,032
Total operating expenses	16,739	8,900	44,956	25,592
Loss from operations	(16,739)	(8,900)	(44,956)	(25,592)
Other income (expense):				
Change in fair value of Series B tranche rights	—	(10,631)	—	$ (11,256)
Other expense	—	(2)	(1)	(22)
Interest income	11	2	38	138
Total other income (expense), net	11	(10,631)	37	(11,140)
Net loss and comprehensive loss	$ (16,728)	$ (19,531)	$ (44,919)	$ (36,732)
Accretion of discount and dividends on redeemable convertible preferred stock	—	(2,848)	—	(8,298)
Net loss attributable to common stockholders	$ (16,728)	$ (22,379)	$ (44,919)	$ (45,030)
Net loss per share - basic and diluted	$ (0.65)	$ (21.73)	$ (1.79)	$ (44.58)
Weighted-average number of common shares - basic and diluted	25,748	1,030	25,153	1,010

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

	September 30, 2021	December 31, 2020
Cash and cash equivalents	$ 145,603	$ 130,305
Working capital (1)	135,376	127,407
Right-of-use asset	37,428	41,372
Total assets	202,727	182,263
Long term lease liability	42,329	41,615
Total liabilities	54,885	47,599
Total stockholders' equity	147,842	134,664

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