

**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): **March 10, 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 March 10, 2021, Oncorus, Inc. issued a press release announcing its financial results for the fourth quarter and full year ended December 31, 2020. 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	<a href="#">Press release issued by Oncorus, Inc. on March 10, 2021</a>

**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.

Company Name

Date: March 10, 2021

By: \_\_\_\_\_  
/s/ John McCabe  
**John McCabe**  
**Chief Financial Officer**



### **Oncorus Reports Fourth Quarter and Full Year 2020 Financial Results and Provides Business Highlights**

- 2020 marked year of notable progress for Oncorus. Key highlights included:
  - Transitioned to clinical-stage company with initiation of Phase 1 clinical trial of lead viral immunotherapy candidate, ONCR-177, for the treatment of solid tumors
  - Announced clinical trial collaboration and supply agreement with Merck to evaluate combination of ONCR-177 with KEYTRUDA® (pembrolizumab) as part of ongoing ONCR-177 Phase 1 clinical trial
  - Completed IPO, receiving \$98.4 million in aggregate gross proceeds
  - Commenced strategic planning for operational and manufacturing scale-up, including signing of a 15-year lease to build a state-of-the-art, 88,000 square foot GMP viral immunotherapy clinical manufacturing facility
  - \$130.3 million in cash and cash equivalents as of December 31, 2020
- In February 2021, Oncorus completed an underwritten public offering of common stock, resulting in aggregate gross proceeds of \$57.0 million
- Company anticipates continued growth and progress in 2021 across its pipeline and business, including initial interim data readout of ONCR-177 Phase 1 clinical trial in second half of 2021

**CAMBRIDGE, Mass., March 10, 2021** – Oncorus, Inc. (Nasdaq:ONCR), a viral immunotherapies company focused on driving innovation to transform outcomes for cancer patients, today reported fourth quarter and full year 2020 financial results and provided business highlights.

“2020 was a year of significant evolution for Oncorus as we successfully transitioned to a clinical-stage and publicly-traded company,” said Theodore (Ted) Ashburn, M.D., Ph.D., President and Chief Executive Officer of Oncorus. “In addition to moving our lead viral immunotherapy candidate, ONCR-177, into a clinical trial, we continued to advance multiple pipeline candidates across our oncolytic Herpes Simplex Virus (oHSV) and Synthetic Virus Platforms. We also began to plan operational and manufacturing scale-up to support our anticipated growth in the coming years.”

Dr. Ashburn continued, “Bolstered by a strong cash position, we anticipate multiple milestones in 2021 that will further advance Oncorus’ leadership in the viral immunotherapy space. These include the initial interim data readout from our ongoing ONCR-177 clinical trial, the nomination of our first intravenously administered synthetic virus clinical candidates as well as our second intratumorally administered oHSV clinical candidate, and the completion of the first buildout phase of our GMP clinical manufacturing facility. We look forward to continued growth throughout 2021, driven by our mission to realize the full promise of viral immunotherapy for cancer patients.”

Oncorus anticipates reporting interim data from its ongoing Phase 1 clinical trial of its lead oHSV-based clinical candidate ONCR-177 in patients with solid tumor indications in the second half of 2021 through the second half of 2022. The company plans to nominate its first synthetic virus clinical candidates, coxsackievirus A21 and Seneca Valley Virus programs, in the first half of 2021 and its second oHSV clinical candidate, which will specifically target brain cancer, including glioblastoma multiforme, in the second half of 2021.

## Fourth Quarter and Full Year 2020 and Recent Highlights

### Recent Highlights

- **Recently completed public offering of common stock.** In February 2021, Oncorus completed an underwritten public offering of common stock, at a public offering price of \$19.00 per share, raising \$57.0 million in aggregate gross proceeds.
- **Announced buildout of Good Manufacturing Practice (GMP) viral immunotherapy clinical manufacturing facility.** In January 2021, Oncorus announced the signing of a 15-year lease to build a state-of-the-art, 88,000 square foot GMP viral immunotherapy clinical manufacturing facility in Andover, Mass. The facility 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 studies and clinical studies. Oncorus anticipates the first phase of the facility's buildout will be completed in late 2021, including process development and quality control, with GMP multi-product manufacturing capabilities and full operation commencing in early 2023. Oncorus plans to continue partnering with contract manufacturing organizations to provide additional support and capacity. The company expects to employ up to 100 Oncorus team members at the site.
- **Announced publication of ONCR-177 preclinical data demonstrating potent and durable antitumor activity.** In January 2021, Oncorus announced the recent publication of preclinical data supporting the clinical development of ONCR-177. In the paper, entitled, "ONCR-177, an Oncolytic HSV-1 Designed to Potently Activate Systemic Antitumor Immunity" (Haines, et al., 2020), published online in the journal *Cancer Immunology Research*, ONCR-177 demonstrated potent and durable antitumor activity in multiple immune-competent tumor models. The preclinical activity of ONCR-177 was shown to be driven by Oncorus' unique combination of five complementary immunomodulatory transgene payloads in addition to its retention of g34.5. A herpes simplex virus 1 (HSV-1) gene, g34.5 allows the virus to replicate in the presence of host antiviral immune responses.

### Fourth Quarter and Full Year 2020 Highlights

- **Appointed Steve Harbin as Chief Operating Officer (COO) and Chief of Staff.** In December 2020, Oncorus appointed Steve Harbin as COO and Chief of Staff, to lead planning and execution of its anticipated operational and manufacturing scale-up. Mr. Harbin brings more than 30 years of diverse operational experience in biotech, pharmaceuticals and in-vitro diagnostics. His experience includes serving in several executive committee roles at Moderna, Inc. for six years, where he was a key driver of the company's successful growth strategy, overseeing clinical and non-clinical manufacturing operations, supply chain, facilities and human resources. Previously Mr. Harbin served as Senior Vice President, Global Operations for France-based bioMérieux SA, and also held multiple leadership roles within Eli Lilly and Company globally.

- **Expanded Board of Directors with appointment of Scott Canute.** In December 2020, Oncorus expanded its Board with the appointment of Scott Canute. Mr. Canute has nearly 40 years of broad experience in the biopharmaceutical industry, including leading global manufacturing and operations strategy and execution for Genzyme Corporation and Eli Lilly and Company.
- **Completed initial public offering.** In October 2020, Oncorus completed the initial public offering of shares of its common stock at a public offering price of \$15.00 per share, and raised \$98.4 million in aggregate gross proceeds, including shares sold to the underwriters pursuant to a partial exercise of their option to purchase additional shares. On October 2, 2020, Oncorus' common stock commenced trading on the Nasdaq Global Market under the ticker symbol "ONCR".
- **Publication of preclinical data characterizing ONCR-177's safety strategies.** In September 2020, ONCR-177's safety strategies and their ability to enhance oHSV tolerability without impeding potency were characterized in a paper published in *Molecular Therapy* on ONCR-159, the unarmed version of ONCR-177, titled, "Design of an Interferon-Resistant Oncolytic HSV-1 Incorporating Redundant Safety Modalities for Improved Tolerability." (Kennedy et al., 2020). Oncorus' oHSV platform incorporates two complementary and proprietary safety approaches, including a microRNA attenuation strategy to allow unencumbered viral replication in tumor cells while preventing replication in healthy tissues, and engineered proprietary mutations into UL37 to eliminate the virus' ability to transport, replicate and establish latency inside neurons.
- **Announced clinical trial collaboration with Merck.** In July 2020, Oncorus entered into a clinical trial collaboration and supply agreement with Merck (NYSE:MRK), known as MSD outside of the United States and Canada, through a subsidiary, to evaluate the combination of ONCR-177 with KEYTRUDA® (pembrolizumab), as part of the ongoing Phase 1 clinical trial of ONCR-177 in adult patients with advanced and/or refractory cutaneous, subcutaneous or metastatic nodal solid tumors.
- **Initiated Phase 1 clinical trial of ONCR-177.** In June 2020, Oncorus initiated a Phase 1 clinical trial of its lead product candidate, ONCR-177, an intratumorally 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 and to determine the recommended Phase 2 dose, as well as its preliminary anti-tumor activity, 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 interim data from the Phase 1 clinical trial in the second half of 2021 through the second half of 2022.

## Fourth Quarter Financial Results

- Cash and cash equivalents were \$130.3 million as of December 31, 2020 compared to \$45.3 million as of December 31, 2019.
- Research and development expenses for the quarter ended December 31, 2020 were \$7.6 million compared to \$5.9 million for the corresponding period in 2019. The increase in research and development expenses was mainly attributable to increases in clinical trial costs for the company's Phase 1 clinical trial as well as increased personnel-related expenses driven by increased headcount.
- General and administrative expenses for the quarter ended December 31, 2020 were \$4.0 million compared to \$3.1 million for the corresponding period in 2019. The increase in general and administrative expenses was primarily attributable to increases in personnel-related expenses driven by increased headcount as well as increased costs associated with the Company's transition to a public company in the fourth quarter of 2020.
- Net loss attributable to common stockholders for the quarter ended December 31, 2020 was \$(11.8) million, or \$(0.56) per share, compared to a net loss attributable to common stockholders of \$(11.5) million, or \$(1.78) per share for the same period in 2019. The share and loss per share amounts in the fourth quarter of 2020 reflect the impact of the company's IPO, which closed in October 2020.

## Financial Guidance

Based upon its current operating plans and cash and cash equivalents at December 31, 2020, plus the net proceeds from the public offering of common stock in February 2021, the company 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 and intravenously administered viral immunotherapies for multiple indications with significant unmet needs based on our oncolytic Herpes Simplex Virus (oHSV) Platform and Synthetic Virus Platform. Designed to deliver next-generation viral immunotherapy impact, our oHSV platform improves upon key characteristics of this therapeutic class to enhance potency without sacrificing safety, including greater capacity to encode transgenes to drive systemic immunostimulatory activity, retention of full replication competency to enable high tumor-killing potency, and orthogonal safety strategies to restrict viral activity to tumor cells. Our lead program, ONCR-177, is designed to be directly administered into a tumor, resulting in high local concentrations of the therapeutic agent, as well as low systemic exposure to the therapy, which we believe could potentially limit systemic toxicities. Please visit [www.oncorus.com](http://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; Oncorus' expectations regarding upcoming milestones for its other potential product candidates, including the timing for nomination of candidates from its two Synthetic Virus Platform development programs and its second oHSV Platform program, ONCR-GBM; expectations regarding the buildout timeline of its viral immunotherapy clinical manufacturing facility and its belief that its current cash resources will be sufficient to fund its operations 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 a clinical trial 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 and obtain regulatory approval; 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, to be 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  
617-221-8006  
[alada@soleburytrout.com](mailto:alada@soleburytrout.com)

**Media Contact:**

Liz Melone  
[liz.melone@oncorus.com](mailto:liz.melone@oncorus.com)

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

	Three Months Ended		Year Ended	
	December 31,		December 31,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	\$ 7,593	\$ 5,864	\$ 27,153	\$ 24,047
General and administrative	3,968	3,141	10,000	7,119
Total operating expenses	<u>11,561</u>	<u>9,005</u>	<u>37,153</u>	<u>31,166</u>
Loss from operations	(11,561)	(9,005)	(37,153)	(31,166)
Other income (expense):				
Change in fair value of Series B tranche rights	—	—	(11,256)	—
Other expense	(11)	(40)	(33)	(47)
Interest income	5	178	143	509
Total other income (expense), net	<u>(6)</u>	<u>138</u>	<u>(11,146)</u>	<u>462</u>
Net loss and comprehensive loss	<u>\$(11,567)</u>	<u>\$ (8,867)</u>	<u>\$(48,299)</u>	<u>\$(30,704)</u>
Accretion of discount and dividends on redeemable convertible preferred stock	(229)	(2,678)	(8,527)	(4,287)
Net loss attributable to common stockholders	<u>\$(11,796)</u>	<u>\$(11,545)</u>	<u>\$(56,826)</u>	<u>\$(34,991)</u>
Net loss per share—basic and diluted	<u>\$ (0.56)</u>	<u>\$ (11.78)</u>	<u>\$ (9.35)</u>	<u>\$ (37.42)</u>
Weighted-average number of common shares—basic and diluted	<u>21,126</u>	<u>980</u>	<u>6,080</u>	<u>935</u>

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

	December 31, 2020	December 31, 2019
Cash and cash equivalents	\$ 130,305	\$ 45,286
Working capital (1)	127,407	40,963
Right-of-use asset (2)	41,372	—
Total assets	182,263	50,826
Long term lease liability (2)	41,615	—
Total liabilities	47,599	8,491
Redeemable convertible preferred stock	—	116,632
Total stockholders' equity (deficit)	\$ 134,664	\$ (74,297)

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

(2) Reflects the adoption of ASC 842, *Leases*, as of January 1, 2020 resulting in capitalization of right of use assets and a corresponding liability for the Company's operating leases