

**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 4, 2021

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.)

50 Hampshire Street, Suite 401
Cambridge, Massachusetts
(Address of Principal Executive Offices)

02139
(Zip Code)

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

Not Applicable

(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 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 August 4, 2021, Oncorus, Inc. issued a press release announcing its financial results for the second quarter ended June 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.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press release issued by Oncorus, Inc. on August 4, 2021



Oncorus Reports Second Quarter 2021 Financial Results and Provides Business Highlights

- Continues to progress Phase 1 clinical trial of ONCR-177, company's lead oncolytic Herpes Simplex Virus (oHSV) viral immunotherapy candidate; on track to report initial interim data in 4Q'21
- Nominated company's first intravenously (IV) administered Synthetic viral RNA (vRNA) immunotherapy candidates, ONCR-021 (Synthetic CVA21) and ONCR-788 (Synthetic SVV)
- Anticipates first phase of GMP clinical manufacturing facility, including process development and quality control, to be completed in 2021, as previously guided
- Expanded Board of Directors with appointments of Eric H. Rubin, M.D., and Barbara Yanni
- \$159.9 million in cash and cash equivalents as of June 30, 2021

CAMBRIDGE, Mass., August 4, 2021 – Oncorus, Inc. (Nasdaq: ONCR), a viral immunotherapies company focused on driving innovation to transform outcomes for cancer patients, today reported second quarter 2021 financial results and highlighted recent achievements and developments.

"We're pleased that our Phase 1 clinical trial of ONCR-177, our lead oHSV candidate, continues to enroll and progress as expected, and we remain on track to report initial clinical data in the fourth quarter of this year. ONCR-177 is unique among oHSVs in that it retains the ability to resist interferon via retention of y34.5 and is armed with five complementary immunomodulatory payloads in order to drive systemic activity," said Theodore (Ted) Ashburn, M.D., Ph.D., President and Chief Executive Officer at Oncorus. "This quarter, we also announced the nomination of our lead Synthetic vRNA immunotherapy candidates, ONCR-021 and ONCR-788, which we plan to investigate in multiple cancers, including those of the lung. Our proprietary Synthetic vRNA Immunotherapy Platform involves a novel combination of RNA- and viral immunotherapy-based modalities. To date, we believe that neither of these modalities has reached its full potential due to several well-established challenges, which we believe we can overcome through our novel and innovative approach and, in doing so, potentially create a new pillar of therapy for cancer patients."

Second Quarter 2021 and Recent Highlights

- **Continued to progress Phase 1 clinical trial of ONCR-177.** Oncorus continues to enroll patients in a Phase 1 clinical trial of its lead oHSV product candidate, ONCR-177, an intratumorally (iTU) administered oHSV viral immunotherapy being developed for multiple solid tumor indications. The Phase 1 open-label, multi-center, 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. Oncorus anticipates reporting initial interim data from the Phase 1 trial in the fourth quarter of 2021.
- **Announced nomination of its first Synthetic vRNA immunotherapy clinical candidates, ONCR-021 and ONCR-788.** In May 2021, Oncorus nominated its first Synthetic vRNA immunotherapy clinical candidates, ONCR-021 and ONCR-788. Oncorus' pioneering IV-administered approach involves encapsulating the genomes of RNA viruses known to kill cancer cells (i.e., oncolytic viruses (OVs)) in a lipid nanoparticle (LNP), creating a Synthetic vRNA immunotherapy. ONCR-021 encodes an optimized strain of Cocksackievirus A21 (CVA21), and ONCR-788 encodes a

modified version of the Seneca Valley Virus (SVV). Both CVA21 and SVV have extensive clinical experience and favorable safety profiles when administered IV. Oncorus' novel Synthetic vRNA approach holds the potential for IV-administration and avoids the challenge of neutralizing antibodies seen in previous approaches with IV-administered OVs. 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 other cancer treatments.

Click [here](#) to read a white paper published by Oncorus' leadership on its Synthetic vRNA Immunotherapy Platform and lead candidates and [here](#) for the slide deck presented at Oncorus' recent investor meeting. Click [here](#) to view an animation depicting Oncorus' novel Synthetic vRNA immunotherapy approach.

- **Continued to advance second oHSV viral immunotherapy candidate, ONCR-GBM, toward candidate nomination.** 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 combination of payloads intended to address the specific drivers of immune suppression in brain cancer.
- **Progressed buildout of Good Manufacturing Practice (GMP) viral immunotherapy clinical manufacturing facility.** Oncorus continues to make progress building out its state-of-the-art, 88,000 square foot GMP viral immunotherapy clinical manufacturing facility in Andover, Massachusetts. The facility, for which Oncorus has signed a 15-year lease, is intended to provide a comprehensive solution for Oncorus' Chemistry, Manufacturing and Controls (CMC) development needs, enabling the manufacture, quality control and supply of clinical-grade viral immunotherapies for investigational new drug (IND)-enabling and clinical studies. The company remains on track to complete the first phase of the facility's buildout in 2021, including process development and quality control, with GMP multi-product manufacturing capabilities and full operation expected to commence in the first half of 2023.
- **Expanded Board of Directors with two new appointments.** Oncorus expanded its Board with the appointments of Eric H. Rubin, M.D., and Barbara Yanni, in June 2021 and July 2021, respectively. Dr. Rubin currently serves as Senior Vice President of Global Clinical Oncology at Merck, known as MSD outside of the United States and Canada. Ms. Yanni was formerly Vice President and Chief Licensing Officer at Merck, prior to her retirement in 2014.

Second Quarter Financial Results

- Cash and cash equivalents were \$159.9 million as of June 30, 2021 compared to \$130.3 million as of December 31, 2020.

- Research and development expenses for the quarter ended June 30, 2021 were \$10.7 million compared to \$6.7 million for the corresponding quarter in 2020. The increase in research and development expenses was mainly attributable to increased personnel-related expenses, including stock-based compensation, which was driven by increased headcount, 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 June 30, 2021 were \$4.9 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 personnel-related expenses, including stock-based compensation, which was driven by increased compensation and increased headcount and other increased costs, such as insurance expense and professional and consultant expenses, related to operating as a public company.
- Net loss attributable to common stockholders for the quarter ended June 30, 2021 was \$15.5 million, or \$0.60 per share, compared to a net loss attributable to common stockholders of \$12.1 million, or \$12.09 per share for the same quarter in 2020. The share and net loss per share amounts in the second quarter of 2021 reflect the impact of the company's 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 (iT_u) 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; the preclinical and clinical development of ONCR-021 and ONCR-788, including expectations regarding timing for filing INDs, as well as the product candidates' therapeutic potential and clinical benefits and the utility and potential of Oncorus' Synthetic vRNA Immunotherapy Platform; Oncorus' expectations regarding upcoming milestones for its other potential product candidates, including the timing for nomination of a candidate from its second oHSV Platform program, ONCR-GBM; expectations regarding manufacturing capabilities including the buildout timeline of Oncorus' viral immunotherapy clinical manufacturing facility; 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 and efficacy of ONCR-177, ONCR-021 and ONCR-788 and obtain regulatory approval; Oncorus' ability to secure adequate quantities of viral immunotherapies manufactured in accordance with regulatory requirements; the expansion of Oncorus' in-house manufacturing capabilities; the adequacy of Oncorus' cash resources and availability of financing on commercially reasonable terms; 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. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements.

Investor Contact:

Alan Lada
Solebury Trout
alada@soleburytrout.com

Media Contact:

Liz Melone
liz.melone@oncorus.com

Oncorus, Inc.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	\$ 10,660	\$ 6,741	\$ 19,107	\$ 12,633
General and administrative	4,889	2,007	9,111	4,059
Total operating expenses	15,549	8,748	28,218	16,692
Loss from operations	(15,549)	(8,748)	(28,218)	(16,692)
Other income (expense):				
Change in fair value of Series B tranche rights	—	(625)	—	(625)
Other expense	—	(9)	—	(20)
Interest income	21	8	27	136
Total other income (expense), net	21	(626)	27	(509)
Net loss and comprehensive loss	\$ (15,528)	\$ (9,374)	\$ (28,191)	\$ (17,201)
Accretion of discount and dividends on redeemable convertible preferred stock	—	(2,725)	—	(5,450)
Net loss attributable to common stockholders	\$ (15,528)	\$ (12,099)	\$ (28,191)	\$ (22,651)
Net loss per share – basic and diluted	\$ (0.60)	\$ (12.09)	\$ (1.13)	\$ (22.67)
Weighted-average number of common shares – basic and diluted	25,684	1,001	24,851	999

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

	June 30, 2021	December 31, 2020
Cash and cash equivalents	\$ 159,920	\$ 130,305
Working capital (1)	151,945	127,407
Right-of-use asset	40,018	41,372
Total assets	215,610	182,263
Long term lease liability	42,234	41,615
Total liabilities	52,978	47,599
Total stockholders' equity	162,632	134,664

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