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): May 4, 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** **(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 May 4, 2021, Oncorus, Inc. issued a press release announcing its financial results for the first quarter ended March 31, 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 May 4, 2021

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: May 4, 2021

By: /s/ John McCabe

John McCabe
Chief Financial Officer

Oncorus Reports First Quarter 2021 Financial Results and Provides Business Highlights

— Enrollment continues in Phase 1 clinical trial of lead oncolytic Herpes Simplex Virus (oHSV) viral immunotherapy candidate ONCR-177; initial interim data expected in 2H'21 —
— Company plans to nominate first two intravenously (IV) administered synthetic viral RNA (vRNA) immunotherapy candidates in 1H'21 —
— Buildout of GMP clinical manufacturing capabilities and facility remain on track; process development activities anticipated to begin at facility in 2H'21 —
— Received $57.0 million in aggregate gross proceeds in February 2021 from public offering —

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

"We began 2021 with strong momentum, announcing the buildout of our GMP manufacturing facility which is now well underway, and we continue to advance our ambitious goals on behalf of cancer patients," said Theodore (Ted) Ashburn, M.D., Ph.D., President and Chief Executive Officer of Oncorus.

Dr. Ashburn further commented, "We continue to enroll patients in a Phase 1 clinical trial of ONCR-177, our lead oncolytic Herpes Simplex Virus (oHSV) clinical candidate, and expect initial interim data later this year. We also anticipate nominating our first two synthetic viral RNA (vRNA) immunotherapy candidates in the first half of 2021. These candidates are comprised of vRNA coding for oncolytic viruses encapsulated within lipid nanoparticles, or LNPs – proprietary technologies developed by the Oncorus team. We have designed this novel approach to enable the systemic, repeat intravenous (IV) administration of viral immunotherapies, the so-called 'holy grail' of this modality, to date unattainable. We're excited to introduce this breakthrough approach and discuss these candidates in more detail at an upcoming virtual investor event."

First Quarter 2021 and Recent Highlights

- **Enrolling Phase 1 clinical trial of ONCR-177.** Oncorus is currently enrolling a Phase 1 clinical trial of its lead 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. The trial will determine the recommended Phase 2 dose, as well as investigate ONCR-177's 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 has an ongoing clinical trial collaboration with Merck involving KEYTRUDA and anticipates reporting interim data from the Phase 1 trial in the second half of 2021 through the second half of 2022.

- **Advancing lead Synthetic vRNA Immunotherapy Platform programs toward clinical candidate nomination.** Oncorus continues to advance its lead synthetic, IV administered vRNA immunotherapy programs based on the Coxsackievirus A21 (CVA21) and the Seneca Valley Virus (SVV). The company expects to nominate clinical candidates for both programs in the first half of 2021. IV administration of viral immunotherapies is an attractive approach for improving the standard of care for many cancer patients because it allows for all tumors, including micro-metastases, to be directly treated. In addition, it allows for the potential treatment of certain tumors, such as those of the lung, that are less amenable to repeat iTu injection of anti-cancer therapies due to safety and feasibility considerations. Oncorus' Synthetic vRNA Immunotherapy Platform includes a novel LNP delivery strategy designed to overcome the challenges caused by neutralizing antibodies, which have limited the efficacy of previous industry efforts to treat tumors utilizing IV administration of OVs.
- **Advancing second oHSV viral immunotherapy candidate, ONCR-GBM.** 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 select a combination of payloads intended to address the specific drivers of immune suppression in brain cancer. Oncorus plans to nominate its ONCR-GBM clinical candidate in the second half of 2021.
- **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 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.
- **Completed follow-on public offering.** In February 2021, Oncorus completed an underwritten public offering of common stock, at a price of $19.00 per share, raising $57.0 million in aggregate gross proceeds.

First Quarter Financial Results

- Cash and cash equivalents were $172.6 million as of March 31, 2021 compared to $130.3 million as of December 31, 2020.

- Research and development expenses for the quarter ended March 31, 2021 were $8.4 million compared to $5.9 million for the corresponding quarter in 2020. The increase in research and development expenses was mainly attributable to increased rent expense related to the Company's new manufacturing facility, increased personnel-related expenses, including stock-based compensation, driven by increased headcount and increased clinical trial costs for the Company's ongoing Phase 1 clinical trial of ONCR-177.
- General and administrative expenses for the quarter ended March 31, 2021 were $4.2 million compared to $2.1 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, driven by increased compensation and increased headcount and 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 March 31, 2021 was $12.7 million, or $0.53 per share, compared to a net loss attributable to common stockholders of $10.6 million, or $10.59 per share for the same quarter in 2020. The share and loss per share amounts in the first 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 and intravenously administered viral immunotherapies for multiple indications with significant unmet needs 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 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 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 vRNA Immunotherapy 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, 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.

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

	Three Months Ended March 31,	
	2021	2020
Operating expenses:		
Research and development	$ 8,447	$ 5,892
General and administrative	4,222	2,052
Total operating expenses	12,669	7,944
Loss from operations	(12,669)	(7,944)
Other income (expense):		
Other expense	—	(11)
Interest income	6	128
Total other income (expense), net	6	117
Net loss and comprehensive loss	$(12,663)	$ (7,827)
Accretion of discount and dividends on redeemable convertible preferred stock	—	(2,725)
Net loss attributable to common stockholders	$(12,663)	$(10,552)
Net loss per share—basic and diluted	$ (0.53)	$ (10.59)
Weighted-average number of common shares—basic and diluted	24,009	996

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

	March 31, 2021	December 31, 2020
Cash and cash equivalents	$172,622	$ 130,305
Working capital (1)	168,763	127,407
Right-of-use asset	40,847	41,372
Total assets	225,107	182,263
Long term lease liability	42,083	41,615
Total liabilities	48,852	47,599
Total stockholders' equity	$176,255	$ 134,664

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