

---

---

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549**

---

**FORM 10-Q**

---

(Mark One)

**QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2020

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-39575

---

**ONCORUS, INC.**

(Exact Name of Registrant as Specified in its Charter)

---

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

47-3779757  
(I.R.S. 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

---

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 (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

As of November 6, 2020, the registrant had 22,615,994 shares of common stock, \$0.0001 par value per share, outstanding.

---

---

**Table of Contents**

	<b>Page</b>
<a href="#">SPECIAL NOTE REGARDING FORWARD LOOKING STATEMENTS</a>	1
<a href="#">SUMMARY RISK FACTORS</a>	2
<b>PART I. FINANCIAL INFORMATION</b>	4
Item 1. <a href="#">Financial Statements (Unaudited)</a>	4
<a href="#">Condensed Consolidated Balance Sheets</a>	4
<a href="#">Condensed Consolidated Statements of Operations and Comprehensive Loss</a>	5
<a href="#">Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Deficit</a>	6
<a href="#">Condensed Consolidated Statements of Cash Flows</a>	7
<a href="#">Notes to Unaudited Interim Condensed Consolidated Financial Statements</a>	8
Item 2. <a href="#">Management's Discussion and Analysis of Financial Condition and Results of Operations</a>	20
Item 3. <a href="#">Quantitative and Qualitative Disclosures About Market Risk</a>	30
Item 4. <a href="#">Controls and Procedures</a>	30
<b>PART II. OTHER INFORMATION</b>	31
Item 1. <a href="#">Legal Proceedings</a>	31
Item 1A. <a href="#">Risk Factors</a>	31
Item 2. <a href="#">Unregistered Sales of Equity Securities and Use of Proceeds</a>	72
Item 3. <a href="#">Defaults Upon Senior Securities</a>	72
Item 4. <a href="#">Mine Safety Disclosures</a>	72
Item 5. <a href="#">Other Information</a>	72
Item 6. <a href="#">Exhibits</a>	73
<a href="#">Signatures</a>	74

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q, including statements regarding our future results of operations or financial condition, business strategy and plans, and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements because they contain words such as “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “hope,” “intend,” “may,” “might,” “objective,” “ongoing,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” or “would” or the negative of these words or other similar terms or expressions. These forward-looking statements include, but are not limited to, statements concerning the following:

- the impact of the COVID-19 pandemic on our business and operations, results of operations and financial performance, including impacts on initiation, patient enrollment, development and operation of our preclinical studies and clinical trials;
- the initiation, timing, progress and expected results of our preclinical studies, clinical trials and our research and development programs, including our ongoing Phase 1 clinical trial and the timing of initiation for future clinical trials for our lead product candidate, ONCR-177;
- our success in identifying and developing future potential candidates from our oncolytic HSV-1 platform, or oHSV Platform, and our synthetic platform, or Synthetic Platform;
- our ability to advance product candidates into, and successfully complete, clinical trials;
- the timing or likelihood of our ability to receive the required regulatory approvals and clearances to successfully market and sell our products in the United States and certain other countries;
- the commercialization of our product candidates, if approved;
- our expectations regarding the potential market size and the rate and degree of market acceptance for any product candidates that we develop;
- the potential benefits of strategic collaboration agreements and our ability to enter into strategic arrangements;
- the effects of competition with respect to ONCR-177 or any of our other current or future product candidates, as well as innovations by current and future competitors in our industry;
- our ability to fund our working capital requirements;
- our intellectual property position, including the scope of protection we are able to establish, maintain and enforce for intellectual property rights covering our product candidates;
- our financial performance and our ability to effectively manage our anticipated growth;
- our ability to obtain additional funding for our operations; and
- other risks and uncertainties, including those listed under Part II, Item 1A. Risk Factors.

These forward-looking statements are based on our management’s current expectations, estimates, forecasts and projections about our business and the industry in which we operate, and management’s beliefs and assumptions and are not guarantees of future performance or development. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described under “Risk Factors” and elsewhere in this Quarterly Report. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this report may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based on information available to us as of the date of this report. While we believe that information provides a reasonable basis for these statements, that information may be limited or incomplete. Our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all relevant information.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance, or events and circumstances reflected in the forward-looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Quarterly Report on Form 10-Q to conform these statements to new information, actual results or changes in our expectations, except as required by law.

## SUMMARY RISK FACTORS

You should consider carefully the risks described under “Risk Factors” in Part II, Item 1A of this Quarterly Report on Form 10-Q. A summary of risks that could materially and adversely affect our business, financial condition, operating results and prospects include the following:

- We have a limited operating history. We have incurred significant losses since our inception and anticipate that we will incur significant and increasing losses for the foreseeable future and we may never achieve or maintain profitability.
- We will require substantial additional financing to advance the development of our product candidates, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital could force us to delay, limit, reduce or terminate our product development programs, potential commercialization efforts or other operations.
- We have never generated any revenue from product sales and may never become profitable.
- Our product candidates are in early stages of development, are not approved for commercial sale and might never receive regulatory approval or become commercially viable.
- We currently have only one product candidate, ONCR-177, in clinical development. A failure of this product candidate in clinical development would adversely affect our business and may require us to discontinue development of other product candidates based on the same therapeutic approach.
- Public health crises such as pandemics, including the coronavirus disease, or COVID-19, or similar outbreaks could materially and adversely affect our preclinical studies and clinical trials, business, financial condition and results of operations.
- Preclinical and clinical development involve a lengthy and expensive process with an uncertain outcome, and delays can occur for a variety of reasons outside of our control.
- If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.
- Serious adverse events, undesirable side effects or other unexpected properties of our current or future product candidates may be identified during development or after approval, which could halt their development or lead to the discontinuation of our clinical development programs, refusal by regulatory authorities to approve our product candidates or, if discovered following marketing approval, revocation of marketing authorizations or limitations on the use of our product candidates thereby limiting the commercial potential of such product candidate.
- We anticipate that many of our product candidates will be used in combination with third-party drugs, some of which may still be in development, and we have limited or no control over the supply, regulatory status or regulatory approval of such drugs.
- We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.
- We rely, and expect to continue to rely, on third parties to conduct, supervise, and monitor our preclinical studies and clinical trials. If those third parties do not perform satisfactorily, including failing to meet deadlines for the completion of such trials or failing to comply with regulatory requirements, we may be unable to obtain regulatory approval for our product candidates or any other product candidates that we may develop in the future.
- If the manufacturers upon which we rely fail to produce any product candidates in the volumes that we require on a timely basis, or fail to comply with stringent regulations applicable to biopharmaceutical manufacturers, we may face delays in the development and commercialization of, or be unable to meet demand for, any product candidates, which may have an adverse effect on our business.
- If we are unable to successfully commercialize any product candidate for which we receive regulatory approval, or experience significant delays in doing so, our business will be materially harmed.
- We face significant competition from other biopharmaceutical and biotechnology companies, academic institutions, government agencies, and other research organizations, which may result in others discovering, developing or commercializing products more quickly or marketing them more successfully than us. If their product candidates are shown to be safer or more effective than ours, our commercial opportunity may be reduced or eliminated.
- Even if any of our product candidates receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, hospitals, cancer treatment centers, third-party payors and others in the medical community necessary for commercial success. The revenues that we generate from their sales may be limited, and we may never become profitable.
- Negative developments in the field of immuno-oncology could damage public perception of our oHSV and Synthetic Platforms and our product candidates, including ONCR-177, and negatively affect our business.

---

## [Table of Contents](#)

- If we are unable to obtain, maintain and protect our intellectual property rights for our technology and product candidates, or if our intellectual property rights are inadequate, our competitive position could be harmed.
- We are highly dependent on our key personnel, including our Chief Executive Officer, Chief Scientific Officer and Senior Vice President, Clinical Development. If we are not successful in attracting, motivating and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

## PART I—FINANCIAL INFORMATION

## Item 1. Financial Statements.

## ONCORUS, INC.

**Condensed Consolidated Balance Sheets**  
(in thousands, except for par value data)  
(unaudited)

	SEPTEMBER 30, 2020	DECEMBER 31, 2019
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 54,019	\$ 45,286
Prepaid expenses and other current assets	1,577	615
Total current assets	55,596	45,901
Property and equipment, net	4,506	4,475
Deferred offering costs	1,507	—
Other assets	450	450
Total assets	<u>\$ 62,059</u>	<u>\$ 50,826</u>
<b>Liabilities, redeemable convertible preferred stock and stockholders' deficit</b>		
Current liabilities:		
Accounts payable	\$ 1,470	\$ 942
Accrued expenses	3,155	3,521
Deferred rent	500	467
Other current liabilities	8	8
Total current liabilities	5,133	4,938
Series B tranche rights (Note 5)	—	1,876
Deferred rent, net of current portion	1,295	1,677
Total liabilities	6,428	8,491
Commitments and contingencies (Note 9)		
<b>Redeemable convertible preferred stock:</b>		
Series A-1 redeemable convertible preferred stock, \$0.0001 par value, 76,500 shares authorized; 76,500 shares issued and outstanding as of September 30, 2020 and December 31, 2019; liquidation preference of \$68,436 at September 30, 2020	68,220	63,494
Series B redeemable convertible preferred stock, \$0.0001 par value, 104,225 shares authorized; 104,225 and 62,535 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively; liquidation preference of \$94,492 at September 30, 2020	105,668	53,138
<b>Stockholders' deficit:</b>		
Common stock, \$0.0001 par value, 227,000 shares authorized; 1,072 and 989 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	—	—
Additional paid-in capital	—	—
Accumulated deficit	(118,257)	(74,297)
Total stockholders' deficit	(118,257)	(74,297)
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	<u>\$ 62,059</u>	<u>\$ 50,826</u>

The accompanying notes are an integral part of these interim condensed consolidated financial statements.

## ONCORUS, INC.

## Condensed Consolidated Statements of Operations and Comprehensive Loss

(in thousands, except per share data)

(unaudited)

	THREE MONTHS ENDED		NINE MONTHS ENDED	
	SEPTEMBER 30,		SEPTEMBER 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	\$ 6,927	\$ 6,221	\$ 19,560	\$ 18,183
General and administrative	1,973	1,513	6,032	3,978
Total operating expenses	8,900	7,734	25,592	22,161
Loss from operations	(8,900)	(7,734)	(25,592)	(22,161)
Other income (expense):				
Change in fair value of Series B tranche rights	(10,631)	—	(11,256)	—
Other expense	(2)	(3)	(22)	(7)
Interest income	2	164	138	331
Total other income (expense), net	(10,631)	161	(11,140)	324
Net loss and comprehensive loss	\$ (19,531)	\$ (7,573)	\$ (36,732)	\$ (21,837)
Accretion of discount and dividends on redeemable convertible preferred stock	(2,848)	(1,578)	(8,298)	(1,609)
Net loss attributable to common stockholders	\$ (22,379)	\$ (9,151)	\$ (45,030)	\$ (23,446)
Net loss per share attributable to common stockholders—basic and diluted	\$ (21.73)	\$ (9.67)	\$ (44.58)	\$ (25.48)
Weighted-average number of common shares outstanding—basic and diluted	1,030	946	1,010	920

The accompanying notes are an integral part of these interim condensed consolidated financial statements.

**ONCORUS, INC.**
**Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Deficit**  
(in thousands, except share amounts)  
(unaudited)

	SERIES A-1 REDEEMABLE CONVERTIBLE PREFERRED STOCK		SERIES B REDEEMABLE CONVERTIBLE PREFERRED STOCK		COMMON STOCK		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED DEFICIT	TOTAL STOCKHOLDERS' DEFICIT
	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT			
<b>Balance at December 31, 2018</b>	76,499,992	\$ 60,893	—	\$ —	881,376	\$ —	\$ 906	\$ (40,983)	\$ (40,077)
Series A-1 preferred stock accretion	—	31	—	—	—	—	(31)	—	(31)
Stock-based compensation expense	—	—	—	—	—	—	210	—	210
Vesting of restricted common stock	—	—	—	—	38,862	—	—	—	—
Exercise of options to purchase common stock	—	—	—	—	17,443	—	28	—	28
Net loss	—	—	—	—	—	—	—	(14,264)	(14,264)
<b>Balance at June 30, 2019</b>	76,499,992	60,924	—	—	937,681	—	1,113	(55,247)	(54,134)
Issuance of Series B preferred stock	—	—	55,486,215	45,638	—	—	—	—	—
Series A-1 and Series B preferred stock dividends and accretion	—	976	—	602	—	—	(1,347)	(231)	(1,578)
Stock-based compensation expense	—	—	—	—	—	—	201	—	201
Vesting of restricted common stock	—	—	—	—	16,225	—	—	—	—
Exercise of options to purchase common stock	—	—	—	—	16,734	—	33	—	33
Net loss	—	—	—	—	—	—	—	(7,573)	(7,573)
<b>Balance at September 30, 2019</b>	76,499,992	\$ 61,900	55,486,215	\$ 46,240	970,640	\$ —	\$ —	\$ (63,051)	\$ (63,051)
<b>Balance at December 31, 2019</b>	76,499,992	\$ 63,494	62,535,183	\$ 53,138	988,700	\$ —	\$ —	\$ (74,297)	\$ (74,297)
Series A-1 and Series B preferred stock dividends and accretion	—	3,140	—	2,310	—	—	(624)	(4,826)	(5,450)
Stock-based compensation expense	—	—	—	—	—	—	619	—	619
Vesting of restricted common stock	—	—	—	—	14,026	—	—	—	—
Exercise of options to purchase common stock	—	—	—	—	1,562	—	5	—	5
Net loss	—	—	—	—	—	—	—	(17,201)	(17,201)
<b>Balance at June 30, 2020</b>	76,499,992	66,634	62,535,183	55,448	1,004,288	—	—	(96,324)	(96,324)
Issuance of Series B preferred stock	—	—	41,690,117	35,826	—	—	—	—	—
Series A-1 and Series B preferred stock dividends and accretion	—	1,586	—	1,262	—	—	(446)	(2,402)	(2,848)
Settlement of Series B tranche rights	—	—	—	13,132	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	340	—	340
Vesting of restricted common stock	—	—	—	—	5,171	—	—	—	—
Exercise of options to purchase common stock	—	—	—	—	62,500	—	106	—	106
Net loss	—	—	—	—	—	—	—	(19,531)	(19,531)
<b>Balance at September 30, 2020</b>	76,499,992	\$ 68,220	104,225,300	\$ 105,668	1,071,959	\$ —	\$ —	\$ (118,257)	\$ (118,257)

The accompanying notes are an integral part of these interim condensed consolidated financial statements.



## ONCORUS, INC.

## Condensed Consolidated Statements of Cash Flows

(in thousands)

(unaudited)

	NINE MONTHS ENDED SEPTEMBER 30,	
	2020	2019
<b>Operating activities:</b>		
Net loss	\$ (36,732)	\$ (21,837)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	983	786
Stock-based compensation	959	411
Change in fair value of Series B tranche rights	11,256	—
Changes in:		
Prepaid expenses and other current assets	(962)	(253)
Accounts payable	103	(91)
Accrued expenses and other current liabilities	(885)	2,506
Deferred rent	(349)	(317)
Net cash used in operating activities	(25,627)	(18,795)
<b>Investing Activities</b>		
Purchase of property and equipment	(1,014)	(598)
Net cash used in investing activities	(1,014)	(598)
<b>Financing activities</b>		
Proceeds from issuance of Series B preferred stock and tranche liability	35,826	47,303
Payment of deferred offering costs	(563)	—
Proceeds from exercise of options to purchase common stock	111	61
Net cash provided by financing activities	35,374	47,364
Increase in cash and cash equivalents	8,733	27,971
Cash and cash equivalents at beginning of period	45,286	20,079
Cash and cash equivalents at end of period	<u>\$ 54,019</u>	<u>\$ 48,050</u>
<b>Non-cash investing and financing activities</b>		
Purchase of property and equipment in accrued expenses	<u>\$ —</u>	<u>\$ 114</u>
Accretion of discount and dividends on preferred stock	<u>\$ 8,298</u>	<u>\$ 1,609</u>
Deferred offering costs in accounts payable and accrued expenses	<u>\$ 944</u>	<u>\$ —</u>
Settlement of Series B tranche rights	<u>\$ 13,132</u>	<u>\$ —</u>

The accompanying notes are an integral part of these interim condensed consolidated financial statements.

**ONCORUS INC.****Notes to Unaudited Interim Condensed Consolidated Financial Statements****1. Nature of the Business and Basis of Presentation****Organization**

Oncorus, Inc. (the “Company”) is a biopharmaceutical company focused on developing next-generation viral immunotherapies to transform outcomes for cancer patients. Using its two platforms, the Company is developing a pipeline of intratumorally and intravenously administered product candidates designed to selectively attack and kill tumor cells.

The Company’s operations to date have focused on organization and staffing, business planning, raising capital, acquiring and developing the Company’s technology, establishing the Company’s intellectual property portfolio, identifying potential product candidates and undertaking preclinical studies, clinical trials and manufacturing. The Company does not have any product candidates approved for sale and has not generated any revenue from product sales. The Company’s product candidates are subject to long development cycles and the Company may be unsuccessful in its efforts to develop, obtain regulatory approval for or market its product candidates.

On October 6, 2020, the Company completed an initial public offering (“IPO”), in which the Company issued and sold 5,800,000 shares of its common stock at a public offering price of \$15.00 per share. On October 14, 2020, the Company sold an additional 757,991 shares of common stock at \$15.00 per share pursuant to the underwriters’ partial exercise of their option to purchase additional shares of common stock. The total gross proceeds from the IPO were \$98.4 million and the Company raised approximately \$88.2 million in net proceeds after deducting underwriting discounts and commissions and offering expenses payable by the Company.

Upon the closing of the IPO, all of the outstanding shares of convertible preferred stock automatically converted into 14,951,519 shares of common stock at the applicable conversion ratio then in effect. Subsequent to the closing of the IPO, there were no shares of preferred stock outstanding. In connection with the closing of the IPO, the Company filed its amended and restated certificate of incorporation pursuant to which it is authorized to issue up to 100,000,000 shares designated as common stock and 10,000,000 shares designated as preferred stock, all with a par value of \$0.0001 per share. The condensed consolidated financial statements as of September 30, 2020, including share and per share amounts, do not give effect to the IPO, as it closed subsequent to September 30, 2020.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, possible failure of preclinical studies or clinical trials, the need to obtain marketing approval for its product candidates, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, the need to successfully commercialize and gain market acceptance of any of the Company’s products that are approved and the ability to secure additional capital to fund operations. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing, and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure, and extensive compliance-reporting capabilities. Even if the Company’s drug development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

**Basis of Presentation and Liquidity**

The accompanying unaudited interim condensed consolidated financial statements have been prepared in conformity with U.S. generally accepted accounting principles (“GAAP”). Any reference in these notes to applicable guidance is meant to refer to authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification (“ASC”) and as amended by Accounting Standards Updates (“ASU”) of the Financial Accounting Standards Board (“FASB”).

In the opinion of management, the accompanying unaudited interim condensed consolidated financial statements include all normal and recurring adjustments (which consist primarily of accruals and estimates that impact the financial statements) which are considered necessary to present fairly the Company’s financial position as of September 30, 2020, its results of operations for the three and nine months ended September 30, 2020 and 2019, its changes in redeemable preferred convertible preferred stock and stockholders’ deficit for the three and nine months September 30, 2020 and 2019 and its cash flows for the nine months ended September 30, 2020 and 2019.

The accompanying unaudited interim condensed consolidated financial statements should be read in conjunction with the Company’s audited consolidated financial statements and the accompanying notes for the year ended December 31, 2019 included in the Company’s final prospectus that forms part of the Company’s Registration Statement on Form S-1 (File No. 333-248757), filed with the Securities and Exchange Commission (the “SEC”) pursuant to Rule 424(b)(4) and dated October 1, 2020 (the “Prospectus”). The condensed consolidated balance sheet data as of December 31, 2019 presented for comparative purposes was derived from the Company’s audited consolidated financial statements but does not include all disclosures required by U.S. GAAP. The results for the three and nine months ended September 30, 2020 are not necessarily indicative of the operating results to be expected for the full year or for any other subsequent interim period.

The Company’s significant accounting policies are disclosed in the audited consolidated financial statements for the year ended December 31, 2019 included in the Prospectus. Since the date of the audited consolidated financial statements for the year ended December 31, 2019 included in the Prospectus, there have been no changes to its significant accounting policies.

On September 23, 2020 and September 25, 2020, the Company’s board of directors and stockholders, respectively, approved a one-for-12.0874 reverse split of the Company’s issued and outstanding common stock and a proportional adjustment to the existing conversion ratios for the outstanding shares of convertible preferred stock, which became effective on September 25, 2020. Accordingly, all share and per share amounts for all periods presented in the accompanying unaudited interim condensed consolidated financial statements and notes thereto have been retroactively adjusted, where applicable, to reflect the reverse stock split, including reclassification of par, additional paid-in capital and accumulated deficit amounts as a result of the split adjustment.

## [Table of Contents](#)

The Company's unaudited interim condensed consolidated financial statements as of September 30, 2020 have been prepared on the basis of the Company continuing as a going concern for the next 12 months. Management believes that the Company's existing cash and cash equivalents, together with the net proceeds from the IPO, will allow the Company to continue its operations for at least the next 12 months. In the absence of a significant source of recurring revenue, the continued viability of the Company is dependent on its ability to continue to raise additional capital to finance its operations. If the Company is unable to obtain additional funding, the Company may be forced to delay, reduce or eliminate some or all of its research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect its business prospects, or the Company may be unable to continue operations.

## **2. Summary of Significant Accounting Policies**

### ***COVID-19 Pandemic***

With the ongoing COVID-19 global pandemic, the Company has implemented business continuity plans designed to address and mitigate the impact of the COVID-19 pandemic on its employees and its business, including its preclinical studies and its ongoing clinical trial. The Company has taken measures to secure its research and development activities, while work in its laboratories and facilities has been re-organized to reduce risks of COVID-19 transmission. Given the global impact and the other risks and uncertainties associated with the pandemic, the Company's business, financial condition and results of operations could be materially adversely affected. The Company continues to closely monitor the COVID-19 pandemic and evolve its business continuity plans, clinical development plans and response strategy to mitigate any potential impact. As of the date of issuance of these financial statements, the Company is not aware of any specific event or circumstance that would require the Company to update its estimates, assumptions and judgments or revise the carrying value of its assets or liabilities. Actual results could differ from those estimates, and any such differences may be material to the Company's financial statements.

### ***Principles of Consolidation***

The accompanying unaudited interim condensed consolidated financial statements of the Company include the accounts of its wholly owned subsidiary, Oncorus Securities Corporation. All intercompany transactions have been eliminated in consolidation. The Company has one operating segment.

### ***Use of Estimates***

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. On an ongoing basis, the Company's management evaluates its estimates, which include, but are not limited to, the estimated fair value of the Company's common stock and share-based awards utilized for stock-based compensation purposes, the Company's Series B tranche rights (see Note 5), accrued expenses, and amounts of expenses during the reported period. The Company bases its estimates on historical experience and other market-specific or other relevant assumptions that it believes to be reasonable under the circumstances. Actual results may differ from those estimates or assumptions.

### ***Classification and Measurement of Series A-1 and Series B Redeemable Convertible Preferred Stock***

Upon the closing of the IPO on October 6, 2020, all shares of preferred stock converted into common stock. Prior to the IPO, the Company classified its Series A-1 Redeemable Convertible Preferred Stock ("Series A-1") and Series B Redeemable Convertible Preferred Stock ("Series B") outside of permanent equity because the shares of Series A-1 and Series B contained certain redemption features that resulted in the Series A-1 and Series B being redeemable (i) at the option of the holder or (ii) upon the occurrence of events that were not solely within the control of the Company. As a result of these redemption provisions, the Series A-1 and Series B were recorded outside of permanent equity and were subject to subsequent measurement under the guidance provided under ASC 480-10-S99. While the Series A-1 and Series B were not currently redeemable, the Series A-1 and Series B were probable of becoming redeemable, and the Company elected to recognize changes in the redemption amount over the period from the date of issuance to the earliest possible redemption date. Changes in the redemption amount were recognized as a deemed dividend and presented as a reduction to income attributable to common stockholders.

## [Table of Contents](#)

### ***Deferred Offering Costs***

The Company capitalizes certain legal, professional, accounting and other third-party fees that are directly associated with in-process equity issuances as deferred offering costs until such equity issuances are consummated. After consummation of the equity issuance, these costs are recorded as a reduction in the capitalized amount associated with the equity issuance. The Company recorded deferred offering costs related to the IPO of approximately \$1.5 million as of September 30, 2020. Upon the closing the IPO in October 2020, the deferred offering costs were recorded against the IPO proceeds as a reduction of additional paid-in capital.

### ***Concentration of Credit Risk and of Significant Suppliers***

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents. The Company has all of its cash at one financial institution, that management believes to be of high credit quality, in amounts that exceed federally insured limits. Cash equivalents consist of money market funds that invest primarily in U.S. government-backed securities and treasuries.

The Company is dependent upon a third-party contract manufacturer and third-party contract research organizations for the performance of portions of its testing for pre-clinical and clinical studies. The Company believes that its relationships with these organizations are satisfactory, and that alternative suppliers of these services are available in the event of the loss of one or more of these suppliers.

### ***Fair Value Measurements***

Certain assets and liabilities of the Company are carried at fair value under GAAP. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

**Level 1**—Valuations based on quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.

**Level 2**—Valuations based on quoted prices for similar assets or liabilities in markets that are not active or for which all significant inputs are observable, either directly or indirectly, such as quoted market prices, interest rates, and yield curves.

**Level 3**—Valuations that require inputs that reflect the Company's own assumptions that are both significant to the fair value measurement and unobservable.

To the extent a valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair values requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized as Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The Company's cash equivalents, classified within Level 1, are valued using net asset value per share for the money market funds.

The tranche rights granted to the Series B stockholders (the "Series B Tranche Rights") were classified within Level 3 of the fair value hierarchy because they were valued using significant inputs not observable in the market. The valuation of the tranche rights used assumptions the Company believed would be made by a market participant. The Company assessed these estimates on an ongoing basis as additional data impacting the assumptions was obtained. Refer to Note 5 for additional information regarding the valuation of the tranche rights.

The Company believes that the carrying amounts of prepaid expenses, other current assets, accounts payable, and accrued expenses approximate their fair value due to the short-term nature of those instruments.

### ***Research Contract Costs and Accruals***

The Company has entered into various research service arrangements under which vendors perform various services. The Company records accrued expenses for estimated costs incurred under the arrangements. When evaluating the adequacy of the accrued expenses, the Company analyzes the progress of the studies, trials or other services performed, including invoices received and contracted costs. Judgments and estimates are made in determining the accrued expense balances at the end of each reporting period.

### ***Net Loss Per Share***

Net loss per share attributable to common stockholders is calculated using the two-class method, which is an earnings allocation formula that determines net loss per share for the holders of the Company's shares of common stock and participating securities. Prior to conversion in connection with the IPO, the Company's Series A-1 and Series B contained participating rights in any dividend paid by the Company and were therefore participating securities. Net loss attributable to common stockholders and participating securities is allocated to each share on an as-converted basis as if all of the earnings for the period had been distributed. However, the participating securities do not include a contractual obligation to share in the losses of the Company and are not included in the calculation of net loss per share in the periods that have a net loss. In addition, common stock equivalent shares (whether or not participating) are excluded from the computation of diluted earnings per share in periods in which they have an anti-dilutive effect on net loss per share.

## [Table of Contents](#)

Diluted net loss per share is computed using the more dilutive of (a) the two-class method or (b) the if-converted method and treasury stock method, as applicable. In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders since dilutive shares of common stock are not assumed to have been issued if their effect is anti-dilutive. Diluted net loss per share is equivalent to basic net loss per share for the periods presented herein because common stock equivalent shares from the Series A-1, Series B, restricted stock, stock option awards and outstanding warrants to purchase common stock (see Note 10) were anti-dilutive.

### **Recently Issued Accounting Pronouncements**

In February 2016, the FASB issued ASU No. 2016-02, *Leases* (“ASU 2016-02”). ASU 2016-02 will require lessees to recognize most leases on their balance sheet as a right-of-use asset and a lease liability. Leases will be classified as either operating or finance leases, and classification will be based on criteria similar to current lease accounting, but without explicit bright lines. For emerging growth companies (“EGCs”) such as the Company, ASU 2016-02, as amended, will be effective for annual reporting periods beginning after December 15, 2021 and interim periods for fiscal years beginning after December 15, 2022, with early adoption permitted. The Company is currently evaluating the full impact that the adoption of ASU 2016-02 is expected to have on its financial statements; however the adoption of ASU 2016-02 will require the recognition at the adoption date of both a lease liability, based on the present value of future lease payments, and a corresponding right-to-use asset, which amounts the Company expects to be material.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820)—Disclosure Framework* (“ASU 2018-13”), which improves the disclosure requirements for fair value measurements. For EGCs, ASU 2018-13 was effective for the Company for annual reporting periods beginning after December 15, 2019, including interim periods within those fiscal years. The Company adopted ASU 2018-13 effective as of January 1, 2020 and that adoption did not have a material impact on the consolidated financial statements.

### **3. Fair Value Measurements**

The following table presents information about the Company’s financial assets and liabilities measured at fair value on a recurring basis (in thousands):

	FAIR VALUE MEASUREMENTS AS OF SEPTEMBER 30, 2020			
	LEVEL 1	LEVEL 2	LEVEL 3	TOTAL
Assets:				
Money market funds	\$51,555	\$ —	\$ —	\$51,555
	<u>\$51,555</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$51,555</u>
	FAIR VALUE MEASUREMENTS AS OF DECEMBER 31, 2019			
	LEVEL 1	LEVEL 2	LEVEL 3	TOTAL
Assets:				
Money market funds	\$38,430	\$ —	\$ —	\$38,430
	<u>\$38,430</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$38,430</u>
Liabilities:				
Series B tranche rights	\$ —	\$ —	\$ 1,876	\$ 1,876
	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 1,876</u>	<u>\$ 1,876</u>

## [Table of Contents](#)

### 4. Accrued Expenses

At September 30, 2020 and December 31, 2019, accrued expenses consisted of the following (in thousands):

	SEPTEMBER 30, 2020	DECEMBER 31, 2019
Accrued research and development costs	\$ 890	\$ 1,614
Accrued compensation	901	961
Accrued professional fees	1,176	564
Miscellaneous accrued expenses	188	382
Total accrued expenses	<u>\$ 3,155</u>	<u>\$ 3,521</u>

### 5. Series B Tranche Rights

Included in the terms of the purchase agreement for the Series B (“Series B Purchase Agreement”) were Series B Tranche Rights granted to the purchasers of the Series B.

The Series B Tranche Rights provided the holders with the right to purchase additional shares of Series B, in a second tranche, upon either the achievement by the Company of certain clinical development milestones for the Company’s primary clinical candidate, as set forth in the Series B Purchase Agreement, or upon the election of certain holders of the Series B prior to August 5, 2021. In the second tranche, the Company had the ability to sell up to 41,690,117 shares of Series B at \$0.8597 per share. The Company reached the clinical development milestones set forth in the Series B Purchase Agreement in September 2020 and the Company sold 41,690,177 shares of Series B at \$0.8597 per share, resulting in total gross proceeds to the Company of \$35.8 million.

At the time of issuance, the Series B Tranche Rights met the definition of a freestanding financial instrument, as the Series B Tranche Rights were both legally detachable and separately exercisable from the Series B. In addition, the Company determined at the time of issuance that the Series B Tranche Rights met the definition of a liability (or in some circumstances, an asset) because the Series B Tranche Rights (i) embodied an obligation to repurchase the Company’s equity shares and (ii) may have required the Company to settle the obligation by transferring assets. As a result, upon issuance, the respective Series B Tranche Rights were initially recorded at fair value and were subsequently re-measured at the end of each reporting period until settlement. Changes in the fair value were recognized as a component of other income (expense) in the consolidated statements of operations and comprehensive loss.

At December 31, 2019 and at the end of each reporting period prior to settlement in September 2020, the estimated fair value of the Series B Tranche Rights was determined using a probability weighted present value model that considered the probability of triggering the Series B Tranche Rights through achievement of the clinical development milestones specified in the Series B Purchase Agreement. The Company converted the future values to their present values using a discount rate it considered to be appropriate for probability adjusted cash flows. The estimates were based, in part, on subjective assumptions. Significant assumptions for the Series B Tranche Rights valuations at December 31, 2019 and in 2020, prior to settlement, included an 85% to 90% range of probability of achieving the clinical development milestones and discount rates ranging from 0.2% to 1.9%.

The Company remeasured the fair value of the tranche rights for a final time at the date of settlement on September 17, 2020. As the clinical development milestones triggering the tranche closing were achieved, the fair value of the tranche rights at settlement was derived based on the implied intrinsic value of the Series B on the day of the second tranche closing event. The fair value of the Series B at settlement was \$1.18 per share and was based on the probability of the conversion of the Series B upon an IPO and the expected value of the shares, on a converted basis, in an IPO. The increase in the probability of the achievement of the milestone, as well as the increase in the fair value of the Series B, resulted in an increase of \$10.6 million in the fair value of the Series B Tranche Rights in the three months ended September 30, 2020 that was recognized as a loss in the accompanying unaudited interim condensed consolidated statement of operations and comprehensive loss at settlement. The balance of the Series B Tranche Rights of \$13.1 million was reclassified at settlement to increase the Series B carrying value on the accompanying unaudited interim condensed consolidated balance sheet.

A rollforward of the Series B Tranche Rights liability for the nine months ended September 30, 2020 is as follows (in thousands):

	SERIES B TRANCHE RIGHTS
Balance at December 31, 2019	\$ 1,876
Change in fair value	11,256
Reclassification of Series B Tranche Rights upon settlement	<u>(13,132)</u>
Balance at September 30, 2020	<u>\$ —</u>

## **6. Redeemable Convertible Preferred Stock**

At September 30, 2020, the Company had 180,725,292 shares of preferred stock, par value \$0.0001 per share, in authorized capital, which consisted of 76,499,992 authorized, issued and outstanding shares of Series A-1 and 104,225,300 authorized, issued and outstanding shares of Series B.

Upon the closing of the IPO on October 6, 2020, all of the outstanding shares of Series A-1 and Series B automatically converted into an aggregate of 14,951,519 shares of common stock at the applicable conversion ratio then in effect. Subsequent to the closing of the IPO, there were no shares of preferred stock outstanding. In connection with the closing of the IPO, the Company changed its authorized capital to include 10,000,000 shares of undesignated preferred stock with a par value of \$0.0001 per share.

### ***Issuance of Series B Redeemable Convertible Preferred Stock***

In August 2019, the Company authorized and agreed to sell 92,477,021 shares of Series B in two tranches. The first tranche closed on dates between August 5, 2019 and August 27, 2019. On those dates, the Company sold a total of 55,486,215 shares of Series B at \$0.8597 per share, for gross proceeds to the Company of \$47.7 million. In November 2019, the Company authorized and agreed to sell 11,748,279 additional shares of its Series B to new investors on the same terms and conditions as the previous sale of Series B. The first tranche of this sale occurred on November 27, 2019, in which the Company sold 7,048,968 shares of Series B for gross proceeds of \$6.1 million. The Company paid \$0.4 million of issuance costs related to these sales.

In September 2020, the Company achieved the second tranche milestones related to the clinical development of its lead product candidate, ONCR-177. Upon achievement of the milestones, the Series B investors became obligated to purchase additional shares of Series B in a second tranche closing and the Company issued an aggregate of 41,690,117 shares of Series B at \$0.8597 per share, for gross proceeds to the Company of \$35.8 million. Upon closing of the second tranche, the Company considered whether there was any potential beneficial conversion feature, concluding that there was not, as the effective conversion price of the Series B was in excess of the fair value of the Company's common stock.

The following is a description of the rights and privileges of the Series B and A-1 prior to their conversion to common stock upon the IPO in October 2020:

### ***Liquidation***

In the event of any voluntary or involuntary liquidation, dissolution, or winding-up of the affairs of the Company or Deemed Liquidation Event (as defined below), each holder of a share of Series B was entitled to receive, prior and in preference to any distribution of any assets or surplus funds of the Company to the holders of Series A-1 and common stock, an amount equal to \$0.8597 per share, plus any accrued but unpaid dividends. After payment of the full liquidation preference to the holders of Series B, each holder of a share of Series A-1 was entitled to receive, in preference to any distribution of any of the assets or surplus funds of the Company to the holders of common stock, an amount equal to an issuance price of \$0.80 per share, plus any accrued but unpaid dividends. If upon such liquidation event, the assets of the Company available for distribution were insufficient to permit payment in full to the holders of the Series B, the proceeds were to be ratably distributed among the holders of Series B. If the assets of the Company available for distribution were sufficient to pay the Series B holders in full, but insufficient to permit payment in full to the holders of Series A-1, the remaining proceeds were to be ratably distributed among the holders of Series A-1. Any remaining proceeds after full payment to the holders of Series B and Series A-1 that were available to the holders of Series B, Series A-1 and common stock were to be shared proportionately on an as-converted basis. As of September 30, 2020, the aggregate liquidation value of the Series B and A-1 shares was \$94.5 million and \$68.4 million, respectively.

Unless otherwise elected by 68% of the Series B holders, including certain identified Series B holders, a merger or consolidation involving the Company in which the stockholders of the Company did not own a majority of the outstanding shares of the surviving company was considered to be a Deemed Liquidation Event. A sale, lease, transfer, exclusive license or other disposition of all or substantially all of the assets of the Company was also considered a Deemed Liquidation Event.

### ***Redemption***

Upon the demand of the holders of at least 68% of the then outstanding shares of Series B, including certain identified Series B holders, but not prior to August 5, 2026, the Company had the obligation to redeem from each holder of Series B and Series A-1 on an equal basis, in three annual installments, the then outstanding shares of Series B and A-1 at an amount equal to the greater of (a) the Series B and A-1 at their original issue prices of \$0.8597 and \$0.80 per share, respectively, plus any declared but unpaid dividends or (b) the then fair market value of the Series B and Series A-1 on the date of receipt of the redemption request. This redemption feature resulted in the Series B and Series A-1 being redeemable at the option of the holder (based on the passage of time). As a result, the Series B and Series A-1 were recorded outside of permanent equity and subject to subsequent measurement under the guidance provided under ASC 480-10-S99. While the Series B and Series A-1 were not currently redeemable, the Series B and Series A-1 were probable of becoming redeemable, and the Company elected to recognize changes in the redemption amount over the period from the date of issuance to the earliest possible redemption date of the Series B and Series A-1. Changes in the redemption amount were recognized as a deemed dividend and presented as a reduction to income attributable to common stockholders.

### ***Conversion***

Each share of Series B and Series A-1 was convertible at the option of the holder at any time and without the payment of any additional consideration into that number of fully paid and non-assessable shares of common stock as was determined by dividing the original issue price of the Series B or Series A-1 by the conversion price in effect at the time of conversion. The initial conversion prices of the Series B and Series A-1 were equal to the original issuance prices of the Series B and Series A-1, respectively.

## [Table of Contents](#)

All outstanding shares of Series B and Series A-1 were automatically convertible into common stock, based upon either: (i) the vote or written consent of holders of at least 68% of the Series B outstanding at that time, including certain identified Series B holders, or (ii) the closing of a firm commitment, underwritten initial public offering, in which the aggregate proceeds to the Company were at least \$50.0 million, and having a valuation of the Company, immediately prior to the IPO, of at least \$200.0 million. On October 6, 2020, all shares of Series B and Series A-1 converted at a rate of 0.0827 shares of common stock for each share of convertible preferred stock.

### ***Pay to Play Requirement***

All Series B holders were subject to a pay-to-play clause according to which non-participating investors in the second tranche described above would be required to convert all their Series B to common stock at a conversion ratio of one share of common stock for every 10 shares of Series B.

All Series A-1 investors were subject to a pay-to-play clause according to which non-participating investors in later tranches of Series A-1 offering would be required to convert all their shares of Series A-1 to common stock at the then applicable conversion ratio. As of September 6, 2018, three investors chose not to participate in the Company's second tranche of its Series A-1 offering and had an aggregate of 168,750 shares of Series A-1 converted into an aggregate of 13,959 shares of the Company's common stock.

### ***Voting Rights***

The holders of Series B were entitled to vote, together with the holders of Series A-1 and common stock, on all matters submitted to stockholders for a vote. Each share of Series B and Series A-1 were entitled to the number of votes equal to the number of shares of common stock into which each share of Series B and Series A-1 were convertible at the time of such vote. At all times during which at least 2,250,000 shares of Series A-1 remained outstanding, the holders of the outstanding shares of Series A-1 had the exclusive right, separately from the Series B and common stock, to elect three directors of the Company. The holders of the Series B had the right, exclusively and as a separate class, to elect one director of the Company.

### ***Dividends***

Series B holders were entitled to receive dividends at an annual rate of \$0.06877 per share, which accrued from day to day, whether or not such dividends were declared by the Board of Directors, and were cumulative. The dividends were payable only when and if declared by the Board of Directors. The Company could not declare, pay or set aside any dividends on any other shares of capital stock unless the Series B holders first received, or simultaneously received, a dividend in an amount at least equal to the amount of the aggregate accumulated dividends that were accrued but not previously paid, or an amount equal to a formula, which was tied to dividends paid on other classes of stock.

Holders of the Series A-1 were entitled to dividends at an annual rate of \$0.064 per share. Prior to the issuance of the Series B, Series A-1 dividends were payable only when, as, and if declared by the Board of Directors, and the Company was under no obligation to pay any dividends. Upon the issuance of Series B, the Series A-1 dividend terms were modified such that the Series A-1 dividends became cumulative and began accruing from the dates of original issuance of the Series A-1. Dividends were first payable to the Series B holders and, thereafter, to the holders of Series A-1 in the same manner as in the case of Series B (i.e., accrued dividends not yet paid or a payment formula tied to dividends paid on other classes of stock). That is, upon declaring a dividend to common stock, the holders of the Series B and Series A-1 had a right to receive (i) any unpaid cumulative dividends or (ii) dividends that functioned on an "as-if" converted basis, with the Series B holders having a dividend preference over the holders of Series A-1 in the order of payout.

No dividends were paid to the holders of Series B or Series A-1 prior to the conversion of the convertible preferred stock into common stock in connection with the IPO.

## **7. Common Stock**

Each share of common stock is entitled to one vote. The holders of shares of common stock are entitled to receive dividends, if and when declared by the Board of Directors. Prior to the IPO, the voting, dividend, and liquidation rights of the holders of common stock were subject to, and qualified by, the rights, powers, and preferences of the holders of Series B and Series A-1 as described above.

Upon the closing of the IPO, Company changed its authorized capital stock to include 100,000,000 shares designated as common stock with a par value of \$0.0001 per share.

### ***Restricted Stock***

The Company issued restricted stock to its founders and certain officers of the Company. In general, the shares of restricted stock vest over a four-year period, with 25% of the shares vesting after one year, followed by monthly vesting over the remaining three years. A summary of non-vested restricted stock during the nine months ended September 30, 2020 is as follows:

## [Table of Contents](#)

	<u>AMOUNT</u>	<u>WEIGHTED-AVERAGE GRANT DATE FAIR VALUE</u>
Balance at December 31, 2019	41,602	\$ 1.57
Repurchases	—	—
Issuances	—	—
Vested	(19,197)	1.57
Balance at September 30, 2020	<u>22,405</u>	<u>\$ 1.57</u>

### **Common Stock Warrants**

The Company issued warrants to purchase common stock (the “Common Stock Warrants”) in connection with its Series A financing in March 2016. The Common Stock Warrants allow for the holders to purchase 71,544 shares of common stock at \$1.21 per share. As of September 30, 2020, all of the Common Stock Warrants were fully exercisable. The Common Stock Warrants expire in 2031.

### **Reserved Shares**

The Company had reserved shares of common stock for the conversion or exercise of the following securities:

	<u>SEPTEMBER 30, 2020</u>
Conversion of Series A-1	6,328,894
Conversion of Series B	8,622,625
Exercise of Common Stock Warrants	71,544
Exercise of options to purchase common stock	2,109,151
Vesting of restricted stock	22,405
Shares available for issuance under the 2016 Plan	19,048
Total	<u>17,173,667</u>

### **8. Equity Incentive Plan**

The Company adopted the 2016 Equity Incentive Plan, as amended, (the “2016 Plan”) on March 31, 2016. The 2016 Plan provided for the granting of stock options, restricted stock awards, restricted stock units, stock appreciation rights and other stock awards to employees, directors and non-employees. The Company reserved 2,736,105 shares of common stock for grants under the 2016 Plan. All option awards were granted with an exercise price equal to or greater than the market price of the Company’s stock at the date of grant. Option awards generally vest over three to four years. Certain option awards provide for accelerated vesting if there is a change in control as defined in the 2016 Plan.

On September 23, 2020, the Company adopted the 2020 Equity Incentive Plan (“the 2020 Plan”), which became effective upon the execution of the underwriting agreement related to the IPO and will serve as the successor to the 2016 Plan. The 2020 Plan authorizes the award of stock options, restricted stock awards (“RSAs”), stock appreciation rights (“SARs”), restricted stock units (“RSUs”), cash awards, performance awards and stock bonus awards. Under the 2020 Plan, 2,800,000 shares of common stock, plus any reserved shares not issued or subject to outstanding grants under the 2016 Plan on the effective date of the 2020 Plan are reserved for issuance pursuant to awards granted under the 2020 Plan. The number of shares reserved for issuance under the 2020 Plan will increase automatically on January 1 of each fiscal year, starting on January 1, 2021 and ending on and including January 1, 2030, by the number of shares equal to 5% of the aggregate number of outstanding shares of common stock as of the immediately preceding December 31, or a lesser number of shares as may be determined by the board of directors (or an authorized committee thereof).

## [Table of Contents](#)

Total stock-based compensation (including both stock option awards and restricted stock awards) was as follows:

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2020	2019	2020	2019
	(in thousands)			
General and administrative	\$ 172	\$ 112	\$ 512	\$ 255
Research and development	168	89	447	156
<b>Total stock-based compensation</b>	<b>\$ 340</b>	<b>\$ 201</b>	<b>\$ 959</b>	<b>\$ 411</b>

Total stock-based compensation by award type was as follows:

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2020	2019	2020	2019
	(in thousands)			
Restricted stock	\$ 8	\$ 27	\$ 24	\$ 89
Stock options	332	174	935	322
<b>Total stock-based compensation</b>	<b>\$ 340</b>	<b>\$ 201</b>	<b>\$ 959</b>	<b>\$ 411</b>

In November 2018, the Company granted an employee an option to purchase 85,943 shares of the Company's common stock having an exercise price per share equal to the fair value of the Company's common stock on the date of the grant. This grant is included in the outstanding options in the summary table below. Vesting of the option is based on certain performance criteria and shall vest as follows: (i) 16.66% of the shares vested upon the first closing of the Company's Series B stock financing, (ii) 33.33% of the shares vest in 24 equal monthly installments beginning with the first month following the initial closing of the Series B stock financing, (iii) 25% of the shares vested upon the IPO and (iv) 25% of the shares vest in 24 equal monthly installments beginning with the first month following the IPO. Upon the closing of the Series B financing in August 2019, the option vested immediately with respect to 14,323 shares, and an additional 28,647 option shares began vesting over the following 24 months. Upon the closing of the IPO in October 2020, the option vested immediately with respect to 21,485 shares and the remainder began vesting at that time.

In September 2020, the Company granted, contingent upon the Company entering into an underwriting agreement related to the IPO, certain employee options to purchase a total of 363,150 shares of the Company's common stock having an exercise price equal to the IPO price. These options were granted on October 1, 2020, are not included in the table below and no stock compensation was recorded for these grants as of September 30, 2020.

A summary of option activity is presented below:

	SHARES	WEIGHTED AVERAGE EXERCISE PRICE	WEIGHTED- AVERAGE REMAINING CONTRACTUAL TERM (YEARS)	AGGREGATE INTRINSIC VALUE (IN THOUSANDS)
Outstanding at December 31, 2019	1,991,066	\$ 3.41		
Granted	182,147	7.47		
Exercised	(64,062)	1.70		
Canceled, expired or forfeited	—	—		
<b>Outstanding at September 30, 2020</b>	<b>2,109,151</b>	<b>\$ 3.81</b>	<b>8.4</b>	<b>\$ 23,604</b>
<b>Vested at September 30, 2020</b>	<b>791,272</b>	<b>\$ 2.70</b>	<b>7.8</b>	<b>\$ 9,736</b>

The weighted average grant date fair value per share of options granted to employees, directors and non-employee consultants during the nine months ended September 30, 2020 and 2019 was \$5.36 and \$3.24, respectively. Total unrecognized compensation expense related to stock options amounted to \$3.8 million at September 30, 2020 and is expected to be incurred over a weighted-average period of 3.0 years.

## [Table of Contents](#)

The total fair value of restricted shares vested during the nine months ended September 30, 2020 and 2019 was \$0.02 million and \$0.09 million, respectively.

At September 30, 2020, there were 19,048 shares of common stock available for grant under the 2016 Plan.

On September 23, 2020, the Company adopted the 2020 Employee Stock Purchase Plan, or the ESPP, which became effective upon the execution of the underwriting agreement related to the IPO. The Company has initially reserved 280,000 shares of common stock for sale under the ESPP. The aggregate number of shares reserved for sale under the ESPP will increase automatically on January 1st of each fiscal year starting on January 1, 2021 and ending on and including January 1, 2030, by the number of shares equal to the lesser of (a) 1% of the total number of shares of common stock outstanding on the last day of the fiscal year prior to the date of such automatic increase and (b) 560,000 shares, provided that prior to the date of any such increase, the board of directors may determine a less number of shares for such increase.

## 9. Commitments and Contingencies

### *Leases*

In May 2016, the Company entered into an operating lease agreement for its corporate headquarters in Cambridge, Massachusetts, with a seven-year term that expires in January 2024. Rental payments related to the lease commenced in January 2017.

In connection with this lease, the Company was entitled to cash incentives from the landlord to be used for the construction of leasehold improvements within the facility. The Company received \$2.7 million of such incentives, which were recorded as deferred rent on the balance sheet and are being amortized to rent expense over the lease term.

The Company recognizes rent expense on a straight-line basis over the lease period and has recorded deferred rent for rent expense incurred but not yet paid. The Company recorded rent expense related to office and lab space under the lease of \$0.4 million for each of the three months ended September 30, 2020 and 2019 and \$1.1 million of rent expense for each of the nine months ended September 30, 2020 and 2019. The amount of variable rent expense for these periods was immaterial.

Future minimum lease payments for the Company's operating leases as of September 30, 2020 were as follows (in thousands):

<u>YEARS ENDING DECEMBER 31,</u>	
2020 (three months remaining)	\$ 370
2021	1,523
2022	1,569
2023	1,616
2024	48
	<u>\$5,126</u>

## [Table of Contents](#)

### ***License and Royalty Agreements***

The Company has entered into license and royalty agreements for intellectual property with certain parties. Such arrangements require ongoing payments, including payments upon the achievement of certain development, regulatory and commercial milestones, receipt of sublicense income, as well as royalties on commercial sales.

Payments under these arrangements are expensed as incurred. In connection with the first patient dosing in the Company's clinical trial in June 2020, the Company became obligated to make certain milestone payments totaling \$0.8 million.

The Company's material license and collaboration agreements are summarized below.

#### ***Ospedale San Raffaele S.r.l. and Fondazione Telethon***

In December 2015, the Company entered into a license agreement with Ospedale San Raffaele S.r.l. and Fondazione Telethon, as amended, for the use of certain patents and technology. The Company made an initial payment of \$0.1 million, which amount was recorded as research and development expense. Under the terms of the license, the Company is required to pay an annual maintenance fee, up to \$3.9 million in milestone payments for the first indication, up to \$5.7 million in milestone payments for each subsequent indication and a low single digit tiered royalty on net sales of any covered products. The agreement terminates upon the expiration of the last remaining royalty obligation for a licensed product.

#### ***University of Pittsburgh***

In March 2016, the Company entered into a license agreement, as amended, with University of Pittsburgh for the use of certain patents and technology. The Company made an initial payment of \$0.1 million, which amount was recorded as research and development expense. Under the terms of the license, the Company is required to pay an annual maintenance fee and up to \$2.6 million in milestone payments through first commercial product sale and a low single digit royalty on net product revenue, subject to annual minimum amounts, through the expiration of the patent claims.

#### ***Northwestern University***

In December 2018, the Company entered into a license agreement with Northwestern University for the use of certain patents and technology. The Company made an initial payment of \$0.1 million, which amount was recorded as research and development expense. Under the terms of the license, the Company is required to pay an annual maintenance fee and up to \$4.1 million in milestone payments through the first commercial product sale and an annual low single digit royalty on net sales, subject to annual minimum amounts, through the later of ten years from the first commercial sale or the expiration of the patent claims.

#### ***WuXi Biologics Ireland Limited***

In July 2019, the Company entered into a license agreement with this entity for the use of certain patents and technology. Under the terms of the license, the Company agreed to an initial license payment of \$0.3 million and is required to pay milestone payments for the first product developed, as well as additional products, in addition to royalties on net product revenue. For the first product developed, the Company is required to pay up to \$8.0 million in certain clinical milestone payments. For the first three products developed, the Company is also required to pay up to \$27.0 million in commercial milestone payments for each product that achieves specified net sales levels along with product approvals in several countries. The Company also agreed to pay tiered royalties on net sales of licensed products ranging in the low-single digits. The obligation to pay royalties under the license agreement expires on a licensed product-by-licensed product and country-by-country basis upon expiry of the last valid claim of the licensed patents that cover such licensed product in such country.

### ***Related Party License and Royalty Agreements***

In connection with the prior sale of Series A redeemable convertible preferred stock, which was later converted to Series A-1, certain investors are entitled to receive, in the aggregate, a royalty from the Company equal to 1% of net sales of Company products discovered or developed prior to an IPO by the Company. The royalty obligation expires upon the later of twelve years from the first commercial sale or the expiration of the patent.

Also in connection with the sale of Series A redeemable convertible preferred stock, the Company entered into a patent assignment agreement with an investor under which that investor would receive \$1.0 million upon regulatory approval of a product in the United States and an annual low single-digit royalty on net product revenue. The Company is not currently developing any product candidates using the patent that was assigned to the Company.

In September 2016, the Company entered into a sublicense agreement with an entity affiliated with a stockholder of the Company for the use of certain patents and technology. Under the terms of the license, the Company is required to pay up to \$7.6 million in milestone payments through first commercial product sale and an annual mid-single digit royalty on net sales through the expiration of the patent claims. This agreement was terminated in May 2020.

### ***Litigation***

The Company is not currently party to any material legal proceedings. At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies. The Company expenses as incurred the costs related to such legal proceedings.

## [Table of Contents](#)

### 10. Net Loss Per Share

The following securities that could potentially dilute basic net loss per share in the future were not included in the computation of diluted net loss per share for the periods presented, because to do so would have been antidilutive:

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2020	2019	2020	2019
Series A-1	6,328,894	6,328,894	6,328,894	6,328,894
Series B	8,622,625	4,590,404	8,622,625	4,590,404
Outstanding stock options	2,109,151	1,936,493	2,109,151	1,936,493
Restricted stock	22,405	57,828	22,405	57,828
Common stock warrants	71,544	71,544	71,544	71,544
Total	<u>17,154,619</u>	<u>12,985,163</u>	<u>17,154,619</u>	<u>12,985,163</u>

### 11. Subsequent Events

The Company has evaluated subsequent events from the balance sheet date through the date on which these financial statements were issued. Subsequent to the issuance of the financial statements, the following events occurred and required disclosure in, or revision to, the financial statements:

On October 6, 2020, the Company completed the IPO, in which the Company issued and sold 5,800,000 shares of its common stock at a public offering price of \$15.00 per share. On October 14, 2020, the Company sold an additional 757,991 shares of common stock at \$15.00 per share pursuant to the underwriters' partial exercise of their option to purchase additional shares of common stock. The total gross proceeds of the IPO were \$98.4 million and the Company raised approximately \$88.2 million in net proceeds after deducting underwriting discounts and commissions and offering expenses payable by the Company. Upon the closing of the IPO, all of the outstanding shares of Series A-1 and Series B convertible preferred stock converted into an aggregate of 14,951,519 shares of common stock at the applicable conversion ratio then in effect and the Company changed its authorized capital stock to 100,000,000 shares designated as common stock, and 10,000,000 shares designated as preferred stock, all with a par value of \$0.0001 per share.

## **Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.**

*You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited interim condensed consolidated financial statements and related notes, appearing elsewhere in this Quarterly Report on Form 10-Q and (ii) the audited consolidated financial statements and related notes and management’s discussion and analysis of financial condition and results of operations for the fiscal year ended December 31, 2019 included in our final prospectus for our initial public offering, or IPO, dated October 1, 2020 and filed with the Securities and Exchange Commission, or SEC, pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, or the Securities Act, which we refer to as the Prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the “Risk Factors” section of this Quarterly Report on Form 10-Q, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. Please also see the section of this report titled “Special Note Regarding Forward-Looking Statements”.*

### **Introduction**

Our Management’s Discussion and Analysis of Financial Condition and Results of Operations, or MD&A, is provided in addition to the accompanying unaudited interim condensed consolidated financial statements and notes to assist readers in understanding our results of operations, financial condition, and cash flows. MD&A is organized as follows:

*Overview* - A discussion of our business and overall analysis of financial and other highlights in order to provide context for the remainder of MD&A.

*Results of Operations* - An analysis of our financial results comparing the three and nine months ended September 30, 2020 to the three and nine months ended September 30, 2019.

*Liquidity and Capital Resources* - An analysis of changes in our unaudited interim condensed consolidated balance sheets and cash flows, and discussion of our financial condition and potential sources of liquidity.

*Critical Accounting Policies and Significant Judgments and Estimates* - A discussion of critical accounting policies and those that require us to make subjective estimates and judgments.

### **Overview**

We are a biopharmaceutical company focused on developing next-generation viral immunotherapies to transform outcomes for cancer patients. Using our two distinct proprietary platforms, we are developing a pipeline of intratumorally and intravenously administered product candidates designed to selectively attack and kill tumor cells and deliver transgenes to stimulate multiple arms of the immune system against tumors. Our lead product candidate, ONCR-177, is an intratumorally administered viral immunotherapy based on our oncolytic HSV-1 platform, referred to as our oHSV Platform, which leverages the Herpes Simplex Virus-1, or HSV-1, a virus which has been clinically proven to effectively treat certain cancers. Utilizing this proprietary platform, we are engineering our product candidates, such as ONCR-177, to carry greater numbers of immunostimulatory transgenes than viral immunotherapies that are either currently approved or in clinical development. These transgenes are designed to drive strong systemic anti-tumor immunity to elicit tumor responses at injected and distant non-injected tumor sites, or abscopal activity. In addition, viruses from our oHSV Platform maintain full viral replication competency in tumors and are designed to be selectively attenuated in normal tissues. We believe this unique combination of features allows us to break the safety versus potency trade-off that has generally limited the viral immunotherapy field to date. In June 2020, we initiated a Phase 1 clinical trial of ONCR-177 in several different tumor types. We are also developing a broad pipeline of product candidates that leverages our second platform, which we refer to as our Synthetic Platform, to enable repeat intravenous administration of viral immunotherapies in order to treat cancers that are less amenable to intratumoral injection due to safety and feasibility reasons, such as cancers of the lung.

From inception through September 30, 2020, we have raised an aggregate of \$150.9 million of gross proceeds through the issuance of redeemable convertible preferred stock. As of September 30, 2020, we had cash and cash equivalents on hand of \$54.0 million.

We completed an initial public offering, or IPO, of our common stock, in October 2020, in which we issued an aggregate of 6,557,991 shares of common stock at a public offering price of \$15.00 per share. The aggregate net proceeds to us from the IPO were approximately \$88.2 million, after deducting underwriting discounts and commissions and \$3.3 million of offering expenses payable by us.

Since inception, we have incurred significant operating losses. Our net losses were \$36.7 million and \$21.8 million for the nine months ended September 30, 2020 and 2019, respectively. As of September 30, 2020, we had an accumulated deficit of \$118.3 million. We expect to continue to incur significant and increasing expenses and operating losses for the foreseeable future, as we advance our current and future product candidates through preclinical and clinical development, manufacture drug product and drug supply, seek regulatory approval for our current and future product candidates, maintain and expand our intellectual property portfolio, hire additional research and development and business personnel and operate as a public company.

## [Table of Contents](#)

Since inception, our operations have focused on organizing and staffing our company, business planning, raising capital, acquiring and developing our technology, establishing our intellectual property portfolio, identifying potential product candidates and undertaking preclinical studies and manufacturing. We do not have any products approved for sale and have not generated any revenue from product sales. We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for our product candidates. In addition, if we obtain regulatory approval for our product candidates and do not enter into a third-party commercialization partnership, we expect to incur significant expenses related to developing our commercialization capability to support product sales, marketing, manufacturing and distribution activities.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity offerings and debt financings or other sources, such as potential collaboration agreements, strategic alliances and licensing arrangements. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on acceptable terms, or at all. Our failure to raise capital or enter into such agreements as, and when needed, could have a material adverse effect on our business, results of operations and financial condition.

### ***Impact of the COVID-19 Pandemic on Our Business***

In March 2020, the World Health Organization declared COVID-19 a global pandemic and the United States declared a national emergency with respect to COVID-19. In response to the COVID-19 pandemic, a number of governmental orders and other public health guidance measures have been implemented across much of the United States, including in the locations of our office, clinical trial sites and third parties on whom we rely. We anticipate that our clinical development timelines could be negatively affected by COVID-19, which could materially and adversely affect our business, financial condition and results of operations. Further, we have implemented a work-from-home policy allowing employees who can work from home to do so, while those needing to work in laboratory facilities work in shifts to reduce the number of people gathered together at one time. Business travel has been suspended, and online and teleconference technology is used to meet virtually rather than in person. We have taken measures to secure our research and development project activities, while work in laboratories has been organized to reduce risk of COVID-19 transmission. Our increased reliance on personnel working from home may negatively impact productivity, or disrupt, delay or otherwise adversely impact our business. For example, with our personnel working from home, some of our research activities that require our personnel to be in our laboratories could be delayed.

### **Recent Developments**

#### ***Series B Tranche Financing***

In 2019, we conducted a Series B redeemable convertible preferred stock, or Series B, financing with the funding to occur in two tranches. We closed the first tranche of the Series B financing in August 2019 and November 2019, raising a total of \$53.8 million of gross proceeds and we closed the second and final tranche of the Series B financing in September 2020 upon the achievement of certain clinical development milestones for our primary product candidate, ONCR-177. The second and final tranche of the Series B financing provided for an additional \$35.8 million of gross proceeds.

#### ***Reverse Stock Split***

On September 25, 2020, we effected a 1-for-12.0874 reverse stock split of our issued and outstanding common stock and a proportional adjustment to the existing conversion ratios for the outstanding shares of Series A-1 redeemable convertible preferred stock, or Series A-1, and Series B. Accordingly, all share and per share amounts for all periods presented in this Quarterly Report on Form 10-Q have been retroactively adjusted to reflect the reverse stock split on a retroactive basis.

#### ***Initial Public Offering***

In October 2020, we completed our IPO, in which we issued an aggregate of 6,557,191 shares of common stock for aggregate net proceeds of approximately \$88.2 million, after deducting underwriting discounts and commissions and offering expenses payable by us of \$3.3 million. Our shares of common stock began trading on the Nasdaq Global Market under the ticker symbol "ONCR" on October 2, 2020. Upon closing of our IPO, all outstanding shares of Series A-1 and Series B converted into an aggregate of 14,951,519 shares of common stock.

### **Components of Operating Results**

#### ***Research and Development Expenses***

Research and development expenses consist primarily of costs incurred for our research and development activities, including our product candidate discovery efforts, preclinical and clinical studies under our research programs, which include:

- employee-related expenses, including salaries, benefits and stock-based compensation expense for our research and development personnel;

## Table of Contents

- costs of funding research performed by third parties that conduct research and development and preclinical and clinical activities on our behalf;
- costs of manufacturing drug product and drug supply related to our current or future product candidates;
- costs of conducting preclinical studies and clinical trials of our product candidates;
- consulting and professional fees related to research and development activities, including equity-based compensation to non-employees;
- costs of maintaining our laboratory, including purchasing laboratory supplies and non-capital equipment used in our preclinical studies;
- costs related to compliance with clinical regulatory requirements;
- facility costs and other allocated expenses, which include expenses for rent and maintenance of facilities, insurance, depreciation and other supplies; and
- fees for maintaining licenses and other amounts due under our third-party licensing agreements.

Research and development costs are expensed as incurred. Costs for certain activities are recognized based on an evaluation of the progress to completion of specific tasks using data such as information provided to us by our vendors and analyzing the progress of our preclinical and clinical studies or other services performed. Significant judgment and estimates are made in determining the accrued expense balances at the end of any reporting period.

We track external research and development costs on a program-by-program basis beginning, with respect to each program, upon our internal nomination of a candidate in that program for further preclinical and clinical development. External costs include fees paid to consultants, contractors and vendors, including contract manufacturing organizations, or CMOs, and clinical research organizations, or CROs, in connection with our preclinical, clinical and manufacturing activities and license milestone payments related to candidate development. We do not allocate employee costs, costs associated with our discovery efforts, costs incurred for laboratory supplies, and facilities, including depreciation, or other indirect costs, to specific product development programs because these costs are deployed across multiple product development programs and, as such, are not separately classified. Our lead product candidate, ONCR-177, was nominated for further development in October 2018.

The successful development of our product candidates is highly uncertain. We cannot reasonably estimate or know the nature, timing, and estimated costs of the efforts that will be necessary to complete development of our current or future product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from the sale of our product candidates, if they are approved. This is due to the numerous risks and uncertainties associated with developing product candidates, including the uncertainty of:

- the scope, rate of progress, and expenses of our ongoing research activities as well as any preclinical studies and clinical trials and other research and development activities;
- establishing an appropriate safety profile;
- successful enrollment in and completion of clinical trials;
- whether our product candidates show safety and efficacy in our clinical trials;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- commercializing product candidates, if and when approved, whether alone or in collaboration with others; and
- continued acceptable safety profile of the products following any regulatory approval.

A change in the outcome of any of these variables with respect to the development of our current and future product candidates would significantly change the costs and timing associated with the development of those product candidates.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect research and development costs to increase significantly for the foreseeable future as we commence clinical trials and continue the development of our current and future product candidates. However, we do not believe that it is possible at this time to accurately project expenses through commercialization. There are numerous factors associated with the successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control will impact our clinical development programs and plans.

### ***General and Administrative Expenses***

General and administrative expenses include salaries and other compensation-related costs, including stock-based compensation, for personnel in executive, finance and accounting, business development, operations and administrative roles. Other significant costs include professional service and consulting fees including legal fees relating to intellectual property and corporate matters, accounting fees, recruiting costs, costs for consultants who we utilize to supplement our personnel, insurance costs, travel costs, facility and office-related costs not included in research and development expenses and depreciation and amortization.

We anticipate that our general and administrative expenses will increase in the future as our business expands to support expected growth in research and development activities, including our future clinical programs. These increases will likely include increased costs related to the hiring of additional personnel and fees to outside service providers, among other expenses. We also anticipate increased expenses associated with being a public company, including costs for audit, legal, regulatory and tax-related services related to compliance with the rules and regulations of the Securities and Exchange Commission, or the SEC, and listing standards applicable to companies listed on a national securities exchange, director and officer insurance premiums, and investor relations costs. In addition, if we obtain regulatory approval for any of our product candidates and do not enter into a third-party commercialization collaboration, we expect to incur significant expenses related to building a sales and marketing team to support product sales, marketing and distribution activities.

### ***Other Income (Expense)***

Other income (expense) primarily includes changes in fair value of the Series A-1 and Series B tranche rights and interest income, net.

Included in the terms of the Series A-1 stock purchase agreement in July 2016 were tranche rights granted to the holders of the Series A-1. The tranche rights provided the holders with the right to purchase additional shares of Series A-1 and Series A-2 redeemable convertible preferred stock, or Series A-2, in two additional tranches under certain events. The tranche rights met the definition of a freestanding financial instrument as the tranche rights were legally detachable and separately exercisable from the Series A-1. The tranche rights were initially recorded at fair value as an asset or a liability on our consolidated balance sheet and were subsequently re-measured at fair value at the end of each reporting period and at settlement. The changes in the fair value were recognized as a component of other income (expense). Changes in the fair value of the tranche rights were recognized until the tranche obligations were settled in full in September 2018.

Included in the terms of the Series B stock purchase agreement in August 2019 were tranche rights granted to the holders of the Series B. The tranche rights provided the Series B holders with the right to purchase additional shares of Series B in an additional tranche under certain events. The tranche rights met the definition of a freestanding financial instrument as the tranche rights were legally detachable and separately exercisable from the Series B. The tranche rights were initially recorded at fair value as a liability on our consolidated balance sheet. The tranche rights were subsequently re-measured at fair value at the end of each reporting period and at settlement, which occurred in September 2020, when the second and final tranche of the Series B financing closed. Changes in the fair value were recognized as a component of other income (expense).

Interest income primarily consists of interest income from our cash and cash equivalents.

[Table of Contents](#)

**Results of Operations**

The following table summarizes our results of operations for the periods indicated.

	THREE MONTHS ENDED SEPTEMBER 30,		CHANGE		NINE MONTHS ENDED SEPTEMBER 30,		CHANGE	
	2020	2019	\$	%	2020	2019	\$	%
	(in thousands, except percentages)							
Operating expenses:								
Research and development	\$ 6,927	\$ 6,221	\$ 706	11%	\$ 19,560	\$ 18,183	\$ 1,377	8%
General and administrative	1,973	1,513	460	30	6,032	3,978	2,054	52
Total operating expenses	8,900	7,734	1,166	15	25,592	22,161	3,431	15
Loss from operations	(8,900)	(7,734)	(1,166)	(15)	(25,592)	(22,161)	(3,431)	(15)
Total other income (expense), net	(10,631)	161	(10,792)	(6,703)	(11,140)	324	(11,464)	(3,538)
Net loss	\$ (19,531)	\$ (7,573)	\$ (11,958)	(158)%	\$ (36,732)	\$ (21,837)	\$ (14,895)	(68)%

**Three Months Ended September 30, 2020 Compared to the Three Months Ended September 30, 2019**

**Research and Development Expenses**

The table below summarizes our research and development expenses by product candidate or development program and unallocated research and development expenses for each of the periods presented:

	THREE MONTHS ENDED SEPTEMBER 30,		CHANGE
	2020	2019	
	(in thousands)		
Direct external expenses by program			
ONCR-177	\$ 2,282	\$ 2,140	\$ 142
Platform development, early stage research and unallocated expenses:			
Employee compensation and related	2,131	1,566	565
External research, development and consulting	874	920	(46)
Laboratory supplies	821	648	173
Facility-related	349	328	21
Other expenses	470	619	(149)
Total research and development	\$ 6,927	\$ 6,221	\$ 706

Research and development expenses increased from \$6.2 million for the three months ended September 30, 2019 to \$6.9 million for the three months ended September 30, 2020. The increase of \$0.7 million, or 11%, was primarily the result of:

- a \$0.1 million increase in direct external expenses for our product candidate ONCR-177, which was attributable to increased clinical trial costs associated with our Phase 1 trial of ONCR-177;
- a \$0.6 million increase in employee compensation costs, including salaries, bonus and employee benefits, due to increased headcount in 2020 as compared to 2019. Employee compensation costs also increased due to higher stock compensation expense from increased stock option grants to existing and new employees at higher share prices in 2020 compared to 2019;
- a \$0.2 million increase in laboratory supply costs associated with our increased headcount and lab-related activities; and
- a \$0.1 million decrease in other expenses due to a license payment made in 2019 that did not recur in 2020, offset by increased depreciation expense for new equipment.

## [Table of Contents](#)

### **General and Administrative Expenses**

	THREE MONTHS ENDED SEPTEMBER 30,		CHANGE
	2020	2019	
	(in thousands)		
Employee compensation and related	\$ 775	\$ 583	\$ 192
Professional service and consultant fees	890	577	313
Facility-related	112	88	24
Other expenses	196	265	(69)
Total general and administrative expenses	<u>\$ 1,973</u>	<u>\$ 1,513</u>	<u>\$ 460</u>

General and administrative expenses increased from \$1.5 million for the three months ended September 30, 2019 to \$2.0 million for the three months ended September 30, 2020. The increase of \$0.5 million, or 30%, was primarily the result of:

- a \$0.2 million increase in employee compensation costs, primarily related to increased headcount associated with our growth as well as higher stock compensation expenses in 2020 compared to 2019, due to an increased number of stock options granted at higher share prices to existing and new employees;
- a \$0.3 million increase in professional service and consultant fees primarily related to increased audit activities and fees, increased corporate legal fees associated with our growth and increased legal intellectual property activity as we incurred fees to broaden our intellectual property portfolio; and
- a \$0.1 million decrease in other expenses primarily related to decreased travel and related expenses due to the COVID-19 pandemic.

### **Other Income (Expense)**

Other income (expense) for the three months ended September 30, 2020 decreased by \$10.8 million compared to the three months ended September 30, 2019 due to a loss of \$10.6 million in 2020 related to an increase in the fair value of the Series B tranche rights liability that was recorded at settlement. The significant increase in the fair value of the Series B tranche liability was due to reaching the second tranche clinical milestones and the increased fair value of the underlying Series B at the date of settlement. A decrease in interest income from 2019 to 2020, primarily due to lower returns on invested cash, also contributed to the overall decrease.

### **Nine Months Ended September 30, 2020 Compared to the Nine Months Ended September 30, 2019**

#### **Research and Development Expenses**

The table below summarizes our research and development expenses by product candidate or development program and unallocated research and development expenses for each of the periods presented:

	NINE MONTHS ENDED SEPTEMBER 30,		CHANGE
	2020	2019	
	(in thousands)		
Direct external expenses by program			
ONCR-177	\$ 6,540	\$ 7,173	\$ (633)
Platform development, early stage research and unallocated expenses:			
Employee compensation and related	6,170	4,361	1,809
External research, development and consulting	2,444	2,008	436
Laboratory supplies	2,170	2,118	52
Facility-related	1,034	995	39
Other expenses	1,202	1,528	(326)
Total research and development	<u>\$ 19,560</u>	<u>\$ 18,183</u>	<u>\$ 1,377</u>

## [Table of Contents](#)

Research and development expenses increased from \$18.2 million for the nine months ended September 30, 2019 to \$19.6 million for the nine months ended September 30, 2020. The increase of \$1.4 million, or 8%, was primarily the result of:

- a \$0.6 million decrease in direct external expenses for our product candidate ONCR-177, which was attributable to a combination of decreased production costs due to the timing of production activity in 2020 compared to 2019, decreased consultant expenses as we increased headcount in 2020 and reduced consultant activity, increased clinical trial costs as we began our Phase 1 clinical trial in 2020 and increased license costs which related to milestone payment obligations associated with the first patient being dosed in our Phase 1 clinical trial of ONCR-177;
- a \$1.8 million increase in employee compensation costs, including salaries, bonus and employee benefits, due to increased headcount in 2020 as compared to 2019. Employee compensation costs also increased due to higher stock compensation expense from increased stock option grants to existing and new employees at higher share prices in 2020 compared to 2019;
- a \$0.4 million increase in external research, development and consulting costs that was primarily attributable to costs related to the increased development activity of potential candidates from our Synthetic Platform; and
- a \$0.3 million decrease in other expenses primarily related to a license payment in 2019 that did not recur in 2020 as well as reduced travel and office related expenses due to the COVID-19 pandemic.

### **General and Administrative Expenses**

	NINE MONTHS ENDED SEPTEMBER 30,		CHANGE
	2020	2019	
	(in thousands)		
Employee compensation and related	\$ 2,453	\$ 1,456	\$ 997
Professional service and consultant fees	2,560	1,523	1,037
Facility-related	357	306	51
Other expenses	662	693	(31)
Total general and administrative expenses	<u>\$ 6,032</u>	<u>\$ 3,978</u>	<u>\$ 2,054</u>

General and administrative expenses increased from \$4.0 million for the nine months ended September 30, 2019 to \$6.0 million for the nine months ended September 30, 2020. The increase of \$2.1 million, or 52%, was primarily the result of:

- a \$1.0 million increase in employee compensation costs, primarily related to increased headcount associated with our growth as well as higher stock compensation expenses in 2020 compared to 2019 due to an increased number of stock options granted at higher share prices to existing and new employees; and
- a \$1.0 million increase in professional service and consultant fees primarily related to increased legal fees associated with corporate matters and increased intellectual property activity as we incurred fees to broaden our intellectual property portfolio.

### **Other Income (Expense)**

Other income (expense) for the nine months ended September 30, 2020 decreased by \$11.5 million compared to the nine months ended September 30, 2019 due to a loss of \$11.3 million in 2020 related to the increase in the fair value of the Series B tranche rights liability and a decrease in interest income from 2019 to 2020 primarily due to lower returns on invested cash.

## **Liquidity and Capital Resources**

### **Sources of Liquidity**

From inception through September 30, 2020, we funded our operations with gross proceeds of \$150.9 million from sales of redeemable convertible preferred stock. As of September 30, 2020, our cash and cash equivalents totaled \$54.0 million. In 2019, we conducted a Series B financing with the funding to occur in two tranches. We closed the first tranche of the Series B financing in August 2019 and November 2019, raising a total of \$53.8 million of gross proceeds. We closed the second and final tranche of the Series B financing in September 2020 upon the achievement of certain clinical development milestones for our primary product candidate, ONCR-177. The second and final tranche of the Series B financing provided an additional \$35.8 million of gross proceeds.

We completed an initial public offering, or IPO, in October 2020, in which we issued an aggregate of 6,557,991 shares of common stock at a public offering price of \$15.00 per share. The aggregate net proceeds received by us from the IPO were approximately \$88.2 million, after deducting underwriting discounts and commissions and \$3.3 million of offering expenses.

## [Table of Contents](#)

### Cash Flows

	NINE MONTHS ENDED SEPTEMBER 30,	
	2020	2019
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	\$ (25,627)	\$ (18,795)
Investing activities	(1,014)	(598)
Financing activities	35,374	47,364
Net increase (decrease) in cash and cash equivalents	<u>\$ 8,733</u>	<u>\$ 27,971</u>

### Operating Activities

#### *Nine Months Ended September 30, 2020 Compared to the Nine Months Ended September 30, 2019*

Net cash used in operating activities for the nine months ended September 30, 2020 was \$25.6 million and was primarily related to our net loss for the period of \$36.7 million, partially offset by non-cash charges consisting of depreciation and amortization of \$1.0 million, stock-based compensation expense of \$1.0 million and a change in fair value of the Series B tranche rights liability of \$11.3 million. Our cash used in operations was increased by a \$2.1 million cash outflow related to changes in certain operating assets and liabilities. The cash outflow included an increase in prepaid expenses and other current assets of \$1.0 million which was related to the timing of payments to vendors in advance of services being performed. The cash outflow also included a decrease in accrued expenses of \$0.9 million related to the timing of invoicing and a decrease in deferred rent of \$0.3 million related to the timing of rent payments in comparison to the rent expense, which is being recorded on a straight-line basis. This cash outflow was partially offset by an increase in accounts payable of \$0.1 million which related to the timing of invoicing and payments.

Net cash used in operating activities for the nine months ended September 30, 2019 was \$18.8 million and was primarily related to our net loss for the period of \$21.8 million, partially offset by non-cash charges consisting of depreciation and amortization of \$0.8 million and stock-based compensation expense of \$0.4 million. Our cash used in operations was decreased by a \$1.8 million cash inflow from changes in certain operating assets and liabilities. This cash inflow was driven by a \$2.5 million increase in accrued expenses related to an increase in expense activity as well as the timing of invoices. This inflow was partially offset by cash outflows related to an increase in prepaid expenses and other current assets of \$0.3 million related to an increase in payments to vendors in advance of work being performed, a decrease in deferred rent of \$0.3 million related to the timing of payments in comparison to the rent expense, which is being recorded on a straight-line basis and a decrease in accounts payable of \$0.1 million due to the timing of invoicing and payments.

### Investing Activities

Net cash used in investing activities for nine months ended September 30, 2020 and 2019 was \$1.0 million and \$0.6 million, respectively, and consisted of the purchase of property and equipment.

### Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2020 and 2019 was \$35.4 million and \$47.4 million, respectively, and primarily consisted of proceeds from the issuance of Series B. Financing activities in 2020 also includes \$0.6 million of payments of offering costs related to the IPO.

### Funding Requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue our research and development, initiate clinical trials, and seek marketing approval for our current and any of our future product candidates. In addition, if we obtain marketing approval for any of our current or our future product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution, which costs we may seek to offset through entry into collaboration agreements with third parties. We also expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

## [Table of Contents](#)

We believe that our existing cash and cash equivalents, together with the net proceeds received from the IPO in October 2020, will enable us to fund our operating expenses and capital expenditure requirements into 2023. We have based this estimate on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Our future capital requirements will depend on a number of factors, including:

- the costs of conducting preclinical studies and clinical trials;
- the costs of manufacturing;
- the scope, progress, results and costs of discovery, preclinical development, laboratory testing, and clinical trials for product candidates we may develop, if any;
- the costs, timing, and outcome of regulatory review of our product candidates;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the achievement of milestones or occurrence of other developments that trigger payments under any license or collaboration agreements we might have at such time;
- the costs and timing of future commercialization activities, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, obtaining, maintaining and enforcing our intellectual property rights, and defending intellectual property-related claims;
- our headcount growth and associated costs as we expand our business operations and research and development activities; and
- the costs of operating as a public company.

Our cash and cash equivalents as of September 30, 2020, along with the proceeds from our IPO, will not be sufficient to complete development of ONCR-177 or any other product candidate. Accordingly, we will be required to obtain further funding to achieve our business objectives.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of public or private equity offerings and debt financings or other sources, such as potential collaboration agreements, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interests may be diluted, and the terms of these securities may include liquidation or other preferences that could adversely affect your rights as a common stockholder. Additional debt financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, that could adversely impact our ability to conduct our business.

If we raise funds through potential collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates, or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

### **Critical Accounting Policies and Significant Judgments and Estimates**

Our unaudited interim condensed consolidated financial statements and accompanying notes have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these unaudited interim condensed consolidated financial statements requires us to make judgments and estimates that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the unaudited interim condensed consolidated financial statements and the reported amounts of expenses during the reported periods. We base our estimates on historical experience, known trends and events, and various other factors that we believe to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions. On an ongoing basis, we evaluate our judgments and estimates in light of changes in circumstances, facts, and experience. The effects of material revisions in estimates, if any, will be reflected in the consolidated financial statements prospectively from the date of change in estimates.

There have been no significant changes to our critical accounting policies from those described in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in the Prospectus.

### **Off-Balance Sheet Arrangements**

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

### **Contractual Obligations**

During the three months ended September 30, 2020, there were no material changes to our contractual obligations and commitments from those included in the Prospectus.

### **Emerging Growth Company and Smaller Reporting Company Status**

We are an “emerging growth company,” or EGC, under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Section 107 of the JOBS Act provides that an EGC can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. Thus, an EGC can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of the delayed adoption of new or revised accounting standards and, therefore, we will be subject to the same requirements to adopt new or revised accounting standards as private entities.

As an EGC, we may also take advantage of certain exemptions and reduced reporting requirements under the JOBS Act. Subject to certain conditions, as an EGC:

- we may present only two years of audited financial statements and only two years of related Management’s Discussion and Analysis of Financial Condition and Results of Operations in our annual reports on Form 10-K filed with the SEC;
- we will avail ourselves of the exemption from providing an auditor’s attestation report on our internal control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act;
- we will avail ourselves of the exemption from complying with any requirement that may be adopted by the Public Company Accounting Oversight Board, or PCAOB, regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis;
- we may provide reduced disclosure about our executive compensation arrangements in our proxy statements filed with the SEC; and
- we will not require nonbinding advisory votes on executive compensation or stockholder approval of any golden parachute payments.

We will remain an EGC until the earliest of (i) December 31, 2025, (ii) the last day of the fiscal year in which we have total annual gross revenues of \$1.07 billion or more, (iii) the date on which we have issued more than \$1 billion in non-convertible debt during the previous rolling three-year period, or (iv) the date on which we are deemed to be a large accelerated filer under the Securities Exchange Act of 1934, as amended, or the Exchange Act.

We are also a “smaller reporting company,” meaning that the market value of our stock held by non-affiliates is less than \$700 million and our annual revenue was less than \$100 million during our most recently completed fiscal year. We may continue to be a smaller reporting company for so long as (i) the market value of our stock held by non-affiliates is less than \$250 million or (ii) our annual revenue is less than \$100 million during our most recently completed fiscal year and the market value of our stock held by non-affiliates is less than \$700 million.

If we are a smaller reporting company at the time we cease to be an EGC, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to EGCs, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

### **Recent Accounting Pronouncements**

Refer to Note 2 in the accompanying notes to our unaudited interim condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q for a discussion of recent accounting pronouncements.

### **Item 3. Quantitative and Qualitative Disclosures About Market Risk.**

We are exposed to market risk related to changes in interest rates. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our cash equivalents, in the form of a money market fund, are primarily invested in U.S. Treasury obligations. However, because of the short-term nature of the investments in our portfolio, an immediate one percentage point change in market interest rates would not have a material impact on the fair market value of our investment portfolio or on our financial position or results of operations.

We are not currently exposed to significant market risk related to changes in foreign currency exchange rates; however, we have contracted with and may continue to contract with foreign vendors that are located in Europe. Our operations may be subject to fluctuations in foreign currency exchange rates in the future.

Inflation generally affects us by increasing our cost of labor. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the year ended December 31, 2019 and the nine months ended September 30, 2020.

### **Item 4. Controls and Procedures.**

#### **Evaluation of Disclosure Controls and Procedures**

We maintain “disclosure controls and procedures,” as defined in Rule 13a-15(e) and Rule 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2020, the end of the period covered by this Quarterly Report on Form 10-Q. Based on the evaluation of our disclosure controls and procedures as of September 30, 2020, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

#### **Changes in Internal Control over Financial Reporting**

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

#### **Inherent Limitations on Effectiveness of Controls**

Our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving the desired control objectives. Our management recognizes that any control system, no matter how well designed and operated, is based upon certain judgments and assumptions and cannot provide absolute assurance that its objectives will be met. Similarly, an evaluation of controls cannot provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected.

## PART II—OTHER INFORMATION

### Item 1. Legal Proceedings.

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. We are not currently a party to any material legal proceedings, and we are not aware of any pending or threatened legal proceeding against us that we believe could have an adverse effect on our business, operating results or financial condition.

### Item 1A. Risk Factors.

*Our business is subject to numerous risks. You should consider carefully the risks and uncertainties described below, in addition to other information contained in this Quarterly Report on Form 10-Q as well as our other public filings with the Securities and Exchange Commission, or the SEC. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business. If any of the following risks or others not specified below materialize, it could have a material adverse effect on our business, financial condition, results of operations and growth prospects and cause the trading price of our common stock to decline.*

#### Risks Related to Our Financial Position and Need for Additional Capital

***We have a limited operating history. We have incurred significant losses since our inception and anticipate that we will incur significant and increasing losses for the foreseeable future and we may never achieve or maintain profitability.***

We have a limited operating history, and we are early in our development efforts. Since our inception in April 2015, we have incurred significant operating losses. Our net loss was \$30.7 million for the year ended December 31, 2019, and \$36.7 million for the nine months ended September 30, 2020. As of September 30, 2020, we had an accumulated deficit of \$118.3 million. Through September 30, 2020, we funded our operations primarily through the sale of redeemable convertible preferred stock. Since inception, we have devoted substantially all of our financial resources and efforts to organizing and staffing our company, business planning, raising capital, acquiring and developing our technology, establishing our intellectual property portfolio, identifying potential product candidates and undertaking preclinical studies, commencing a clinical trial and manufacturing. We are still in the early stages of development of our product candidates, and we have not completed development of any products. We expect to continue to incur significant and increasing operating losses for the foreseeable future. We expect that it will be several years, if ever, before we have a commercialized product. The net losses we incur may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if, and as, we:

- advance the clinical trial for our lead product candidate, ONCR-177;
- continue the ongoing and planned preclinical and clinical development of our other development programs;
- discover and develop new product candidates, and conduct research and development activities, preclinical studies and clinical trials;
- initiate preclinical studies and clinical trials for any additional product candidates that we may pursue in the future;
- manufacture preclinical, clinical and commercial supplies of our product candidates;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- maintain, expand and protect our intellectual property portfolio;
- hire additional research and development, clinical, scientific and management personnel;
- add operational, financial and management information systems and personnel;
- ultimately establish a sales, marketing and distribution infrastructure to commercialize any product candidate for which we may obtain regulatory approval and we commercialize on our own or in collaboration with others; and
- incur additional legal, accounting and other expenses operating as a newly public company.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials, obtaining regulatory approval for product candidates and manufacturing, marketing and selling products for which we may obtain marketing approval and satisfying any post-marketing requirements. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts or even continue our operations.

## [Table of Contents](#)

***We will require substantial additional financing to advance the development of our product candidates, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital could force us to delay, limit, reduce or terminate our product development programs, potential commercialization efforts or other operations.***

The development of biopharmaceutical product candidates is capital-intensive. Our operations have consumed substantial amounts of cash since inception. As of September 30, 2020, our cash and cash equivalents were \$54.0 million. In October 2020, we completed an IPO that provided net proceeds of approximately \$88.2 million. We expect to continue to spend substantial amounts to continue the preclinical and clinical development of our current and future programs. If we are able to gain marketing approval of any product candidate that we develop, including ONCR-177, we will require significant additional amounts of cash in order to launch and commercialize such product either alone or in collaboration with others. Because the design and outcome of our ongoing, anticipated and any future clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any product candidate we develop.

Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing ONCR-177 and our other product candidates and programs, and of conducting preclinical studies and clinical trials and any delays related to the COVID-19 pandemic;
- the timing of, and the costs involved in, obtaining marketing approvals for ONCR-177 and future product candidates we develop if clinical trials are successful;
- the success of any future collaborations;
- the cost of commercialization activities for any approved product, including marketing, sales and distribution costs;
- the cost and timing of establishing, equipping, and operating our planned manufacturing activities;
- the cost of manufacturing ONCR-177 and future product candidates for clinical trials in preparation for marketing approval and commercialization;
- our ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- our ability to establish and maintain healthcare coverage and adequate reimbursement for our future products, if any;
- the timing, receipt, and amount of sales of, or royalties on, our future products, if any;
- the emergence of competing cancer therapies and other adverse market developments; and
- the impact of the COVID-19 pandemic, which may exacerbate the magnitude of the factors discussed above.

We do not have any committed external source of funds or other support for our development efforts. Until we can generate sufficient product revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings and debt financings, or other sources such as potential collaborations, strategic alliances, licensing arrangements and other arrangements. Based on our research and development plans, we expect that our cash and cash equivalents, including the net proceeds from the IPO, will enable us to fund our planned operating expenses and capital expenditure requirements into 2023. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. In addition, because the design and outcome of clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of ONCR-177 or any future product candidates.

Our cash and cash equivalents, including the net proceeds from the IPO, will not be sufficient to complete development of ONCR-177 or any other product candidate. Accordingly, we will be required to obtain further funding to achieve our business objectives. Adequate additional funding may not be available to us on acceptable terms, or at all. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. If we are unable to raise additional funding in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue our research and development initiatives. We could also be required to seek collaborators for our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to our product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves. Any of these events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

***We have never generated any revenue from product sales and may never become profitable.***

Our ability to generate revenue from product sales and achieve profitability depends on our ability, alone or with future partners, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize, our development programs. We have no products approved for commercial sale, have not generated any revenue from product sales, and do not anticipate generating any revenue from product sales until after we have received marketing approval for the commercial sale of a product candidate, if ever. Our ability to generate revenue and achieve profitability depends heavily on our success in achieving a number of goals, including:

- completing research regarding, and preclinical and clinical development of product candidates and programs, including ONCR-177, and identifying and developing new product candidates;
- obtaining marketing approvals for any product candidates for which we complete clinical trials;
- developing a sustainable and scalable manufacturing process for ONCR-177 and future product candidates, including establishing and maintaining supply and manufacturing relationships with third parties;
- launching and commercializing product candidates for which we obtain marketing approvals, either directly by establishing a sales force and marketing, medical affairs and distribution infrastructure or, alternatively, with a collaborator or distributor;
- establishing and maintaining healthcare coverage and adequate reimbursement for our future products, if any;
- obtaining market acceptance of product candidates that we develop as viable treatment options;
- addressing any competing technological and market developments;
- identifying, assessing, acquiring and developing new product candidates;
- negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter and performing our obligations in such collaborations;
- maintaining, protecting, and expanding our portfolio of intellectual property rights, including patents, trade secrets, and know-how; and
- attracting, hiring, and retaining qualified personnel.

Even if ONCR-177 or any future product candidates that we develop are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any such product candidate that we commercialize on our own or in collaboration with others. Our expenses could increase beyond expectations if we are required by the U.S. Food and Drug Administration, or FDA, or comparable foreign regulatory authorities, to change our manufacturing processes or assays, or to perform clinical, nonclinical, or other types of studies in addition to those that we currently anticipate.

If we are successful in obtaining regulatory approvals to market ONCR-177 or any future product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain marketing approval, the accepted price for the product, the ability to get reimbursement at any price, and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indications approved by regulatory authorities are narrower than we expect, the labels for our product candidates contain significant safety warnings, regulatory authorities impose burdensome or restrictive distribution requirements, or the reasonably accepted patient populations for treatment are narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. If we are not able to generate revenue from the sale of any approved products, we could be prevented from or significantly delayed in achieving profitability.

***Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.***

To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our common stockholders will be diluted, our fixed payment obligations may increase, any such securities may have rights senior to those of our common stock, and the terms may include liquidation or other preferences and anti-dilution protections that adversely affect the rights of our common stockholders. Any future debt financings we undertake, if available, are likely to involve restrictive covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through licensing or collaboration arrangements with third parties, we may have to relinquish valuable rights to our product candidates, or grant licenses on terms that are not favorable to us. We also could be required to seek collaborators for product candidates at an earlier stage than otherwise would be desirable or relinquish our rights to product candidates or technologies that we otherwise would seek to develop or commercialize ourselves.

Failure to obtain capital when needed on acceptable terms may force us to delay, limit or terminate our product development and commercialization of our current or future product candidates, which could have a material and adverse effect on our business, financial condition, results of operations and prospects. Securing additional financing could also require a substantial amount of time from our management and may divert a disproportionate amount of their attention away from daily activities, which may adversely affect our management's ability to oversee the development of ONCR-177 or any future product candidates.

## [Table of Contents](#)

### ***Our short operating history may make it difficult to evaluate the success of our business to date and to assess our future viability.***

We are an early-stage company. We were founded and commenced operations in 2015. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, acquiring and developing our technology, establishing our intellectual property portfolio, identifying potential product candidates and undertaking preclinical studies, commencing a clinical trial and manufacturing. All of our research programs are still in the preclinical or early-stage clinical development, and their risk of failure is high. We have not yet demonstrated an ability to initiate or successfully complete any clinical trials, including large-scale, pivotal clinical trials, obtain marketing approvals, manufacture a commercial-scale therapy, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Typically, it takes about 10 to 15 years to develop a new therapy from the time it is discovered to when it is available for treating patients. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history. In addition, as a new business, we may encounter unforeseen expenses, difficulties, complications, delays, and other known and unknown factors. We will need to transition from a company primarily focused on research and in the early stages of a clinical trial to a company capable of supporting clinical activities on a larger scale and commercial activities. We may not be successful in such a transition.

### ***We have generated significant net operating loss (NOL) carryforwards and research and development tax credits, and our ability to utilize our net operating loss carryforwards and research and development tax credits to reduce future tax payments may be limited or restricted.***

We have generated significant NOL carryforwards and research and development tax credits, or R&D credits, as a result of our incurrence of losses and our conduct of research activities since inception. As of December 31, 2019, we had federal and state NOL carryforwards of \$66.4 million and \$65.3 million, respectively. We do not anticipate generating revenue from sales of products for the foreseeable future, if ever, and we may never achieve profitability. Our U.S. federal NOL carryforwards generated prior to 2018 will expire if not utilized beginning in 2035. These NOL carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under the Tax Cuts and Jobs Act, as modified by the CARES Act, U.S. federal NOLs incurred in tax years beginning after December 31, 2017 may be carried forward indefinitely, but the utilization of U.S. federal NOLs generated in tax years beginning after December 31, 2020 is limited. As of December 31, 2019, we also had federal and state R&D credit carryforwards of \$2.3 million and \$1.1 million, respectively. Our federal R&D credit carryforwards begin to expire in 2035 and our state R&D credit carryforwards begin to expire in 2030. These R&D credit carryforwards could expire unused and be unavailable to offset future income tax liabilities.

Under Sections 382 and 383 of the Code, and corresponding provisions of state law, if a corporation undergoes an “ownership change,” the corporation’s ability to use its pre-change NOL carryforwards and R&D credits to offset its post-change income and taxes, respectively, may be limited. For purposes of these rules, an “ownership change” generally occurs if one or more stockholders or groups of stockholders who own at least 5% of our stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. The application of these rules could limit the amount of NOLs or R&D credit carryforwards that we can utilize annually to offset future taxable income or tax liabilities. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

Our NOL and R&D credit carryforwards are subject to review and possible adjustment by U.S. and state tax authorities.

### **Risks Related to Product Discovery, Development and Regulatory Approval**

#### ***Our product candidates are in early stages of development, are not approved for commercial sale and might never receive regulatory approval or become commercially viable. We have never generated any revenue from product sales and may never be profitable.***

We are very early in our development efforts and all of our product candidates are in research, preclinical or early-stage clinical development. We have not completed the development of any product candidates, we currently generate no revenue and we may never be able to develop a marketable product. We only recently commenced clinical development of our lead product candidate, ONCR-177, in June 2020. Additionally, we have a portfolio of programs, including our two lead synthetic viral immunotherapy programs, which are based on coxsackievirus A21, or CVA21, and Seneca Valley Virus, or SVV, that are in earlier stages of discovery and preclinical development and may never advance to clinical-stage development. Our ability to generate product revenues, which we do not expect will occur for several years, if ever, will depend on obtaining regulatory approvals for, and successfully commercializing our product candidates, either alone or in collaboration with others, and we cannot guarantee that we will ever obtain regulatory approval for any of our product candidates. Before obtaining regulatory approval for the commercial distribution of our product candidates, we, or a future collaborator, must conduct extensive preclinical tests and clinical trials to demonstrate the safety and efficacy in humans of our product candidates.

The success of our current and future product candidates will depend on several factors, including the following:

- successful completion of preclinical studies and clinical trials;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- acceptance of an investigational new drug application, or IND, for our planned clinical trials or future clinical trials;
- successful enrollment and completion of clinical trials;
- successful data from our clinical trials that support an acceptable risk-benefit profile of our product candidates in the intended populations;
- receipt of regulatory and marketing approvals from applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our product candidates;
- making arrangements with third-party manufacturers for, or establishing, clinical and commercial manufacturing capabilities;
- successfully launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;
- acceptance of any products we develop and their benefits and uses, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- obtaining and maintaining healthcare coverage and adequate reimbursement from third-party payors; and

- maintaining a continued acceptable safety profile of the products following approval.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our drug candidates, which would materially harm our business.

## [Table of Contents](#)

***We currently have only one product candidate, ONCR-177, in clinical development. A failure of this product candidate in clinical development would adversely affect our business and may require us to discontinue development of other product candidates based on the same therapeutic approach.***

We have invested a significant portion of our efforts and financial resources in our oncolytic HSV-1 platform, referred to as our oHSV Platform, and our synthetic viral platform, referred to as our Synthetic Platform and, in particular, in the development of our lead product candidate, ONCR-177. We commenced clinical trials of ONCR-177 in June 2020.

We have only submitted an IND application with respect to one product candidate, ONCR-177, and we have not previously submitted a Biologics License Application, or BLA, to the FDA, or similar regulatory approval filings to comparable foreign authorities, for any product candidate, and we cannot be certain that our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials.

Since ONCR-177 is based on our oHSV Platform, if ONCR-177 fails in development as a result of any underlying problem with our oHSV Platform, then we may be required to discontinue development of all product candidates that are based on this therapeutic approach. If we were required to discontinue development of ONCR-177 or our other future product candidates, or if any of them were to fail to receive regulatory approval or achieve sufficient market acceptance, we could be prevented from or significantly delayed in achieving profitability. We can provide no assurance that we would be successful at developing other product candidates based on an alternative therapeutic approach.

***Our product candidates are based on a novel approach to the treatment of cancer, which makes it difficult to predict the time and cost of product candidate development.***

We have concentrated all of our research and development efforts on product candidates based on our oHSV Platform and Synthetic Platform, each of which is novel. Our Synthetic Platform has not yet produced a product candidate that has been tested in clinical trials and we only recently commenced clinical development of ONCR-177, which is based on our oHSV Platform. Our future success depends on the successful development of these platforms. There can be no assurance that any development problems we experience in the future will not cause significant delays or unanticipated costs, or that such development problems can be solved. Should we encounter development problems, including unfavorable preclinical or clinical trial results, the FDA or foreign regulatory authorities may refuse to approve our product candidates, or may require additional information, tests, or trials, which could significantly delay product development and significantly increase our development costs. Moreover, even if we are able to provide the requested information or trials to the FDA, there would be no guarantee that the FDA would accept them or approve our product candidates. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process, or developing or qualifying and validating product release assays, other testing and manufacturing methods, and our equipment and facilities in a timely manner, which may prevent us from completing our clinical trials or commercializing our product candidates on a timely or profitable basis, if at all.

In addition, the clinical trial requirements of the FDA and comparable foreign regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The FDA and comparable foreign regulatory authorities have limited experience with the approval of viral immunotherapies. There are only three viral immunotherapies approved globally, H101, Rigvir, and talimogene laherparepvec, or T-VEC, and only T-VEC has received FDA approval to date. Any viral immunotherapies that are approved may be subject to extensive post-approval regulatory requirements, including requirements pertaining to manufacturing, distribution and promotion. We may need to devote significant time and resources to compliance with these requirements.

***Preclinical and clinical development involve a lengthy and expensive process with an uncertain outcome, and delays can occur for a variety of reasons outside of our control.***

In order to obtain FDA approval to market a new biological product, we must demonstrate proof of safety, purity and potency or efficacy in humans. To meet these requirements, we will have to conduct adequate and well-controlled clinical trials. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our planned INDs in the United States. We only have one product candidate currently being evaluated in clinical development, ONCR-177. The rest of our programs are in preclinical development, have not yet been evaluated in IND-enabling studies and their risk of failure is high. We cannot be certain of the timely completion or outcome of our preclinical testing and studies or clinical trials and cannot predict if the FDA will accept our proposed clinical programs or if the outcome of our preclinical testing and studies or clinical trials will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin and we cannot be sure that our planned clinical trials will begin on time or that our ongoing clinical trials will be completed on schedule.

Conducting preclinical testing and clinical development is a lengthy, time-consuming and expensive process. The length of time may vary substantially according to the type, complexity and novelty of the program, and often can be several years or more per program. Delays associated with programs for which we are directly conducting preclinical testing and studies may cause us to incur additional operating expenses. Moreover, we may be affected by delays associated with the preclinical testing and studies of certain programs that are the responsibility of any potential future partners over which we have no control. The commencement and rate of completion of preclinical studies and clinical trials for a product candidate may be delayed by many factors, including, for example:

- inability to generate sufficient preclinical or other in vivo or in vitro data to support the initiation of clinical trials;

## Table of Contents

- unexpected toxicities observed in preclinical IND-enabling studies precluding the identification of a safe dose to move forward in human clinical trial;
- delays in production or manufacturing of clinical supply;
- delays in reaching a consensus with regulatory agencies on study or trial design; and
- regulatory authorities not allowing us to rely on previous findings of safety and efficacy for other similar but approved products and published scientific literature.

We may experience delays in initiating or completing clinical trials. We also may experience numerous unforeseen events during, or as a result of, any ongoing or future clinical trials that we could conduct that could delay or prevent our ability to receive marketing approval or commercialize ONCR-177 or any future product candidates, including:

- delays or failures related to the COVID-19 pandemic, which may result in clinical site closures, delays to patient enrollment, patients discontinuing their treatment or follow up visits or changes to trial protocols;
- regulators or institutional review boards, or IRBs, may not authorize us or our investigators to commence a clinical trial, conduct a clinical trial at a prospective trial site, or amend trial protocols, or may require that we modify or amend our clinical trial protocols;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites and/or contract research organizations, or CROs;
- clinical trials of our product candidates may produce negative or inconclusive results, or our studies may fail to reach the necessary level of statistical significance, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or be lost to follow-up at a higher rate than we anticipate, or may elect to participate in alternative clinical trials sponsored by our competitors with product candidates that treat the same indications as our product candidates;
- third-party contractors may fail to comply with regulatory requirements or the clinical trial protocol, or meet their contractual obligations to us in a timely manner, or at all, or we may be required to engage in additional clinical trial site monitoring;
- manufacturing delays;
- we, regulators, or IRBs may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks, undesirable side effects, or other unexpected characteristics of the product candidate, or due to findings of undesirable effects caused by a chemically or mechanistically similar therapeutic or therapeutic candidate;
- changes could be adopted in marketing approval policies during the development period, rendering our data insufficient to obtain marketing approval;
- statutes or regulations could be amended or new ones could be adopted;
- changes could be adopted in the regulatory review process for submitted product applications;
- the cost of clinical trials of our product candidates may be greater than we anticipate or we may have insufficient funds for a clinical trial or to pay the substantial user fees required by the FDA upon the submission of a BLA or equivalent authorizations from comparable foreign regulatory authorities;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- we may decide, or regulators may require us, to conduct or gather, as applicable, additional clinical trials, analyses, reports, data, or preclinical trials, or we may abandon product development programs;
- we may fail to reach an agreement with regulators or IRBs regarding the scope, design, or implementation of our clinical trials, and the FDA or comparable foreign regulatory authorities may require changes to our study designs that make further study impractical or not financially prudent;
- regulators may ultimately disagree with the design or our conduct of our preclinical studies or clinical trials, finding that they do not support product candidate approval;

## Table of Contents

- we may have delays in adding new investigators or clinical trial sites, or we may experience a withdrawal of clinical trial sites;
- patients that enroll in our studies may misrepresent their eligibility or may otherwise not comply with the clinical trial protocol, resulting in the need to drop the patients from the study or clinical trial, increase the needed enrollment size for the clinical trial or extend its duration;
- there may be regulatory questions or disagreements regarding interpretations of data and results, or new information may emerge regarding our product candidates;
- the FDA or comparable foreign regulatory authorities may disagree with our trial design, including endpoints, or our interpretation of data from preclinical studies and clinical trials or find that a product candidate's benefits do not outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may not accept data from studies with clinical trial sites in foreign countries;
- the FDA or comparable foreign regulatory authorities may disagree with our intended indications;
- the FDA or comparable foreign regulatory authorities may fail to approve or subsequently find fault with the manufacturing processes or our manufacturing facilities for clinical and future commercial supplies;
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a BLA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may take longer than we anticipate to make a decision on our product candidates; and
- we may not be able to demonstrate that a product candidate provides an advantage over current standards of care or current or future competitive therapies in development.

Our product development costs will also increase if we experience delays in clinical testing or marketing approvals, and we may not have sufficient funding to complete the testing and approval process for any of our current or future product candidates. We may be required to obtain additional funds to complete clinical trials and prepare for possible commercialization of our product candidates. We do not know whether any preclinical tests or clinical trials beyond what we currently have planned will be required, will begin as planned, will need to be restructured, or will be completed on schedule or at all. Significant delays relating to any preclinical studies or clinical trials also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations. In addition, many of the factors that cause, or lead to, delays in clinical trials may ultimately lead to the denial of marketing approval of any of our product candidates. Any delays in our clinical development programs may harm our business, financial condition and results of operations significantly.

***If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.***

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or foreign regulatory authorities. In addition, some of our competitors may have ongoing clinical trials for drug candidates that treat the same indications as our drug candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates.

Patient enrollment is affected by other factors, including:

- availability and efficacy of approved therapies for the disease under investigation;
- patient eligibility criteria for the trial in question;
- risks that enrolled subjects will drop out before completion of the trial, including as a result of contracting COVID-19 or other health conditions or being forced to quarantine;
- perceived risks and benefits of the product candidate under study;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for our anticipated and any future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which could have an adverse effect on our business, financial condition, results of operations, and prospects. In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter patient enrollment difficulties.

***Results of preclinical studies and early clinical trials may not be predictive of results of future clinical trials.***

For our lead product candidate, ONCR-177, we commenced a clinical trial in June 2020, while other product candidates that may be generated from both our oHSV Platform and our Synthetic Platform are in preclinical development. We will be required to conduct additional clinical trials of ONCR-177 before we can submit a marketing application to the applicable regulatory authorities. Clinical development is expensive and can take many years to complete and its outcome is inherently uncertain. ONCR-177 may not perform as we expect in clinical trials, may ultimately have a different or no impact on tumors, may have a different mechanism of action than we expect and may not ultimately prove to be safe and effective.

The results of early clinical trials of ONCR-177 and results of preclinical studies or early clinical trials of any other product candidate we develop, may not be predictive of the results of later-stage clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier development, and we could face similar setbacks. The design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for the product candidates. Even if we, or future collaborators, believe that the results of clinical trials for our product candidates warrant marketing approval, the FDA or comparable foreign regulatory authorities may disagree and may not grant marketing approval of our product candidates.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. Moreover, should there be an issue with the design of any of our clinical trials, our results may be impacted. We may not discover such a flaw until the clinical trial is at an advanced stage.

***Interim and preliminary or topline data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.***

From time to time, we may publish interim topline or preliminary data from clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary or topline data previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between interim or preliminary or topline data and final data could significantly harm our reputation and business prospects.

***Serious adverse events, undesirable side effects or other unexpected properties of our current or future product candidates may be identified during development or after approval, which could halt their development or lead to the discontinuation of our clinical development programs, refusal by regulatory authorities to approve our product candidates or, if discovered following marketing approval, revocation of marketing authorizations or limitations on the use of our product candidates thereby limiting the commercial potential of such product candidate.***

To date, we have not tested any product candidate in humans, other than ONCR-177. The Phase 1 clinical trial for ONCR-177 commenced in June 2020 and we expect to report preliminary data in multiple data readouts beginning in the second half of 2021 through the second half of 2022. We have tested mONCR-177, a mouse version of ONCR-177 in IND-enabling studies conducted in mice, and the most common treatment-related toxicity we have observed to date is low severity lymphocyte hyperplasia in the spleen. Reversible body weight loss was observed after intravenous and intratumoral injection, particularly following the initial administration at the highest dose level. As we continue our development of ONCR-177 and initiate clinical trials of any future product candidates, serious adverse events, undesirable side effects or unexpected characteristics may emerge causing us to abandon these product candidates or limit their development to more narrow uses or subpopulations in which the serious adverse events, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Even if our product candidates initially show promise in early clinical trials, the side effects of therapies are frequently only detectable after they are tested in large, phase 3 clinical trials or, in some cases, after they are made available to patients on a commercial scale after approval. Sometimes, it can be difficult to determine if the serious adverse or unexpected side effects were caused by the product candidate or another factor, especially in oncology subjects who may suffer from other medical conditions and be taking other medications. If serious adverse or unexpected side effects are identified during development and are determined to be attributed to our product candidates, the FDA or comparable foreign regulatory authorities, or IRBs and other reviewing entities, may also require, or we may voluntarily develop, a Risk Evaluation and Mitigation Strategy, or REMS, or other strategies for managing adverse events during clinical development, which could include restrictions on our enrollment criteria, the use of stopping criteria, adjustments to a study's design, or the monitoring of safety data by a data monitoring committee, among other strategies. Any requests from the FDA or comparable foreign regulatory authority for additional data or information could also result in substantial delays in the approval of our product candidates.

Drug-related side effects could also affect subject recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

## [Table of Contents](#)

In addition, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

If any of our product candidates are associated with serious adverse events or undesirable side effects or have properties that are unexpected, we may need to abandon development or limit development of that product candidate to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. The therapeutic-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

***We anticipate that many of our product candidates will be used in combination with third-party drugs, some of which may still be in development, and we have limited or no control over the supply, regulatory status or regulatory approval of such drugs.***

In addition to developing our product candidates as monotherapies, we also anticipate developing our product candidates for use in combination with immune checkpoint inhibitors. For example, we anticipate developing ONCR-177 in combination with the anti-PD-1 checkpoint inhibitor KEYTRUDA (pembrolizumab), which is being supplied by Merck in our ongoing Phase 1 clinical trial. In the future, we may enter into additional agreements for the supply of immune checkpoint inhibitors for use in connection with the development of one or more of our product candidates. Our ability to develop and ultimately commercialize our product candidates used in combination with pembrolizumab or any other immune checkpoint inhibitors will depend on our ability to access such drugs on commercially reasonable terms for the clinical trials and their availability for use with the commercialized product, if approved. We cannot be certain that current or potential future commercial relationships will provide us with a steady supply of such drugs on commercially reasonable terms or at all.

Any failure to maintain or enter into new successful commercial relationships, or the expense of purchasing immune checkpoint inhibitors in the market, may delay our development timelines, increase our costs and jeopardize our ability to develop our product candidates as commercially viable therapies. If any of these occur, our business, financial condition, results of operations, stock price and prospects may be materially harmed.

Moreover, the development of product candidates for use in combination with another product or product candidate may present challenges that are not faced for single agent product candidates. For our product candidates that may be used in combination with immune checkpoint inhibitors, the FDA may require us to use more complex clinical trial designs in order to evaluate the contribution of each product and product candidate to any observed effects. It is possible that the results of these trials could show that any positive previous trial results are attributable to the combination therapy and not our product candidates. Moreover, following product approval, the FDA may require that products used in conjunction with each other be cross labeled for combined use. To the extent that we do not have rights to the other product, this may require us to work with a third party to satisfy such a requirement. Moreover, developments related to the other product may impact our clinical trials for the combination as well as our commercial prospects should we receive marketing approval. Such developments may include changes to the other product's safety or efficacy profile, changes to the availability of the approved product, and changes to the standard of care.

In the event that any future collaborator or supplier of immune checkpoint inhibitors administered in combination with our product candidates does not supply their products on commercially reasonable terms or in a timely fashion, we would need to identify alternatives for accessing these products. This could cause our clinical trials to be delayed and limit the commercial opportunities for our product candidates, in which case our business, financial condition, results of operations, stock price and prospects may be materially harmed.

***We may not be successful in our efforts to expand our pipeline of product candidates and develop marketable products.***

We expect initially to develop our lead product candidate, ONCR-177. A key part of our strategy, however, is to pursue clinical development of additional product candidates, including product candidates based on our Synthetic Platform. Research programs to identify new product candidates require substantial technical, financial and human resources. Developing, obtaining marketing approval for, and commercializing additional product candidates will require substantial additional funding and will be subject to the risks of failure inherent in medical product development. We cannot assure you that we will be able to successfully advance any of these additional product candidates through the development process.

Even if we obtain approval from the FDA or comparable foreign regulatory authorities to market additional product candidates for the treatment of cancer, we cannot assure you that any such product candidates will be successfully commercialized, widely accepted in the marketplace, or more effective than other commercially available alternatives. If we are unable to successfully develop and commercialize additional product candidates our commercial opportunity may be limited and our business, financial condition, results of operations, stock price and prospects may be materially harmed.

## [Table of Contents](#)

***We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.***

Because we have limited financial and managerial resources, we must prioritize our research programs and will need to focus our product candidates on the potential treatment of certain indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may also relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

***If we do not achieve our product development goals in the time frames we announce and expect, the commercialization of our product candidates may be delayed and as a result our share price may decline.***

Drug development is inherently risky and uncertain. We cannot be certain that we will be able to:

- complete IND-enabling preclinical studies or develop manufacturing processes and associated analytical methods that meet current good manufacturing practice, or cGMP, requirements in time to initiate clinical trials in the timeframes we announce;
- obtain sufficient clinical supply of our product candidates to support our anticipated or future clinical trials;
- initiate clinical trials within the timeframes we announce;
- enroll and maintain a sufficient number of subjects to complete any clinical trials; or
- analyze the data collected from any completed clinical trials in the timeframes we announce.

The actual timing of our development milestones could vary significantly compared to our estimates, in some cases for reasons beyond our control. If we are unable to achieve our goals within the timeframes we announce, the commercialization of our product candidates may be delayed and, as a result, the stock price of our common stock could fall.

***Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us or any of our potential future collaboration partners from obtaining approvals for the commercialization of ONCR-177 and any other product candidate we develop.***

Any current or future product candidate we may develop and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction and it is possible that none of the product candidates we may seek to develop in the future will ever obtain regulatory approval.

Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy for that indication. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities and clinical trial sites by, the regulatory authorities. If we do not receive approval from the FDA and comparable foreign regulatory authorities for any of our product candidates, we will not be able to commercialize such product candidates in the United States or in other jurisdictions. If significant delays in obtaining approval for and commercializing our product candidates occur in any jurisdictions, our business, financial condition, results of operations, stock price and prospects will be materially harmed. Even if our product candidates are approved, they may:

- be subject to limitations on the indicated uses or patient populations for which they may be marketed, distribution restrictions, or other conditions of approval;
- contain significant safety warnings, including boxed warnings, contraindications, and precautions;
- not be approved with label statements necessary or desirable for successful commercialization; or
- contain requirements for costly post-market testing and surveillance, or other requirements, including the submission of a REMS to monitor the safety or efficacy of the products.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, takes many years even if successful, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

## [Table of Contents](#)

If we experience delays in obtaining approval or if we fail to obtain approval of any current or future product candidates we may develop, the commercial prospects for those product candidates may be harmed, and our ability to generate revenues will be materially impaired.

***Regulatory approval by the FDA or comparable foreign regulatory authorities is limited to those specific indications and conditions for which approval has been granted, and we may be subject to substantial fines, criminal penalties, injunctions, or other enforcement actions if we are determined to be promoting the use of any products for unapproved or “off-label” uses, resulting in damage to our reputation and business.***

We must comply with requirements concerning advertising and promotion for any product candidates for which we obtain marketing approval. Promotional communications with respect to therapeutics are subject to a variety of legal and regulatory restrictions and continuing review by the FDA, Department of Justice, Department of Health and Human Services’ Office of Inspector General, state attorneys general, members of Congress, and the public. When the FDA or comparable foreign regulatory authorities issue regulatory approval for a product candidate, the regulatory approval is limited to those specific uses and indications for which a product is approved. If we are not able to obtain FDA approval for desired uses or indications for our product candidates, we may not market or promote them for those indications and uses, referred to as off-label uses, and our business, financial condition, results of operations, stock price and prospects will be materially harmed. We also must sufficiently substantiate any claims that we make for any products we develop, including claims comparing our products to other companies’ products, and must abide by the FDA’s strict requirements regarding the content of promotion and advertising.

Because regulatory authorities in the United States generally do not restrict or regulate the behavior of physicians in their choice of treatment within the practice of medicine, physicians may choose to prescribe products for uses that are not described in the product’s labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities. Regulatory authorities do, however, restrict communications by biopharmaceutical companies concerning off-label use. We are prohibited for marking and promoting the products for indications and uses that are not specifically approved by the FDA.

If we are found to have impermissibly promoted any products that we may develop, we may become subject to significant liability and government fines. The FDA and other agencies actively enforce the laws and regulations regarding product promotion, particularly those prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted a product may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

In the United States, engaging in the impermissible promotion of our products, following approval, for off-label uses can also subject us to false claims and other litigation under federal and state statutes. These include fraud and abuse and consumer protection laws, which can lead to civil and criminal penalties and fines, agreements with governmental authorities that materially restrict the manner in which we promote or distribute therapeutic products and conduct our business. These restrictions could include corporate integrity agreements, suspension or exclusion from participation in federal and state healthcare programs, and suspension and debarment from government contracts and refusal of orders under existing government contracts. These False Claims Act lawsuits against manufacturers of drugs and biologics have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements, up to \$3.0 billion, pertaining to certain sales practices and promoting off-label uses. In addition, False Claims Act lawsuits may expose manufacturers to follow-on claims by private payers based on fraudulent marketing practices. This growth in litigation has increased the risk that a biopharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, as well as criminal and civil penalties, agree to comply with burdensome reporting and compliance obligations, and be excluded from Medicare, Medicaid, or other federal and state healthcare programs. If we do not lawfully promote our approved products, if any, we may become subject to such litigation and, if we do not successfully defend against such actions, those actions may have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

In the United States, the promotion of biopharmaceutical products is subject to additional FDA requirements and restrictions on promotional statements. If after one or more of our product candidates obtains marketing approval the FDA determines that our promotional activities violate its regulations and policies pertaining to product promotion, it could request that we modify our promotional materials or subject us to regulatory or other enforcement actions, including issuance of warning letters or untitled letters, suspension or withdrawal of an approved product from the market, requests for recalls, payment of civil fines, disgorgement of money, imposition of operating restrictions, injunctions or criminal prosecution, and other enforcement actions. Similarly, industry codes in foreign jurisdictions may prohibit companies from engaging in certain promotional activities and regulatory agencies in various countries may enforce violations of such codes with civil penalties. If we become subject to regulatory and enforcement actions our business, financial condition, results of operations, stock price and prospects will be materially harmed.

***Obtaining and maintaining marketing approval for our product candidates in one jurisdiction would not mean that we will be successful in obtaining marketing approval of that product candidate in other jurisdictions, which could prevent us from marketing our products internationally.***

Obtaining and maintaining marketing approval of our product candidates in one jurisdiction would not guarantee that we will be able to obtain or maintain marketing approval in any other jurisdiction, while a failure or delay in obtaining marketing approval in one jurisdiction may have a negative effect on the marketing approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable foreign regulatory authorities must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign marketing approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed. If we obtain approval for any product candidate and ultimately commercialize that product in foreign markets, we would be subject to additional risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and the reduced protection of intellectual property rights in some foreign countries.

***Even if our product candidates receive regulatory approval, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense and limit how we manufacture and market our products.***

Any product candidate for which we obtain marketing approval will be subject to extensive and ongoing requirements of and review by the FDA or comparable foreign regulatory authorities, including requirements related to the manufacturing processes, post-approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising, marketing, and promotional activities for such product. These requirements further include submissions of safety and other post-marketing information, including manufacturing deviations and reports, registration and listing requirements, the payment of annual fees, continued compliance with cGMP requirements relating to manufacturing, quality control, quality assurance, and corresponding maintenance of records and documents, and good clinical practices, or GCPs, for any clinical trials that we conduct post-approval.

The FDA and comparable foreign regulatory authorities will continue to closely monitor the safety profile of any product even after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of any of our product candidates, they may withdraw approval, issue public safety alerts, require labeling changes or establishment of a REMS or similar strategy, impose significant restrictions on a product's indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. Any such restrictions could limit sales of the product.

We and any of our suppliers or collaborators, including our contract manufacturers, could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMPs and other FDA regulatory requirements. Application holders must further notify the FDA, and depending on the nature of the change, obtain FDA pre-approval for product and manufacturing changes.

In addition, later discovery of previously unknown adverse events or that the product is less effective than previously thought or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements both before and after approval, may yield various negative results, including:

- restrictions on manufacturing, distribution, or marketing of such products;
- restrictions on the labeling, including required additional warnings, such as black boxed warnings, contraindications, precautions, and restrictions on the approved indication or use;
- modifications to promotional pieces;
- issuance of corrective information;
- requirements to conduct post-marketing studies or other clinical trials;
- clinical holds or termination of clinical trials;
- requirements to establish or modify a REMS or similar strategy;
- changes to the way the product candidate is administered;
- liability for harm caused to patients or subjects;
- reputational harm;
- the product becoming less competitive;
- warning, untitled, or cyber letters;

## Table of Contents

- suspension of marketing or withdrawal of the products from the market;
- regulatory authority issuance of safety alerts, Dear Healthcare Provider letters, press releases, or other communications containing warnings or other safety information about the product candidate;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recalls of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure or detention;
- FDA debarment, suspension and debarment from government contracts, and refusal of orders under existing government contracts, exclusion from federal healthcare programs, consent decrees, or corporate integrity agreements; or
- injunctions or the imposition of civil or criminal penalties, including imprisonment.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, or could substantially increase the costs and expenses of commercializing such product, which in turn could delay or prevent us from generating significant revenues from its marketing and sale. Any of these events could further have other material and adverse effects on our operations and business and could adversely impact our business, financial condition, results of operations, stock price and prospects.

The FDA's policies or those of comparable foreign regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates, limit the marketability of our product candidates, or impose additional regulatory obligations on us. Changes in medical practice and standard of care may also impact the marketability of our product candidates.

If we are slow or unable to adapt to changes in existing requirements, standards of care, or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and be subject to regulatory enforcement action.

Should any of the above actions take place, we could be prevented from or significantly delayed in achieving profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our operations and business and could adversely impact our business, financial condition, results of operations, stock price and prospects.

### **Risks Related to Our Reliance on Third Parties**

***We currently rely on contract manufacturing organizations, or CMOs, to supply components of and manufacture ONCR-177. The loss of these CMOs or their failure to meet their obligations to us could affect our ability to develop ONCR-177 in a timely manner.***

We rely on a limited number of CMOs and have entered into an agreement with a third-party CMO to manufacture ONCR-177 and supply the Phase 1 clinical trial material, in compliance with applicable regulatory and quality standards. While we do not own or operate manufacturing facilities, our team has in-house process development and manufacturing expertise and has internally developed a closed, serum-free manufacturing process. Our proprietary process is then used by third-party contract manufacturers we direct for production of batches of clinical material for us. Although we intend to initiate further development of our in-house manufacturing capabilities in 2021, we intend to continue to rely on third-party contract manufacturers to implement our proprietary process to manufacture our clinical supply for the foreseeable future. Any replacement of a third-party contract manufacturer could require significant effort and expertise because there may be a limited number of qualified replacements. Any delays in obtaining adequate clinical supply that meets the necessary quality standards may delay our development or commercialization.

Our reliance on third-party providers for certain manufacturing activities will reduce our control over these activities but will not relieve us of our responsibility to ensure compliance with all required regulations. Under certain circumstances, these third-party providers may be entitled to terminate their engagements with us. If a third-party provider terminates its engagement with us, or does not successfully carry out its contractual duties, meet expected deadlines or manufacture ONCR-177 or any other product candidates in accordance with regulatory requirements, or if there are disagreements between us and a third-party provider, we may not be able to complete, or may be delayed in completing, the preclinical studies required to support future IND submissions and the clinical trials required for approval of ONCR-177 or any other product candidate. In such instance, we may need to enter into an appropriate replacement third-party relationship, which may not be readily available or available on acceptable terms, which would cause additional delay or increased expense prior to the approval of ONCR-177 or any future product candidate and would thereby have a negative impact on our business, financial condition, results of operations and prospects.

## [Table of Contents](#)

We may rely on additional third parties to manufacture ingredients of our product candidates in the future and to perform quality testing. Reliance on third-party contract manufacturers and service providers entails risks to which we would not be subject if we manufactured the product candidates ourselves, including:

- reduced control for certain aspects of manufacturing activities;
- termination or nonrenewal of the applicable manufacturing and service agreements in a manner or at a time that is costly or damaging to us;
- the possible breach by our third-party manufacturers and service providers of our agreements with them;
- the failure of our third-party manufacturers and service providers to comply with applicable regulatory requirements;
- disruptions to the operations of our third-party manufacturers and service providers caused by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or service provider; and
- the possible misappropriation of our proprietary information, including our trade secrets and know-how.

Any of these events could lead to clinical trial delays or failure to obtain regulatory approval, impact our ability to successfully commercialize any of our product candidates or otherwise harm our business, financial condition, results of operations, stock price and prospects. Some of these events could be the basis for FDA or other regulatory authority action, including injunction, recall, seizure or total or partial suspension of product manufacture.

***We are subject to multiple manufacturing risks, any of which could substantially increase our costs, limit supply of our product candidates and result in delays in our clinical trials.***

The process of manufacturing viral immunotherapies, including our product candidates, is complex, time-consuming, highly regulated and subject to several risks, including:

- product loss during the manufacturing process, including loss caused by contamination, operator error, equipment failure or improper installation or operation of equipment, inconsistency in yields, variability in product characteristics, and difficulties in scaling the production process. In particular, we have experienced manufacturing loss of ONCR-177 clinical supply caused by operator error. We may also experience additional manufacturing losses in the future. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our products or in the manufacturing facilities in which our products are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination;
- the manufacturing facilities in which our product candidates are made could be adversely affected by equipment failures, labor and raw material shortages, natural disasters, power failures and numerous other factors; and
- any adverse developments affecting manufacturing operations for our products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our product candidates. We may also have to take inventory write-offs and incur other charges and expenses for product candidate batches that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives.

We may also make changes to our manufacturing processes at various points during development, for a number of reasons, such as controlling costs, achieving scale, decreasing processing time, increasing manufacturing success rate or other reasons. Such changes carry the risk that they will not achieve their intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of our ongoing or future clinical trials. In some circumstances, changes in the manufacturing process may require us to perform *ex vivo* comparability studies and to collect additional data from patients prior to undertaking more advanced clinical trials. For instance, changes in our process during the course of clinical development may require us to show the comparability of the product used in earlier clinical phases or at earlier portions of a trial to the product used in later clinical phases or later portions of the trial.

Any of these events could substantially increase our costs or lead to delays in our clinical trials.

***We rely, and expect to continue to rely, on third parties to conduct, supervise, and monitor our preclinical studies and clinical trials. If those third parties do not perform satisfactorily, including failing to meet deadlines for the completion of such trials or failing to comply with regulatory requirements, we may be unable to obtain regulatory approval for our product candidates or any other product candidates that we may develop in the future.***

We rely, and will rely, on third-party CROs, study sites and others to conduct, supervise, and monitor our preclinical studies and clinical trials for our product candidates and do not currently plan to independently conduct preclinical studies or clinical trials of any product candidates. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions, and clinical investigators, to conduct our preclinical studies and clinical trials. Although we have agreements governing their activities, we have limited influence over their actual performance and control only certain aspects of their activities. The failure of these third parties to successfully carry out their contractual duties or meet expected deadlines could substantially harm our business because we may be delayed in completing or unable to complete the studies required to support future approval of our product candidates, or we may not obtain marketing approval for or commercialize our product candidates in a timely manner or at all. Moreover, these agreements might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements our product development activities would be delayed and our business, financial condition, results of operations, stock price and prospects may be materially harmed.

## [Table of Contents](#)

Our reliance on these third parties for development activities will reduce our control over these activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and our reliance on third parties does not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our trials is conducted in accordance with the general investigational plan and protocols for the trial. We must also ensure that our preclinical trials are conducted in accordance with the FDA's Good Laboratory Practice, or GLP, regulations, as appropriate. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with standards, commonly referred to as GCPs for conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, clinical investigators, and trial sites. If we or any of our third parties fail to comply with applicable GCPs or other regulatory requirements, we or they may be subject to enforcement or other legal actions, the data generated in our trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional studies.

In addition, we will be required to report certain financial interests of our third-party investigators if these relationships exceed certain financial thresholds or meet other criteria. The FDA or comparable foreign regulatory authorities may question the integrity of the data from those clinical trials conducted by investigators who may have conflicts of interest.

We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our trials complies with the applicable regulatory requirements. In addition, our clinical trials must be conducted with product candidates that were produced under cGMP regulations. Failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We also are required to register certain clinical trials and post the results of certain completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in enforcement actions and adverse publicity.

The third parties with which we work may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting trials or other therapeutic development activities that could harm our competitive position. In addition, such third parties are not our employees, and except for remedies available to us under our agreements with such third parties we cannot control whether or not they devote sufficient time and resources to our ongoing clinical, non-clinical, and preclinical programs. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our preclinical studies or clinical trials in accordance with regulatory requirements or our stated protocols, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements or for other reasons, our trials may be repeated, extended, delayed, or terminated; we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates; we may not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates; or we or they may be subject to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business, financial condition, results of operations, stock price and prospects may be materially harmed.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative providers or to do so on commercially reasonable terms. Switching or adding additional third parties involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines.

We will also rely on other third parties to store and distribute our product candidates for the clinical trials that we conduct. Any performance failure on the part of our distributors could delay clinical development, marketing approval, or commercialization of our product candidates, which could result in additional losses and deprive us of potential product revenue.

***If the manufacturers upon which we rely fail to produce any product candidates in the volumes that we require on a timely basis, or fail to comply with stringent regulations applicable to biopharmaceutical manufacturers, we may face delays in the development and commercialization of, or be unable to meet demand for, any product candidates, and may lose potential revenues.***

For the near future, we will continue to rely on third-party contract manufacturers to manufacture our clinical trial product supplies. There can be no assurance that our clinical product supply will not be limited, interrupted, or of satisfactory quality or continue to be available at acceptable prices. In particular, any replacement of a contract manufacturer could require significant effort and expertise because there may be a limited number of qualified replacements. Any delays in obtaining adequate supplies of our product candidates that meet the necessary quality standards may delay our development or commercialization.

We may not succeed in our efforts to establish manufacturing relationships or other alternative arrangements for any of our product candidates or programs. Any product candidates we develop compete with other products and product candidates for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations that are both capable of manufacturing and filling our viral product for us and willing to do so. If our existing third-party CMOs, or the third-party providers, that we engage in the future should cease to work with us, we likely would experience delays in obtaining sufficient quantities of any product candidates for us to advance our clinical studies and trials while we identify and qualify replacement suppliers. If for any reason we are unable to obtain adequate supplies of any product candidates we develop or the substances used to manufacture them, it will be more difficult for us to develop product candidates and compete effectively.

## [Table of Contents](#)

Further, even if we do establish such collaborations or arrangements, our third-party manufacturers may breach, terminate, or not renew these agreements.

Any problems or delays we experience in preparing for commercial-scale manufacturing of a product candidate or component may result in a delay in product development timelines and FDA or comparable foreign regulatory authority approval of the product candidate or may impair our ability to manufacture commercial quantities or such quantities at an acceptable cost and quality, which could result in the delay, prevention, or impairment of clinical development and commercialization of any product candidates and may materially harm our business, financial condition, results of operations, stock price and prospects.

We currently have only one contract manufacturer for ONCR-177 for use in our clinical trials. In addition, we do not have any long-term commitments from our suppliers of clinical trial material or guaranteed prices for our product candidates or their components. The manufacture of biopharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of therapeutics often encounter difficulties in production, particularly in scaling up initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel or key raw materials, and compliance with strictly enforced federal, state, and foreign regulations. Our current and future contract manufacturers may not perform as agreed. If our manufacturers were to encounter these or other difficulties, our ability to provide product candidates to patients in our clinical trials could be jeopardized.

Contract manufacturers of our product candidates may be unable to comply with our specifications, applicable cGMP requirements or other FDA, state or foreign regulatory requirements. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of a product candidate that may not be detectable in final product testing. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, they will not be able to secure or maintain regulatory approval for their manufacturing facilities. Any such deviations may also require remedial measures that may be costly and/or time-consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business. Any delays in obtaining products or product candidates that comply with the applicable regulatory requirements may result in delays to clinical trials, product approvals, and commercialization. It may also require that we conduct additional studies.

While we are ultimately responsible for the manufacturing of our product candidates and therapeutic substances, other than through our contractual arrangements, we have little control over our manufacturers' compliance with these regulations and standards. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Any new manufacturers would need to either obtain or develop the necessary manufacturing know-how, and obtain the necessary equipment and materials, which may take substantial time and investment. We must also receive FDA approval for the use of any new manufacturers for commercial supply.

A failure to comply with the applicable regulatory requirements, including periodic regulatory inspections, may result in regulatory enforcement actions against our manufacturers or us (including fines and civil and criminal penalties, including imprisonment) suspension or restrictions of production, injunctions, delay or denial of product approval or supplements to approved products, clinical holds or termination of clinical trials, warning or untitled letters, regulatory authority communications warning the public about safety issues with the product candidate, refusal to permit the import or export of the products, product seizure, detention, or recall, operating restrictions, suits under the civil False Claims Act, corporate integrity agreements, consent decrees, withdrawal of product approval, environmental or safety incidents and other liabilities. If the safety of any quantities supplied is compromised due to our manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.

Any failure or refusal to supply our product candidates or components for our product candidates that we may develop could delay, prevent or impair our clinical development or commercialization efforts. Any change in our manufacturers could be costly because the commercial terms of any new arrangement could be less favorable and because the expenses relating to the transfer of necessary technology and processes could be significant.

***We may in the future seek to establish collaborations, and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.***

We may in the future seek collaboration arrangements with other parties for the development or commercialization of our product candidates. The success of any collaboration arrangements may depend on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these arrangements. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision making authority.

## [Table of Contents](#)

Collaborations with biopharmaceutical companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration could adversely affect us financially and could harm our business reputation.

Any future collaborations we might enter into may pose a number of risks, including the following:

- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could fail to make timely regulatory submissions for a product candidate;
- collaborators may not comply with all applicable regulatory requirements or may fail to report safety data in accordance with all applicable regulatory requirements, which could subject them or us to regulatory enforcement actions;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product candidate or product;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation; and
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability.

In addition, if we establish one or more collaborations, all of the risks relating to product development, regulatory approval and commercialization described in this report would also apply to the activities of any such future collaborators.

If any collaborations we might enter into in the future do not result in the successful development and commercialization of products or if one of our future collaborators subsequently terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under such potential future collaboration. If we do not receive the funding we expect under the agreements, our development of our product candidates could be delayed and we may need additional resources to develop our product candidates and our product platform.

Additionally, if any future collaborator of ours is involved in a business combination, the collaborator might deemphasize or terminate development or commercialization of any product candidate licensed to it by us. If one of our future collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our reputation in the business and financial communities could be adversely affected.

We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for any collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms, or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our product platform and our business may be materially and adversely affected.

## Risks Related to Commercialization of Our Product Candidates

***If we are unable to successfully commercialize any product candidate for which we receive regulatory approval, or experience significant delays in doing so, our business will be materially harmed.***

If we are successful in obtaining marketing approval from applicable regulatory authorities for ONCR-177 or any other product candidate, our ability to generate revenues from any such products will depend on our success in:

- launching commercial sales of such products, whether alone or in collaboration with others;
- receiving approved labels with claims that are necessary or desirable for successful marketing, and that do not contain safety or other limitations that would impede our ability to market such products;
- creating market demand for such products through marketing, sales and promotion activities;
- hiring, training, and deploying a sales force or contracting with third parties to commercialize such products in the United States;
- creating partnerships with, or offering licenses to, third parties to promote and sell such products in foreign markets where we receive marketing approval;
- manufacturing such products in sufficient quantities and at acceptable quality and cost to meet commercial demand at launch and thereafter;
- establishing and maintaining agreements with wholesalers, distributors, and group purchasing organizations on commercially reasonable terms;
- maintaining patent and trade secret protection and regulatory exclusivity for such products;
- achieving market acceptance of such products by patients, the medical community, and third-party payors;
- achieving coverage and adequate reimbursement from third-party payors for such products;
- patients' willingness to pay out-of-pocket in the absence of such coverage and adequate reimbursement from third-party payors;
- effectively competing with other therapies; and
- maintaining a continued acceptable safety profile of such products following launch.

To the extent we are not able to do any of the foregoing, our business, financial condition, results of operations, stock price and prospects will be materially harmed.

***We face significant competition from other biopharmaceutical and biotechnology companies, academic institutions, government agencies, and other research organizations, which may result in others discovering, developing or commercializing products more quickly or marketing them more successfully than us. If their product candidates are shown to be safer or more effective than ours, our commercial opportunity may be reduced or eliminated.***

The development and commercialization of cancer immunotherapy products is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary rights. We face competition with respect to our current product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major biopharmaceutical companies, specialty biopharmaceutical companies, and biotechnology companies worldwide. There are a number of large biopharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of solid tumors, including viral immunotherapy and cancer vaccine approaches. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

While certain of our product candidates may be used in combination with other drugs with different mechanisms of action, if and when marketed they will still compete with a number of drugs that are currently marketed or in development that also target cancer. To compete effectively with these drugs, our product candidates will need to demonstrate advantages in clinical efficacy and safety compared to these competitors when used alone or in combination with other drugs.

Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are easier to administer or are less expensive alone or in combination with other therapies than any products that we may develop alone or in combination with other therapies. Our competitors also may obtain FDA or comparable foreign regulatory authorities' approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by third-party payors' coverage and reimbursement decisions.

## [Table of Contents](#)

Many of the companies with which we are competing or may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Mergers and acquisitions in the biopharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in developing or acquiring technologies complementary to, or necessary for, our programs. If we are unable to successfully compete with these companies our business, financial condition, results of operations, stock price and prospects may be materially harmed.

***If we are unable to establish effective marketing, sales and distribution capabilities or enter into agreements with third parties to market and sell our product candidates, if they are approved, the revenues that we generate may be limited and we may never become profitable.***

We currently do not have a commercial infrastructure for the marketing, sale, and distribution of any products that we may develop. If and when our product candidates receive marketing approval, we intend to commercialize our product candidates on our own or in collaboration with others and potentially with pharmaceutical or biotechnology partners in other geographies. In order to commercialize our products, we must build our marketing, sales, and distribution capabilities or make arrangements with third parties to perform these services. We may not be successful in doing so. Should we decide to move forward in developing our own marketing capabilities, we may incur expenses prior to product launch or even approval in order to recruit a sales force and develop a marketing and sales infrastructure. If a commercial launch is delayed as a result of the FDA or comparable foreign regulatory authority requirements or other reasons, we would incur these expenses prior to being able to realize any revenue from sales of our product candidates. Even if we are able to effectively hire a sales force and develop a marketing and sales infrastructure, our sales force and marketing teams may not be successful in commercializing our product candidates. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

We may also or alternatively decide to collaborate with third-party marketing and sales organizations to commercialize any approved product candidates, in which event, our ability to generate product revenues may be limited. To the extent we rely on third parties to commercialize any products for which we obtain regulatory approval, we may receive less revenues than if we commercialized these products ourselves, which could materially harm our prospects. In addition, we would have less control over the sales efforts of any other third parties involved in our commercialization efforts, and could be held liable if they failed to comply with applicable legal or regulatory requirements.

We have no prior experience in the marketing, sale, and distribution of biopharmaceutical products, and there are significant risks involved in building and managing a commercial infrastructure. The establishment and development of commercial capabilities, including compliance plans, to market any products we may develop will be expensive and time consuming and could delay any product launch, and we may not be able to successfully develop this capability. We will have to compete with other biopharmaceutical and biotechnology companies, including oncology-focused companies, to recruit, hire, train, manage, and retain marketing and sales personnel, which is expensive and time consuming and could delay any product launch. Developing our sales capabilities may also divert resources and management attention away from product development.

In the event we are unable to develop a marketing and sales infrastructure, we may not be able to commercialize our product candidates, which could limit our ability to generate product revenues and materially harm our business, financial condition, results of operations, stock price and prospects. Factors that may inhibit our efforts to commercialize our product candidates include:

- the inability to recruit, train, manage, and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or educate adequate numbers of physicians on the benefits of prescribing our product candidates;
- our inability to effectively oversee a geographically dispersed sales and marketing team;
- the costs associated with training personnel, including sales and marketing personnel, on compliance matters and monitoring their actions;
- an inability to secure coverage and adequate reimbursement by third-party payors, including government and private health plans;
- the unwillingness of patients to pay out-of-pocket in the absence of coverage and adequate reimbursement from third-party payors;
- the clinical indications for which the products are approved and the claims that we may make for the products;
- limitations or warnings, including distribution or use restrictions, contained in the products' approved labeling;

## Table of Contents

- any distribution and use restrictions imposed by the FDA or comparable foreign regulatory authorities or to which we agree as part of a mandatory REMS or voluntary risk management plan;
- liability for our personnel, including sales or marketing personnel, who fail to comply with applicable law;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization or engaging a contract sales organization.

***Even if any of our product candidates receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, hospitals, cancer treatment centers, third-party payors and others in the medical community necessary for commercial success. The revenues that we generate from their sales may be limited, and we may never become profitable.***

We have never commercialized a product candidate for any indication. Even if our product candidates are approved by the appropriate regulatory authorities for marketing and sale, they may not gain acceptance among physicians, patients, third-party payors, and others in the medical community. If any product candidates for which we obtain regulatory approval does not gain an adequate level of market acceptance, we could be prevented from or significantly delayed in achieving profitability. Market acceptance of our product candidates by the medical community, patients, and third-party payors will depend on a number of factors, some of which are beyond our control. For example, physicians are often reluctant to switch their patients and patients may be reluctant to switch from existing therapies even when new and potentially more effective or safer treatments enter the market.

Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. If any of our product candidates is approved but does not achieve an adequate level of market acceptance, we could be prevented from or significantly delayed in achieving profitability. The degree of market acceptance of any product for which we receive marketing approval will depend on a number of factors, including:

- the efficacy of our product both as a monotherapy and in combination with marketed checkpoint inhibitors;
- the commercial success of any checkpoint inhibitors with which our product may be co-administered;
- the prevalence and severity of adverse events associated with our product or those products with which it is co-administered;
- the clinical indications for which our product is approved and the approved claims that we may make with respect to the product;
- limitations or warnings contained in the FDA-approved labeling of the product or the labeling approved by comparable foreign regulatory authorities, including potential limitations or warnings for our product that may be more restrictive than other competitive products;
- changes in the standard of care for the targeted indications for our product, which could reduce the marketing impact of any claims that we could make following FDA approval or approval by comparable foreign regulatory authorities, if obtained;
- the relative convenience and ease of administration of our product and any products with which it is co-administered;
- the cost of treatment compared with the economic and clinical benefit of alternative treatments or therapies;
- the availability of coverage and adequate reimbursement by third-party payors, such as private insurance companies and government healthcare programs, including Medicare and Medicaid;
- patients' willingness to pay out-of-pocket in the absence of such coverage and adequate reimbursement from third-party payors;
- the price concessions required by third-party payors to obtain coverage and adequate reimbursement;
- the extent and strength of our marketing and distribution of our product;
- the safety, efficacy, and other potential advantages over, and availability of, alternative treatments already used or that may later be approved;
- distribution and use restrictions imposed by the FDA or comparable foreign regulatory authorities with respect to our product or to which we agree as part of a REMS or voluntary risk management plan;
- the timing of market introduction of our product, as well as competitive products;
- our ability to offer our product for sale at competitive prices;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the extent and strength of our third-party manufacturer and supplier support;
- the actions of companies that market any products with which our product is co-administered;

## [Table of Contents](#)

- the approval of other new products;
- adverse publicity about our product or any products with which it is co-administered, or favorable publicity about competitive products; and
- potential product liability claims.

***The size of the potential market for our product candidates is difficult to estimate and, if any of our assumptions are inaccurate, the actual markets for our product candidates may be smaller than our estimates.***

The potential market opportunities for our product candidates are difficult to estimate and will depend in large part on the drugs with which our product candidates are co-administered and the success of competing therapies and therapeutic approaches. In particular, the market opportunity for viral immunotherapies is hard to estimate given that it is an emerging field with only one existing FDA-approved viral immunotherapy, T-VEC, which has yet to enjoy broad market acceptance. Our estimates of the potential market opportunities are predicated on many assumptions, which may include industry knowledge and publications, third-party research reports, and other surveys. Although we believe that our internal assumptions are reasonable, these assumptions involve the exercise of significant judgment on the part of our management, are inherently uncertain, and their reasonableness has not been assessed by an independent source. If any of the assumptions proves to be inaccurate, the actual markets for our product candidates could be smaller than our estimates of the potential market opportunities.

***Negative developments in the field of immuno-oncology could damage public perception of our oHSV and Synthetic Platforms and our product candidates, including ONCR-177, and negatively affect our business.***

The commercial success of our product candidates will depend in part on public acceptance of the use of cancer viral immunotherapies. Adverse events in clinical trials of our product candidates, including ONCR-177, or in clinical trials of others developing similar products and the resulting publicity, as well as any other negative developments in the field of immuno-oncology that may occur in the future, including in connection with competitor therapies or with checkpoint inhibitors, could result in a decrease in demand for ONCR-177 or any other product candidates that we may develop. These events could also result in the suspension, discontinuation, or clinical hold of or modification to our clinical trials. If public perception is influenced by claims that the use of cancer immunotherapies is unsafe, whether related to our therapies or those of our competitors, our product candidates may not be accepted by the general public or the medical community and potential clinical trial subjects may be discouraged from enrolling in our clinical trials. As a result, we may not be able to continue or may be delayed in conducting our development programs.

As our product candidates consist of modified or synthetic viruses, adverse developments in anti-viral vaccines or clinical trials of other viral immunotherapy products based on viruses may result in a disproportionately negative effect for ONCR-177 or our other product candidates as compared to other products in the field of immuno-oncology that are not based on viruses. Future negative developments in the field of immuno-oncology or the biopharmaceutical industry could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our products. Any increased scrutiny could delay or increase the costs of obtaining marketing approval for ONCR-177 or our other product candidates.

### **Risks Related to Intellectual Property**

***If we are unable to obtain, maintain and protect our intellectual property rights for our technology and product candidates, or if our intellectual property rights are inadequate, our competitive position could be harmed.***

Our commercial success will depend in part on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our technology, including our oHSV Platform and Synthetic Platform, and ONCR-177 and our other product candidates. We also rely in part on trade secret, copyright and trademark laws, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. We seek to protect our proprietary position by filing and prosecuting patent applications in the United States and abroad related to our technology and product candidates.

The patent positions of biotechnology and pharmaceutical companies generally are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our licensed patents and any patents we own are highly uncertain. The steps we have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights, both inside and outside of the United States.

Further, the examination process may require us to narrow the claims for our pending patent applications, which may limit the scope of patent protection that may be obtained if these applications issue. Our pending and future patent applications may not result in patents being issued that protect our product candidates, in whole or in part, or which effectively prevent others from commercializing competitive product candidates. The scope of a patent may also be reinterpreted after issuance. The rights that may be granted under our issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors

## [Table of Contents](#)

from competing with us or otherwise provide us with any competitive advantage. If we are unable to obtain and maintain patent protection for our technology or for ONCR-177 or our other product candidates, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize products similar or superior to ours in a non-infringing manner, and our ability to successfully commercialize ONCR-177 or our other product candidates and future technologies may be adversely affected. It is also possible that we will fail to identify patentable aspects of inventions made in the course of our development and commercialization activities before it is too late to obtain patent protection on them.

In addition, the patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, collaborators, and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. It is also possible that we will fail to identify patentable aspects of our research and development efforts in time to obtain patent protection.

For the core technology in our oHSV Platform and Synthetic Platform and ONCR-177 and our other product candidates, patent applications are pending at each of the U.S. provisional, Patent Cooperation Treaty, or PCT, and national stages with, minimally, filings submitted to the U.S., European Patent Conventions, or EPC, and Japan. As of July 1, 2020, our patent portfolio consisted of 15 issued U.S. patents, 14 pending U.S. patent applications, 11 issued foreign patents and 96 pending foreign applications. Any future provisional patent applications are not eligible to become issued patents until, among other things, we file a non-provisional patent application within 12 months of filing of one or more of our related provisional patent applications. If we do not timely file any non-provisional patent applications, we may lose our priority date with respect to our provisional patent applications and any patent protection on the inventions disclosed in our provisional patent applications. Although we intend to timely file non-provisional patent applications relating to our provisional patent applications, we cannot predict whether any of our future patent applications will result in the issuance of patents that effectively protect our technology or ONCR-177 or our other product candidates, or if any of our future issued patents will effectively prevent others from commercializing competitive products. We may be subject to a third-party preissuance submission of prior art to the U.S. Patent and Trademark Office, or USPTO. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or in some cases not at all until they are issued as a patent. Therefore, we cannot be certain that we were the first to make the inventions claimed in our pending patent applications, or that we were the first to file for patent protection of such inventions.

Our pending applications cannot be enforced against third parties practicing the inventions claimed in such applications unless and until a patent issues from such applications with a claim that covers such third party activity. Because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, issued patents that we license from third parties or own in the future may be challenged in the courts or patent offices in the United States and abroad, including through opposition proceedings, derivation proceedings, post-grant review, *inter partes* review, interference proceedings or litigation. Such proceedings may result in the loss of patent protection, the narrowing of claims in such patents or the invalidity or unenforceability of such patents, which could limit our ability to stop others from using or commercializing similar or identical products, or limit the duration of the patent protection for our technology. Protecting against the unauthorized use of our patented inventions, trademarks and other intellectual property rights is expensive, time consuming, difficult and in some cases may not be possible. In some cases, it may be difficult or impossible to detect third-party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult. If we are unable to obtain, maintain, and protect our intellectual property our competitive advantage could be harmed, and it could result in a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

***If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose intellectual property rights that are important to our business.***

We are a party to license agreements with entities including the University of Pittsburgh, Northwestern University, WuXi Biologics, Ospedale San Raffaele S.r.l. and Fondazione Telethon, and the University of Chicago, and we may need to obtain additional licenses from others to advance our research and development activities or allow the commercialization of our current or future product candidates. These license agreements impose, and we expect that future license agreements will impose, various development, diligence, commercialization, and other obligations on us. For example, under our license agreement with the University of Pittsburgh, we are required to use commercially reasonable efforts to engage in various development and commercialization activities with respect to licensed products, and must satisfy specified milestone and royalty payment obligations. In spite of our efforts, our licensors might conclude that we have materially breached our obligations under such license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by the intellectual property under these license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical to ours and we may be required to cease our development and commercialization our product candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

## [Table of Contents](#)

Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our product candidates, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

***If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.***

In addition to seeking patent protection, we also rely on other proprietary rights, including protection of trade secrets, know-how and confidential and proprietary information. To maintain the confidentiality of our trade secrets and proprietary information, we enter into confidentiality agreements with our employees, consultants, collaborators, contractors, and other third parties who have access to our trade secrets. Our agreements with employees and consultants also provide that any inventions conceived by the individual employee or consultant in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. In addition, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. In the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our employees, consultants or contractors use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions.

Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information including a breach of our confidentiality agreements. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time consuming, and the outcome is unpredictable. In addition, some courts in and outside of the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. The disclosure of our trade secrets or the independent development of our trade secrets by a competitor or other third party would impair our competitive position and may materially harm our business, financial condition, results of operations, stock price and prospects.

***Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could harm our business.***

Our commercial success depends on our ability and the ability of any future collaborators to develop, manufacture, market and sell ONCR-177 and our other product candidates, and to use our related proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current and any other future product candidates, including interference proceedings, post-grant review, *inter partes* review and derivation proceedings before the USPTO. Third parties may assert infringement or other intellectual property claims against us based on existing patents or patents that may be granted in the future. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that we may be subject to claims of infringement of the patent rights of third parties. If we are found to infringe a third party's intellectual property rights, and we are unsuccessful in demonstrating that

such intellectual property rights are invalid or unenforceable, we could be required to obtain a license from such third party to continue developing, manufacturing and commercializing ONCR-177 and our other product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We also could be forced, including by court order, to cease developing, manufacturing, and commercializing ONCR-177 or our other product candidates. In addition, in any such proceeding or litigation, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar material adverse effect on our business. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Furthermore, in addition to developing ONCR-177 as a monotherapy, we also anticipate developing ONCR-177 in combination with the commercially available anti-PD-1 checkpoint inhibitor pembrolizumab. Pembrolizumab, while commercially available in the market, is covered by patents held by Merck. We have entered into a clinical trial collaboration and supply agreement with Merck under which Merck has agreed to supply pembrolizumab for our ongoing Phase 1 clinical trial. We also plan to develop our product candidates in combination with products developed by additional companies that are covered by patents or licenses held by those entities to which we do not have a license or a sublicense. In the event that a labeling instruction is required in product packaging recommending that combination, we could be accused of, or held liable for, infringement of the third-party patents covering the product candidate or product recommended for administration with ONCR-177 or our other product candidates. In such a case, we could be required to obtain a license from the other company or institution to use the required or desired package labeling, which may not be available on commercially reasonable terms, or at all.

### ***We may not be able to protect our intellectual property and proprietary rights throughout the world.***

Filing, prosecuting and defending patents on our technology throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws and practices of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop and/or manufacture their own products, and may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as that in the United States. These products may compete with our products and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the granting or enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to obtain patent rights or stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally in those countries. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to protect and enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property we develop or license.

In addition, the laws of certain foreign countries may not protect our rights to the same extent as the laws of the United States, and those foreign laws may also be subject to change. For example, methods of treatment and manufacturing processes may not be patentable in certain jurisdictions, and the requirements for patentability may differ in certain countries. Furthermore, biosimilar product manufacturers or other competitors may challenge the scope, validity and enforceability of our patents, requiring us to engage in complex, lengthy and costly litigation or proceedings.

Moreover, many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. Many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business and results of operations may be adversely affected.

***Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.***

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payments and other similar provisions during the patent application process and to maintain patents after they are issued. For example, periodic maintenance fees, renewal fees, annuity fees and various other government fees on issued patents and patent applications often must be paid to the USPTO and foreign patent agencies over the lifetime of our licensed patents or any patents we own. In certain circumstances, we may rely on future licensing partners to take the necessary action to comply with these requirements with respect to licensed intellectual property. Although an unintentional lapse can be cured for a period of time by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to obtain and maintain the patents and patent applications covering our products or procedures, we may not be able to stop a competitor from marketing products that are the same as or similar to ONCR-177 or our other product candidates, which could have a material adverse effect on our business.

***Changes to the patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect ONCR-177 and our other product candidates.***

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States or other jurisdictions in which we have or seek patent protection could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act, or the Leahy-Smith Act, signed into law in the United States on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. After March 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

***We may wish to acquire rights to future assets through in-licensing or may attempt to form collaborations in the future with respect to our product candidates, but may not be able to do so, which may cause us to alter or delay our development and commercialization plans.***

The development and potential commercialization of our product candidates will require substantial additional capital to fund expenses. We may, in the future, decide to collaborate with other biopharmaceutical companies for the development and potential commercialization of those product candidates in other countries or territories of the world. We will face significant competition in seeking appropriate collaborators. We may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. If and when we collaborate with a third party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third party. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the following:

- the design or results of clinical trials;
- the likelihood of approval by the FDA or comparable foreign regulatory authorities;
- the potential market for the product candidate;

## [Table of Contents](#)

- the costs and complexities of manufacturing and delivering such product candidate to patients;
- the potential of competing products;
- the existence of uncertainty with respect to our ownership of technology or other rights, which can exist if there is a challenge to such ownership without regard to the merits of the challenge; and
- industry and market conditions generally.

The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. We may also be restricted under any license agreements from entering into agreements on certain terms or at all with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators and changes to the strategies of the combined company. As a result, we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of any product candidate, reduce or delay one or more of our other development programs, delay the potential commercialization or reduce the scope of any planned sales or marketing activities for such product candidate, or increase our expenditures and undertake development, manufacturing or commercialization activities at our own expense. If we elect to increase our expenditures to fund development, manufacturing or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

***We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful and have a material adverse effect on the success of our business.***

Competitors may infringe our licensed patents or any patent we own or misappropriate or otherwise violate our intellectual property rights. Litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets, or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. If we were to initiate legal proceedings against a third party to enforce a patent covering our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. Our licensed patents and any patents we own in the future may become involved in priority or other intellectual property related disputes. Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. Also, third parties may initiate legal proceedings against us to challenge the validity or scope of our owned or licensed intellectual property rights. These proceedings can be expensive and time consuming. Many of our current and potential competitors have the ability to dedicate substantially greater resources to conduct intellectual property related litigations or proceedings than we can. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. Litigation and other intellectual property related proceedings could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, in an infringement proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or other intellectual property related proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation in the United States, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments in any such proceedings. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock, and could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development partnerships that would help us bring our product candidates to market. Any of the foregoing may have a material adverse effect our business, financial condition, results of operations, stock price and prospects.

***We may be subject to claims by third parties asserting that we, our employees or any future collaborators have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.***

Many of our employees, including our senior management team, were previously employed at, or consulted for, universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these people, including each member of our senior management team, executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such previous employment or consulting agreements, that assigned ownership of intellectual property relating to work performed under such agreements to the contracting third party. Although we try to ensure that our employees do not use, claim as theirs, or misappropriate the intellectual property, proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used, claimed as theirs, misappropriated or disclosed intellectual

property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms, or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management. Any of the foregoing may have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

***We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed confidential information of third parties or are in breach of non-competition or non-solicitation agreements with our competitors.***

We could be subject to claims that we or our employees, including senior management, have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of former employers or competitors or others. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we caused an employee to breach the terms of their non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor or other party. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to ONCR-177 and our other product candidates, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers, competitors or other parties. An inability to incorporate such technologies or features would have a material adverse effect on our business, and may prevent us from successfully commercializing ONCR-177 and our other product candidates. In addition, we may lose valuable intellectual property rights or personnel as a result of such claims. Moreover, any such litigation or the threat thereof may adversely affect our ability to hire employees or consultants. A loss of key personnel or their work product could hamper or prevent our ability to develop and commercialize ONCR-177 and our other product candidates, which could have an adverse effect on our business, financial condition, results of operations, stock price and prospects.

***If we obtain any issued patents covering our technology, such patents could be found invalid or unenforceable if challenged in court or before the USPTO or comparable foreign regulatory authority.***

If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering any of our technology, the defendant could counterclaim that the patent covering our product candidate is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be, among other things, an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be, among other things, an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, *inter partes* review, post-grant review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions, such as opposition proceedings. Such proceedings could result in revocation, cancellation or amendment to our patents in such a way that they no longer cover and protect ONCR-177 and our other product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. For example, with respect to the validity of our licensed patents or any patents we obtain in the future, we cannot be certain that there is no invalidating prior art of which we, our or our licensing partner's patent counsel, and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on ONCR-177 and our other product candidates. Such a loss of patent protection could have a material adverse impact on our business.

***Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time, and our product candidates for which we intend to seek approval as biological products may face competition sooner than anticipated.***

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, such as ONCR-177 and our other product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

## [Table of Contents](#)

In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, but no longer than 14 years from the product's approval date, which is limited to the approved indication (or any additional indications approved during the period of extension). However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authorities in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their products earlier than might otherwise be the case, which could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

The enactment of the Biologics Price Competition and Innovation Act of 2009, or BPCIA, as part of the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act, or ACA, created an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an existing brand product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. Certain changes, however, and supplements to an approved BLA, and subsequent applications filed by the same sponsor, manufacturer, licensor, predecessor in interest, or other related entity do not qualify for the 12-year exclusivity period.

ONCR-177 and our other product candidates are all biological product candidates. We anticipate being awarded market exclusivity for each of our biological product candidates that is subject to its own BLA for 12 years in the United States, 10 years in Europe and significant durations in other markets. However, the term of the patents that cover such product candidates may not extend beyond the applicable market exclusivity awarded by a particular country. For example, in the United States, if all of the patents that cover our particular biological product expire before the 12-year market exclusivity expires, a third party could submit a marketing application for a biosimilar product four years after approval of our biological product, the FDA could immediately review the application and approve the biosimilar product for marketing 12 years after approval of our biological product, and the biosimilar sponsor could then immediately begin marketing. Alternatively, a third party could submit a full BLA for a similar or identical product any time after approval of our biological product, and the FDA could immediately review and approve the similar or identical product for marketing and the third party could begin marketing the similar or identical product upon expiry of all of the patents that cover our particular biological product.

There is also a risk that this exclusivity could be changed in the future. For example, this exclusivity could be shortened due to congressional action or through other actions, including future proposed budgets, international trade agreements and other arrangements or proposals. Additionally, there is a risk that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. The extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. It is also possible that payors will give reimbursement preference to biosimilars over reference biologics, even absent a determination of interchangeability.

To the extent that we do not receive any anticipated periods of regulatory exclusivity for our product candidates or the FDA or foreign regulatory authorities approve any biosimilar, interchangeable, or other competing products to our product candidates, it could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

### **Risks Related to Government Regulations**

***If we fail to comply with federal and state healthcare laws, including fraud and abuse and patient privacy and security laws, we could face substantial penalties and our business, financial condition, results of operations, stock price and prospects will be materially harmed.***

Our current and future arrangements with healthcare providers, third-party payors, customers, and others may expose us to broadly applicable healthcare fraud and abuse, patient privacy and security, and other healthcare laws, which may constrain the business or financial arrangements and relationships through which we research, as well as, sell, market and distribute any products for which we obtain marketing approval. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- The federal Anti-Kickback Statute, which prohibits, among other things, individuals and entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs.

## [Table of Contents](#)

- The federal civil and criminal false claims laws, including, without limitation, the civil False Claims Act, and the federal civil monetary penalties law, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment of federal funds, and knowingly making, or causing to be made, a false record or statement material to a false or fraudulent claim to avoid, decrease or conceal an obligation to pay money to the federal government.
- The Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters.
- The federal physician payment transparency requirements, sometimes referred to as the Physician Payments Sunshine Act, created under the ACA and its implementing regulations, which require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by such physicians and their immediate family members, which will be expanded beginning in 2022, to require applicable manufacturers to report such information regarding its relationship with physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse midwives during the previous year.
- HIPAA, as amended by the Health Information Technology for Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose obligations on “covered entities,” including certain healthcare providers, health plans, and healthcare clearinghouses, as well as their respective “business associates” that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity and their subcontractors that use, disclose or otherwise process individually identifiable health information, with respect to safeguarding the privacy, security and transmission of individually identifiable health information.
- Analogous state and foreign anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or that apply regardless of payor; state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state and local laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state laws that require the reporting of information related to drug pricing; state and local laws requiring the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

If we or our operations are found to be in violation of any federal or state healthcare law, or any other governmental laws or regulations that apply to us, we may be subject to penalties, including significant civil, criminal, and administrative penalties, damages, monetary fines, disgorgement, imprisonment, suspension and debarment from government contracts, and refusal of orders under existing government contracts, exclusion from participation in U.S. federal or state health care programs, additional reporting requirements and/or oversight if we become subject to corporate integrity agreements or similar agreement to resolve allegations of non-compliance, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could materially adversely affect our ability to operate our business and our financial results. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, it may be subject to significant criminal, civil or administrative sanctions, including but not limited to, exclusions from participation in U.S. federal or state healthcare programs, which could also materially affect our business.

Although an effective compliance program can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Moreover, achieving and sustaining compliance with such laws may prove costly. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management’s attention from the operation of our business.

***If the government or third-party payors fail to provide adequate coverage, reimbursement and payment rates for our product candidates, or if health maintenance organizations or long-term care facilities choose to use therapies that are less expensive or considered a better value, our revenue and prospects for profitability will be limited.***

In both domestic and foreign markets, sales of our products will depend in part upon the availability of coverage and adequate reimbursement from third-party payors. Such third-party payors include government health programs such as Medicare and Medicaid, managed care providers, private health insurers, and other organizations. Coverage decisions may depend upon clinical and economic standards that disfavor new therapeutic products when more established or lower cost therapeutic alternatives are already available or subsequently become available, even if our products are alone in a class. Third-party payors establish reimbursement levels.

## [Table of Contents](#)

Therefore, even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain a market share sufficient to realize a sufficient return on our or their investments. If reimbursement is not available, or is available only to limited levels, our product candidates may be competitively disadvantaged, and we may not be able to successfully commercialize our product candidates. Alternatively, securing favorable reimbursement terms may require us to compromise pricing and prevent us from realizing an adequate margin over cost.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved therapeutics. Marketing approvals, pricing, and reimbursement for new therapeutic products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a therapeutic before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription biopharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay commercial launch of the product, possibly for lengthy time periods, which may negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval. Our ability to commercialize our product candidates will depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from third-party payors.

The healthcare industry is acutely focused on cost containment, both in the United States and elsewhere. Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. Several third-party payors are requiring that companies provide them with predetermined discounts from list prices, are using preferred drug lists to leverage greater discounts in competitive classes, are disregarding therapeutic differentiators within classes, are challenging the prices charged for therapeutics, and are negotiating price concessions based on performance goals. In addition, third-party payors are increasingly requiring higher levels of evidence of the benefits and clinical outcomes of new technologies, benchmarking against other therapies, seeking performance-based discounts, and challenging the prices charged. We cannot be sure that coverage will be available for any product candidate that we commercialize and, if available, that the reimbursement rates will be adequate. If payors subject our product candidates to maximum payment amounts, or impose limitations that make it difficult to obtain reimbursement, providers may choose to use therapies which are less expensive when compared to our product candidates. Additionally, if payors require high copayments, beneficiaries may seek alternative therapies. We may need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of any products to the satisfaction of hospitals, other target customers and their third-party payors. Such studies might require us to commit a significant amount of management time and financial and other resources. Our products might not ultimately be considered cost-effective. Adequate third-party coverage and reimbursement might not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in product development.

In addition, in the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions both in the United States and in international markets. Third-party coverage and reimbursement for our products or product candidates for which we receive regulatory approval may not be available or adequate in either the United States or international markets, which could have a negative effect on our business, financial condition, results of operations, stock price and prospects.

There may also be delays in obtaining coverage and reimbursement for newly approved therapeutics, and coverage may be more limited than the indications for which the product is approved by the FDA or comparable foreign regulatory authorities. Such delays have made it increasingly common for manufacturers to provide newly approved drugs to patients experiencing coverage delays or disruption at no cost for a limited period in order to ensure that patients are able to access the drug. Moreover, eligibility for reimbursement does not imply that any therapeutic will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new therapeutics, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary, by way of example, according to the use of the product and the clinical setting in which it is used. Reimbursement rates may also be based on reimbursement levels already set for lower cost products or may be incorporated into existing payments for other services.

An inability to promptly obtain coverage and adequate reimbursement from third-party payors for any of our product candidates for which we obtain marketing approval could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

***We are subject to new legislation, regulatory proposals and third-party payor initiatives that may increase our costs of compliance, and adversely affect our ability to market our products, obtain collaborators, and raise capital.***

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any products for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any approved products.

## [Table of Contents](#)

For example, the ACA was passed in March 2010 and substantially changed the way healthcare is financed by both governmental and private insurers, and continues to significantly impact the United States pharmaceutical industry. Since its enactment, there have been executive, judicial and political challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For example, the Tax Act includes a provision repealing the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseparable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case. It is unclear how such litigation and other efforts to repeal and replace the ACA will impact the ACA and our business. Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include, among other things, aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments, will remain in effect through 2030 unless additional Congressional action is taken. The Coronavirus Aid, Relief and Economic Security Act, or CARES Act, which was signed into law in March 2020 and is designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030. In addition, the American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The CMS promulgated regulations governing manufacturers’ obligations and reimbursement under the Medicaid Drug Rebate Program, and promulgated a regulation that limited Medicare Part B payment to certain hospitals for outpatient drugs purchased under the 340B program.

There has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. For example, the Trump administration’s budget proposal for fiscal year 2021 includes a \$135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent “principles” for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Further, the Trump administration previously released a “Blueprint” to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. Additionally, on July 24, 2020, the Trump administration announced four executive orders related to prescription drug pricing that attempt to implement several of the Trump administration proposals, including (i) a policy that would tie certain Medicare Part B drug prices to international drug prices, or the “most favored nation price,” the details of which were released on September 13, 2020 and also expanded the policy to cover certain Part D drugs; (ii) an order that directs the Department of Health and Human Services, or HHS, to finalize the Canadian drug importation proposed rule previously issued by HHS and makes other changes allowing for personal importation of drugs from Canada; (iii) an order that directs HHS to finalize the rulemaking process on modifying the Anti-Kickback Statute safe harbors for discounts for plans, pharmacies, and pharmaceutical benefit managers; (iv) a policy that reduces costs of insulin and EpiPens to patients of federally qualified health centers. The FDA also recently released a final rule, effective November 30, 2020, implementing a portion of the importation executive order providing guidance for states to build and submit importation plans for drugs from Canada. HHS has solicited feedback on some of these measures and has implemented others under its existing authority. Any new laws or regulations that result in additional reductions in Medicare and other healthcare funding could have a material adverse effect on customers for our products, if approved, and, accordingly, on our results of operations.

We expect that the ACA, as well as other federal and state healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria, increased regulatory burdens and operating costs, decreased net revenue from our biopharmaceutical products, decreased potential returns from our development efforts, and additional downward pressure on the price that we receive for any approved product. It is also possible that additional governmental action is taken to address the COVID-19 pandemic. For example, on August 6, 2020, the Trump administration issued an executive order that instructs the federal government to develop a list of “essential” medicines and then buy them and other medical supplies from U.S. manufacturers instead of from companies around the world, including China. The order is meant to reduce regulatory barriers to domestic pharmaceutical manufacturing and catalyze manufacturing technologies needed to keep drug prices low and the production of drug products in the United States. Any reduction in reimbursement from Medicare or other government healthcare programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from commercializing our products and being able to generate revenue, and we could be prevented from or significantly delayed in achieving profitability.

In addition, there have been a number of other legislative and regulatory proposals aimed at changing the biopharmaceutical industry. For instance, the Drug Quality and Security Act of 2013 imposes obligations on manufacturers of biopharmaceutical products related to product tracking and tracing. Further, manufacturers have product investigation, quarantine, disposition, and notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products that would result in serious adverse health consequences of death to humans, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

Compliance with the federal track and trace requirements may increase our operational expenses and impose significant administrative burdens. As a result of these and other new proposals, we may determine to change our current manner of operation, provide additional benefits or change our contract arrangements, any of which could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

***We are subject to the U.S. Foreign Corrupt Practices Act and other anti-corruption laws, as well as import and export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, and other consequences, which could adversely affect our business, financial condition, results of operations, stock price and prospects.***

Our operations are subject to anti-corruption laws, including the U.S. Foreign Corrupt Practices Act, or FCPA, and other anti-corruption laws that apply in countries where we do business. The FCPA and these other anti-corruption laws generally prohibit us and our employees and intermediaries from authorizing, promising, offering, providing, soliciting, or receiving, directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. We can be held liable for the corrupt or other illegal activities of our personnel or intermediaries, even if we do not explicitly authorize or have prior knowledge of such activities.

We are also subject to other laws and regulations governing our international operations, including applicable import and export control regulations, economic sanctions on countries and persons, anti-money laundering laws, customs requirements and currency exchange regulations, collectively referred to as the trade control laws.

We can provide no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws or other legal requirements, including trade control laws. If we are not in compliance with applicable anti-corruption laws or trade control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations, stock price and prospects. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted. An investigation of any potential violations of anti-corruption laws or trade control laws by U.S. or other authorities could also have an adverse impact on our reputation, our business, financial condition, results of operations, stock price and prospects.

***Failure to comply with health and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business.***

We may be subject to or affected by evolving federal, state and foreign data protection laws and regulations, such as laws and regulations that address privacy and data security. In the United States, numerous federal and state laws and regulations, including federal and state health information privacy laws, state data breach notification laws, and federal and state consumer protection laws, such as Section 5 of the Federal Trade Commission Act, govern the collection, use, disclosure and protection of health information and other personal information could apply to our operations. These laws and regulations are subject to differing interpretations and may be inconsistent among jurisdictions, and guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal information. In addition, we may obtain health information from third parties, including research institutions from which we obtain clinical trial data, that are subject to privacy and security requirements under HIPAA, as amended HITECH, and its implementing rules and regulations. Depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

Foreign data protection laws, including European Union, or EU, Regulation 2016/679, known as the General Data Protection Regulation, or GDPR, may also apply to health-related and other personal information obtained outside of the United States. The GDPR went into effect on May 25, 2018. The GDPR introduced new data protection requirements in the EU. Companies that violate the GDPR can face private litigation, restrictions on data processing, as well as fines up to the greater of €20 million or 4% of annual global revenue. The GDPR, which is wide-ranging in scope, imposes several requirements relating to control over personal data by individuals to whom personal data relates, the information that an organization must provide to individuals, the documentation an organization must maintain, the security and confidentiality of personal data, data breach notification, and the use of third party processors in connection with the processing of personal data. The GDPR also imposes strict rules on the transfer of personal data out of the European Economic Area, or EEA, to the United States. Although there are legal mechanisms to allow for the transfer of personal data from the EEA and Switzerland to the United States, there is current litigation challenging such mechanisms, and uncertainty about compliance with EU data protection laws remains. Such mechanisms may not be available or applicable with respect to the personal data processing activities necessary to research, develop, and market our products and services. Further, the United Kingdom's vote in favor of exiting the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is unclear how data transfers to and from the United Kingdom will be regulated. The GDPR, the applicable laws of EU Member States, and the applicable privacy laws of the United Kingdom may impact our business activities and increase our compliance costs and potential liability.

## [Table of Contents](#)

In addition, the California Consumer Privacy Act, or CCPA, took effect on January 1, 2020. The CCPA creates new individual privacy rights for California consumers (as the word is broadly defined in the law) and places increased privacy and security obligations on many organizations that handle personal information of consumers or households. The CCPA will require covered companies to provide new disclosures to consumers about such companies' data collection, use and sharing practices, provide such consumers with data privacy rights such as rights to access and delete their personal information, receive detailed information about how their personal information is used, and opt-out of certain sharing of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for certain data breaches that is expected to increase data breach litigation. The Attorney General and local government attorneys may also bring enforcement actions for alleged violations of the CCPA. Although there are some exemptions for clinical trial data and health information, the CCPA may impact our business activities and increase our compliance costs and potential liability. Many similar privacy laws have been proposed at the federal level and in other states.

Compliance with U.S. and foreign data protection laws and regulations could require us to take on more onerous obligations in our contracts, increase our costs of legal compliance, restrict our ability to collect, use and disclose data, or in some cases, impact our or our partners' suppliers' ability to operate in certain jurisdictions. Our or our vendors' actual or perceived failure to comply with U.S. and foreign data protection laws and regulations could result in government investigations and/or enforcement actions (which could include civil, criminal, and administrative penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could harm our business.

We publish privacy policies, self-certifications, and other documentation regarding our collection, use and disclosure of personal information and/or other confidential information. Although we endeavor to comply with our published policies, certifications, and documentation, we may at times fail to do so or may be perceived to have failed to do so. Moreover, despite our efforts, we may not be successful in achieving compliance if our employees or vendors fail to comply with our published policies, certifications, and documentation. Such failures can subject us to potential international, local, state and federal action if they are found to be deceptive, unfair, or misrepresentative of our actual practices.

***Violations of or liabilities under environmental, health and safety laws and regulations could subject us to fines, penalties or other costs that could have a material adverse effect on the success of our business.***

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures, the handling, use, storage, treatment and disposal of hazardous materials and wastes and the cleanup of contaminated sites. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We would incur substantial costs as a result of violations of or liabilities under environmental requirements in connection with our operations or property, including fines, penalties and other sanctions, investigation and cleanup costs and third-party claims. Although we generally contract with third parties for the disposal of hazardous materials and wastes from our operations, we cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials.

### **Risks Related to Managing Our Growth and Employee and Operational Matters**

***We are highly dependent on our key personnel, including our Chief Executive Officer, Chief Scientific Officer and Senior Vice President, Clinical Development. If we are not successful in attracting, motivating and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.***

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract, motivate and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management and particularly on the services of our scientific personnel including Theodore (Ted) Ashburn, M.D., Ph.D., our President and Chief Executive Officer, Christophe Quéva, Ph.D., our Chief Scientific Officer and Senior Vice President, Research and John Goldberg, M.D., our Senior Vice President, Clinical Development. We believe that their drug discovery and development experience and overall biopharmaceutical company management experience, would be difficult to replace. Any of our executive officers could leave our employment at any time, as all of our employees are "at-will" employees. We currently do not have "key person" insurance on any of our employees. The loss of the services of our key personnel and any of our other executive officers, key employees, and scientific and medical advisors, and our inability to find suitable replacements, could result in delays in our research and development objectives and harm our business.

## [Table of Contents](#)

Recruiting and retaining qualified employees, consultants and advisors for our business, including scientific and technical personnel, also will be critical to our success. Competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies and academic institutions for skilled individuals. In addition, failure to succeed in preclinical studies, clinical trials or applications for marketing approval may make it more challenging to recruit and retain qualified personnel. The inability to recruit, or the loss of services of certain executives, key employees, consultants or advisors, may impede the progress of our research, development and commercialization objectives and have a material adverse effect on our business, financial condition, results of operations and prospects.

***We will need to continue to expand the size of our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.***

As of September 30, 2020, we had 51 employees, including 40 employees engaged in research and development. As our development and commercialization plans and strategies develop, and as we transition into operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical, FDA and comparable foreign regulatory review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize ONCR-177 and any other product candidates we develop will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services. The services include substantially all aspects of clinical trial management and manufacturing. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of ONCR-177 and our other product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring qualified new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize ONCR-177 and our other product candidates and, accordingly, may not achieve our research, development and commercialization goals.

***Public health crises such as pandemics, including the COVID-19 pandemic, or similar outbreaks could materially and adversely affect our business, including the conduct of preclinical studies and clinical trials.***

In March 2020, the World Health Organization declared COVID-19 a global pandemic and the United States declared a national emergency with respect to COVID-19. In response to the COVID-19 pandemic, a number of governmental orders and other public health guidance measures have been implemented across much of the United States, including in the locations of our office, clinical trial sites and third parties on whom we rely. We anticipate that our clinical development timelines could be negatively affected by COVID-19, which could materially and adversely affect our business, financial condition and results of operations. Further, we have implemented a work-from-home policy allowing employees who can work from home to do so, while those needing to work in laboratory facilities work in shifts to reduce the number of people gathered together at one time. Business travel has been suspended, and online and teleconference technology is used to meet virtually rather than in person. We have taken measures to secure our research and development project activities, while work in laboratories has been organized to reduce risk of COVID-19 transmission. Our increased reliance on personnel working from home may negatively impact productivity, or disrupt, delay or otherwise adversely impact our business. For example, with our personnel working from home, some of our research activities that require our personnel to be in our laboratories could be delayed.

As a result of the COVID-19 pandemic, or similar pandemics, and related governmental orders and other public health guidance measures, we have and may in the future experience disruptions that could materially and adversely impact our preclinical studies, clinical trials, business, financial condition and results of operations. Potential disruptions might include but are not limited to:

- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in initiating or expanding clinical trials, including delays or difficulties with clinical site initiation and recruiting clinical site investigators and clinical site staff;

## [Table of Contents](#)

- increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting COVID-19 or other health conditions or being forced to quarantine;
- interruption of key clinical trial activities, such as clinical trial site data monitoring and efficacy, safety and translational data collection, processing and analyses, due to limitations on travel imposed or recommended by federal, state or local governments, employers and others or interruption of clinical trial subject visits, which may impact the collection and integrity of subject data and clinical study endpoints;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- delays or disruptions in preclinical experiments and studies due to restrictions of on-site staff and unforeseen circumstances at CROs and vendors;
- interruption or delays in the operations of the FDA and comparable foreign regulatory agencies;
- interruption of, or delays in receiving, supplies of our product candidates from third-party providers due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- limitations on employee or other resources that would otherwise be focused on the conduct of our clinical trials and preclinical work, including because of sickness of employees or their families, the desire of employees to avoid travel or contact with large groups of people, an increased reliance on working from home, school closures or mass transit disruptions;
- changes in regulations as part of a response to the COVID-19 pandemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether; and
- delays in necessary interactions with regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government or contractor personnel.

The COVID-19 global pandemic continues to rapidly evolve. The extent to which the outbreak may affect our preclinical activities, clinical trials, business, financial condition and results of operations will depend on future developments, which are highly uncertain and cannot be predicted at this time, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and actions to contain the outbreak or treat its impact, such as social distancing and quarantines or lock-downs in the United States, business closures or business disruptions and the effectiveness of actions taken in the United States to contain and treat the disease. Future developments in these and other areas present material uncertainty and risk with respect to our clinical trials, business, financial condition and results of operations.

***We depend on our information technology systems, and any failure of these systems could harm our business. Security breaches, loss of data, and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business, results of operations and financial condition.***

We collect and maintain information in digital and other forms that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the privacy, security, confidentiality, availability and integrity of such confidential information. We have established physical, electronic and organizational measures to safeguard and secure our systems to prevent a data compromise, and rely on commercially available systems, software, tools, and monitoring to provide security for our information technology systems and the processing, transmission and storage of digital information. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information. Our internal information technology systems and infrastructure, and those of our current and any future collaborators, contractors consultants, vendors, and other third parties on which we rely, are vulnerable to damage or unauthorized access or use resulting from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, denial or degradation of service attacks, ransomware, hacking, phishing and other social engineering attacks, attachments to emails, persons inside our organization, or persons with access to systems inside our organization.

The risk of a security breach or disruption or data loss, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. In addition, the prevalent use of mobile devices that access confidential information increases the risk of lost or stolen devices, security incidents, and data security breaches, which could lead to the loss of confidential information or other intellectual property. As a result of the COVID-19 pandemic, we may face increased risks of a security breach or disruption due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have

implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service, negative publicity, and other harm to our business and our competitive position. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Any security compromise affecting us, our partners or our industry, whether real or perceived, could harm our reputation, erode confidence in the effectiveness of our security measures, and lead to regulatory scrutiny. Moreover, if a computer security breach affects our systems or results in the unauthorized access to or unauthorized use, disclosure, release or other unauthorized processing of personal information, our reputation could be materially damaged. In addition, such a breach may require notification to governmental agencies, the media or individuals pursuant to various federal, state, and foreign privacy and security laws, if applicable, including HIPAA, as amended HITECH, and its implementing rules and regulations, as well as regulations promulgated by the Federal Trade Commission, state data breach notification laws, and the GDPR. We would also be exposed to a risk of loss, governmental investigations or enforcement, or litigation and potential liability, any of which could materially adversely affect our business, results of operations and financial condition.

***We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability and have to limit the commercialization of any approved products and/or our product candidates.***

The use of our product candidates in clinical trials, and the sale of any product for which we obtain regulatory approval, exposes us to the risk of product liability claims. We face inherent risk of product liability related to the testing of our product candidates in human clinical trials, including liability relating to the actions and negligence of our investigators, and will face an even greater risk if we commercially sell any product candidates that we may develop. For example, we may be sued if any product candidate we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. Product liability claims might be brought against us by consumers, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of merit or eventual outcome, liability claims may result in:

- loss of revenue from decreased demand for our products and/or product candidates;
- impairment of our business reputation or financial stability;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- diversion of management attention;
- withdrawal of clinical trial participants and potential termination of clinical trial sites or entire clinical programs;
- the inability to commercialize our product candidates;
- significant negative media attention;
- decreases in our stock price;
- initiation of investigations and enforcement actions by regulators; and
- product recalls, withdrawals or labeling, marketing or promotional restrictions, including withdrawal of marketing approval.

We believe we have sufficient insurance coverage in place for our business operations. However, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We intend to expand our insurance coverage to include clinical trials and the sale of commercial products if we obtain FDA or comparable foreign regulatory approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing, or at all. Failure to obtain and retain sufficient product liability insurance at an acceptable cost could prevent or inhibit the commercialization of products we develop. On occasion, large judgments have been awarded in class action lawsuits based on therapeutics that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash, and materially harm our business, financial condition, results of operations, stock price and prospects.

***Our employees, independent contractors, consultants, commercial partners, principal investigators, CMOs, or CROs may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading, which could have a material adverse effect on our business.***

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees, independent contractors, consultants, commercial partners, principal investigators, CMOs or CROs could include intentional, reckless, negligent, or unintentional failures to comply with FDA regulations, comply with applicable fraud and abuse laws, provide accurate information to the FDA, properly calculate pricing information required by federal programs, report financial information or data accurately or disclose unauthorized activities to us. This misconduct could also involve the improper use or misrepresentation of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter this type of misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Moreover, it is possible for a whistleblower to pursue a False Claims Act case against us even if the government considers the claim unmeritorious and/or declines to intervene, which could require us to incur costs defending against such a claim. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations, stock price and prospects, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in U.S. federal healthcare programs, integrity oversight and reporting obligations to resolve allegations of non-compliance, imprisonment, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations.

#### **General Risks Related to an Investment in Our Common Stock**

***An active trading market for our common stock may not develop or be sustained.***

Prior to our IPO in October 2020, there was no public market for shares of our common stock. Although our common stock is traded on the Nasdaq Global Market, an active trading market for our shares may never develop or be sustained. In the absence of an active trading market for our common stock, investors may not be able to sell their common stock at the time that they would like to sell. An inactive trading market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to enter into collaborations or acquire other companies or technologies using our shares as consideration.

## [Table of Contents](#)

***Our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.***

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expense related to the ongoing development of our product candidates, preclinical development programs and our oHSV Platform and Synthetic Platform;
- results of preclinical studies and future clinical trials, or the addition or termination of future clinical trials or funding support by us, or future collaborators or licensing partners;
- our execution of any collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under existing or future arrangements or the termination or modification of any such existing or future arrangements;
- any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- additions and departures of key personnel;
- strategic decisions by us, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- if any of our product candidates receives regulatory approval, the terms of such approval and market acceptance and demand for such product candidates; and
- regulatory developments affecting our product candidates.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

***The market price of our common stock may be volatile and fluctuate substantially.***

Our stock price is likely to be volatile. The stock market in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme price and volume fluctuations that have been often unrelated or disproportionate to the operating performance of the issuer. In particular, the trading prices for pharmaceutical, biopharmaceutical and biotechnology companies have been highly volatile as a result of the impact of the COVID-19 pandemic. The market price for our common stock may be influenced by many factors, including:

- results from, and any delays in, our clinical trial for ONCR-177, our preclinical studies and any other future clinical development programs, including any delays related to the COVID-19 pandemic;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- commencement or termination of collaboration, licensing or similar arrangements for our development programs;
- announcements by our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- failure or discontinuation of any of our development programs;
- results of clinical trials of product candidates of our competitors;
- developments or setbacks related to drugs that are co-administered with any of our product candidates, such as checkpoint inhibitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to the development of ONCR-177 and any other product candidate we may develop;
- variations in our financial results or those of companies that are perceived to be similar to us;
- announcements or expectations of additional financing efforts by us;

## [Table of Contents](#)

- sales of our common stock by us, our insiders or other stockholders;
- expiration of market stand-off or lock-up agreements;
- recommendations and changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, political, and market conditions and overall fluctuations in the financial markets in the United States and abroad; and
- investors' general perception of us and our business.

These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from selling their shares at or above the price paid for the shares and may otherwise negatively affect the liquidity of our common stock.

### ***We could be subject to securities class action litigation.***

In the past, securities class action litigation has often been brought against public companies following declines in the market prices of their securities. This risk is especially relevant for biopharmaceutical companies, which have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and our resources, which could harm our business.

### ***We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.***

Investors should not rely on an investment in our common stock to provide dividend income. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock, which may never occur, as the only way to realize any return on their investment.

### ***Concentration of ownership of our shares of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.***

Following our IPO in October 2020, our directors, executive officers and holders of at least 5% of our outstanding common stock, including their respective affiliated persons and entities, together beneficially own a majority of our outstanding common stock. As a result, if this group were to act together, they would be able to control the outcome of matters requiring stockholder approval, including the election and removal of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. The concentration of voting power and transfer restrictions could delay or prevent an acquisition of our company on terms that other shareholders may desire or result in the management of our company in ways with which other stockholders disagree.

### ***Conflicts of interest may arise because some members of our board of directors are representatives of our principal stockholders.***

Certain of our principal stockholders or their affiliates are venture capital funds or other investment vehicles that could invest in entities that directly or indirectly compete with us. As a result of these relationships, conflicts may arise between the interests of the principal stockholders or their affiliates and the interests of other stockholders, and members of our board of directors that are representatives of such principal stockholders may not be disinterested in such conflicts. Neither the principal stockholders nor the representatives of the principal stockholders on our board of directors, by the terms of our amended and restated certificate of incorporation, are required to offer us any transaction opportunity of which they become aware and could take any such opportunity for themselves or offer it their other affiliates, unless such opportunity is expressly offered to them solely in their capacity as members of our board of directors.

### ***A significant portion of our total outstanding shares of common stock are currently restricted from immediate resale, but may be sold into the market in the near future. This could cause the market price of our shares to drop significantly, even if our business is doing well.***

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of shares of our common stock in the public market, the market price of our common stock could decline significantly.

We have approximately 22.6 million shares of common stock outstanding. Of these shares, approximately 6.6 million shares of common stock sold in the IPO are freely tradable, and the remaining 16.0 million shares of common stock will be available for sale in the public market on March 31, 2021 following the expiration of lock-up agreements entered into by our stockholders in connection with the IPO. The representatives of the underwriters for our IPO may agree to release these stockholders from their lock-up agreements at any time and without notice, which would allow for earlier sales of shares in the public market. Sales of a substantial number of such shares upon expiration of the lock-up agreements, the perception that such sales may occur, or early release of restrictions in the lock-up agreements, could cause the market price of our common stock to fall or make it more difficult to sell shares.

In addition, we filed a registration statement on Form S-8 to register our shares of common stock that are issuable pursuant to our equity incentive plans. Shares registered under this registration statement on Form S-8 will be available for sale in the public market subject to vesting arrangements and exercise of options, the lock-up agreements described above and, in the case of our affiliates, the restrictions of Rule 144 under the Securities Act.

Additionally, the holders of an aggregate of 15.0 million shares of our common stock, or their transferees, have rights, subject to some conditions, to require us to file one or more registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other shareholders. If we were to register the resale of these shares, they could be freely sold in the public market. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

***If securities analysts publish negative evaluations of our stock, the price of our stock could decline.***

The trading market for our common stock will rely, in part, on the research and reports that industry or financial analysts publish about us or our business. If one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which, in turn, could cause our stock price to decline.

***We will incur significantly increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.***

As a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, Nasdaq listing requirements and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance

## [Table of Contents](#)

costs and to make some activities more time consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain sufficient coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. The increased costs may require us to reduce costs in other areas of our business or increase the prices of our services. Moreover, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

### ***We are an “emerging growth company” and a “smaller reporting company” and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies or smaller reporting companies will make our common stock less attractive to investors.***

We are an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including (i) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, (ii) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (iii) exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not approved previously. In addition, as an emerging growth company, we are only required to provide two years of audited financial statements in our annual reports on Form 10-K. Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to take advantage of the benefits of this extended transition period. Our consolidated financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards. Until the date that we are no longer an “emerging growth company” or affirmatively and irrevocably opt out of the exemption provided by Section 7(a)(2)(B) of the Securities Act, upon issuance of a new or revised accounting standard that applies to our consolidated financial statements and that has a different effective date for public and private companies, we will disclose the date on which adoption is required for non-emerging growth companies and the date on which we will adopt the recently issued accounting standard.

We could be an emerging growth company until December 31, 2025, although circumstances could cause us to lose that status earlier, including if we are deemed to be a “large accelerated filer,” which occurs when the market value of our common stock that is held by non-affiliates equals or exceeds \$700.0 million as of the prior June 30, or if we have total annual gross revenue of \$1.07 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31, or if we issue more than \$1.0 billion in non-convertible debt during any three-year period before that time, in which case we would no longer be an emerging growth company immediately. Even after we no longer qualify as an emerging growth company, we may still qualify as a “smaller reporting company,” which would allow us to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

We cannot predict if investors will find our common stock less attractive because we may rely on the exemptions and reduced disclosure obligations applicable to emerging growth companies and smaller reporting companies. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our share price may be more volatile.

### ***If we fail to maintain proper and effective internal controls over financial reporting our ability to produce accurate and timely financial statements could be impaired.***

Pursuant to Section 404 of the Sarbanes-Oxley Act, our management will be required to report upon the effectiveness of our internal control over financial reporting beginning with our second annual report on Form 10-K, which we expect to file in the first quarter of 2022. When we lose our status as an “emerging growth company” and a “smaller reporting company,” our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Securities Exchange Act of 1934, as amended, or the Exchange Act, we will need to implement additional financial and management controls, reporting systems and procedures and hire additional accounting and finance staff.

## Table of Contents

We cannot assure you that there will not be material weaknesses in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness in our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

### ***Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.***

We are subject to the periodic reporting requirements of the Exchange Act. We must design our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make a required related party transaction disclosure. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

### ***Provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.***

Provisions in our amended and restated certificate of incorporation and our amended and restated by laws and provisions of Delaware law may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which investors might otherwise receive a premium for their shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that not all members of the board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- prohibit our stockholders from calling a special meeting of our stockholders;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a stockholder rights plan, or so-called “poison pill,” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 66<sup>2</sup>/3% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns 15% or more of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired 15% or more of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

## [Table of Contents](#)

***Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.***

Our amended and restated certificate of incorporation, which became effective upon the completion of the IPO, provides that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders;
- any action or proceeding asserting a claim against us or any of our current or former directors, officers or other employees, arising out of or pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws;
- any action or proceeding to interpret, apply, enforce or determine the validity of our certificate of incorporation or our bylaws; and
- any action asserting a claim against us or any of our directors, officers or other employees governed by the internal affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage these types of lawsuits. If a court were to find either exclusive forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving such action in other jurisdictions, which could seriously harm our business.

## **Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.**

### ***(a) Sales of Unregistered Securities***

From January 1, 2020 through September 30, 2020, we granted options to purchase an aggregate of 182,147 shares of our common stock, pursuant to our 2016 Equity Incentive Plan, as amended, with a weighted average exercise price of \$7.47 per share. From January 1, 2020 through September 30, 2020, certain of our employees exercised options to purchase an aggregate of 64,062 shares of our common stock pursuant to options issued under our 2016 Equity Incentive Plan, with a weighted average exercise price of \$1.70 per share, for an aggregate purchase price of \$109,000. These issuances were exempt from registration under the Securities Act, pursuant to the exemption provided in Rule 701 of the Securities Act.

### ***(b) Use of Proceeds from Initial Public Offering of Common Stock***

On October 1, 2020, our Registration Statement on Form S-1, as amended (File No. 333-248757) was declared effective in connection with the IPO of our common stock, pursuant to which we registered an aggregate of 6,670,000 shares of our common stock, of which we sold 6,557,991 shares, including the partial exercise of the underwriters' option to purchase additional shares, at a price to the public of \$15.00 per share. The offering closed on October 6, 2020, and, as a result, we received net proceeds of \$88.2 million (after deducting underwriters' discounts and commissions of approximately \$6.9 million and additional offering related costs of approximately \$3.3 million). The joint book-running managers of the offering were Jefferies LLC, Evercore Group L.L.C. and Piper Sandler & Co.

No expenses incurred by us in connection with our IPO were made directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities, or (iii) any of our affiliates. We did not receive any proceeds until the IPO closed on October 6, 2020, which occurred after the end of the period covered by this Quarterly Report on Form 10-Q. Accordingly, we had not used any of the proceeds of the offering as of September 30, 2020.

The principal purposes of the IPO were to create a public market for our common stock and to facilitate our future access to the public equity markets, as well as to obtain additional capital. We anticipate that we will use the net proceeds from the IPO to advance our clinical programs, including ONCR-177, to fund our preclinical programs, to expand our manufacturing capabilities and for working capital and general corporate purposes, which may include capital expenditures, other corporate expenses and acquisitions of complementary technologies or assets. We currently have no agreements or commitments with respect to acquisitions of complementary technologies or assets. The timing and amount of our actual expenditures will be based on many factors, including cash flows from operations.

We intend to invest the net proceeds in a variety of short-term, interest-bearing, investment grade securities. There has been no material change in the planned use of proceeds from our IPO from that described in the final prospectus filed by us with the Securities and Exchange Commission pursuant to Rule 424(b) on October 2, 2020.

## **Item 3. Defaults Upon Senior Securities.**

None.

## **Item 4. Mine Safety Disclosures.**

Not applicable.

**Item 5. Other Information.**

None.

## Table of Contents

### Item 6. Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
3.1	<a href="#"><u>Amended and Restated Certificate of Incorporation of the Registrant (incorporated herein by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-39575), filed with the SEC on October 6, 2020).</u></a>
3.2	<a href="#"><u>Amended and Restated Bylaws of the Registrant (incorporated herein by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-39575), filed with the SEC on October 6, 2020).</u></a>
4.1	<a href="#"><u>Common Stock Certificate of the Registrant (incorporated herein by reference to Exhibit 4.2 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (File No. 333-248757), filed with the SEC on September 28, 2020).</u></a>
10.1*	<a href="#"><u>2020 Equity Incentive Plan.</u></a>
10.2*	<a href="#"><u>2020 Employee Stock Purchase Plan.</u></a>
10.3	<a href="#"><u>Amended and Restated Employment Agreement by and between the Registrant and Theodore (Ted) Ashburn, M.D., Ph.D., effective as of October 6, 2020 (incorporated herein by reference to Exhibit 10.20 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (File No. 333-248757), filed with the SEC on September 28, 2020).</u></a>
10.4	<a href="#"><u>Amended and Restated Employment Agreement by and between the Registrant and John McCabe, effective as of October 6, 2020 (incorporated herein by reference to Exhibit 10.21 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (File No. 333-248757), filed with the SEC on September 28, 2020).</u></a>
10.5	<a href="#"><u>Employment Agreement by and between the Registrant and Christophe Quéva, effective as of October 6, 2020 (incorporated herein by reference to Exhibit 10.22 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (File No. 333-248757), filed with the SEC on September 28, 2020).</u></a>
31.1*	<a href="#"><u>Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u></a>
31.2*	<a href="#"><u>Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u></a>
32.1^	<a href="#"><u>Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u></a>
32.2^	<a href="#"><u>Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u></a>
101.INS	XBRL Instance Document (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the inline XBRL document)
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.SCH, 101.CAL, 101.DEF, 101.LAB and 101.PRE).

\* Filed herewith.

^ This certification is deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference into any filing by the registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such filing.



**ONCORUS, INC.**  
**2020 EQUITY INCENTIVE PLAN**

**ADOPTED BY THE BOARD OF DIRECTORS: SEPTEMBER 15, 2020**  
**APPROVED BY THE STOCKHOLDERS: SEPTEMBER 25, 2020**

## TABLE OF CONTENTS

	<b>Page</b>
1. General	1
2. Shares Subject to the Plan	1
3. Eligibility and Limitations	2
4. Options and Stock Appreciation Rights	3
5. Awards Other Than Options and Stock Appreciation Rights	7
6. Adjustments upon Changes in Common Stock; Other Corporate Events	9
7. Administration	11
8. Tax Withholding	14
9. Miscellaneous	15
10. Covenants of the Company	18
11. Additional Rules for Awards Subject to Section 409A	18
12. Severability	22
13. Termination of the Plan	22
14. Definitions	23

## 1. GENERAL.

**(a) Successor to and Continuation of Prior Plan.** The Plan is the successor to and continuation of the Prior Plan. As of the Effective Date, (i) no additional awards may be granted under the Prior Plan; (ii) the Prior Plan's Available Reserve plus any Returning Shares will become available for issuance pursuant to Awards granted under this Plan; and (iii) all outstanding awards granted under the Prior Plan will remain subject to the terms of the Prior Plan (except to the extent such outstanding awards result in Returning Shares that become available for issuance pursuant to Awards granted under this Plan). All Awards granted under this Plan will be subject to the terms of this Plan.

**(b) Plan Purpose.** The Company, by means of the Plan, seeks to secure and retain the services of Employees, Directors and Consultants, to provide incentives for such persons to exert maximum efforts for the success of the Company and any Affiliate and to provide a means by which such persons may be given an opportunity to benefit from increases in value of the Common Stock through the granting of Awards.

**(c) Available Awards.** The Plan provides for the grant of the following Awards: (i) Incentive Stock Options; (ii) Nonstatutory Stock Options; (iii) SARs; (iv) Restricted Stock Awards; (v) RSU Awards; (vi) Performance Awards; and (vii) Other Awards.

**(d) Adoption Date; Effective Date.** The Plan will come into existence on the Adoption Date, but no Award may be granted prior to the Effective Date.

## 2. SHARES SUBJECT TO THE PLAN.

**(a) Share Reserve.** Subject to adjustment in accordance with Section 2(c) and any adjustments as necessary to implement any Capitalization Adjustments, the aggregate number of shares of Common Stock that may be issued pursuant to Awards will not exceed 5,000,000 shares, which number includes the sum of: (i) 2,800,000 new shares, plus (ii) the Prior Plan's Available Reserve, and plus (iii) the number of Returning Shares, if any, as such shares become available from time to time.

In addition, subject to any adjustments as necessary to implement any Capitalization Adjustments, such aggregate number of shares of Common Stock will automatically increase on January 1 of each calendar year for a period of ten years commencing on January 1, 2021 and ending on (and including) January 1, 2030, in a number of shares of Common Stock equal to 5% of the total number of shares of Capital Stock outstanding on December 31 of the preceding calendar year; provided, however that the Board may act prior to January 1 of a given calendar year to provide that the increase for such year will be a lesser number of shares of Common Stock.

**(b) Aggregate Incentive Stock Option Limit.** Notwithstanding anything to the contrary in Section 2(a) and subject to any adjustments as necessary to implement any Capitalization Adjustments, the aggregate maximum number of shares of Common Stock that may be issued pursuant to the exercise of Incentive Stock Options is 15,000,000 shares.

**(c) Share Reserve Operation.**

**(i) Limit Applies to Common Stock Issued Pursuant to Awards.** For clarity, the Share Reserve is a limit on the number of shares of Common Stock that may be issued pursuant to Awards and does not limit the granting of Awards, except that the Company will keep available at all times the number of shares of Common Stock reasonably required to satisfy its obligations to issue shares pursuant to such Awards. Shares may be issued in connection with a merger or acquisition as permitted by, as applicable, Nasdaq Listing Rule 5635(c), NYSE Listed Company Manual Section 303A.08, NYSE American Company Guide Section 711 or other applicable rule, and such issuance will not reduce the number of shares available for issuance under the Plan.

**(ii) Actions that Do Not Constitute Issuance of Common Stock and Do Not Reduce Share Reserve.** The following actions do not result in an issuance of shares under the Plan and accordingly do not reduce the number of shares subject to the Share Reserve and available for issuance under the Plan: (1) the expiration or termination of any portion of an Award without the shares covered by such portion of the Award having been issued, (2) the settlement of any portion of an Award in cash (*i.e.*, the Participant receives cash rather than Common Stock), (3) the withholding of shares that would otherwise be issued by the Company to satisfy the exercise, strike or purchase price of an Award; (4) the withholding of shares that would otherwise be issued by the Company to satisfy a tax withholding obligation in connection with an Award.

**(iii) Reversion of Previously Issued Shares of Common Stock to Share Reserve.** The following shares of Common Stock previously issued pursuant to an Award and accordingly initially deducted from the Share Reserve will be added back to the Share Reserve and again become available for issuance under the Plan: (1) any shares that are forfeited back to or repurchased by the Company because of a failure to meet a contingency or condition required for the vesting of such shares; (2) any shares that are reacquired by the Company to satisfy the exercise, strike or purchase price of an Award; and (3) any shares that are reacquired by the Company to satisfy a tax withholding obligation in connection with an Award.

**3. ELIGIBILITY AND LIMITATIONS.**

**(a) Eligible Award Recipients.** Subject to the terms of the Plan, Employees, Directors and Consultants are eligible to receive Awards.

**(b) Specific Award Limitations.**

**(i) Limitations on Incentive Stock Option Recipients.** Incentive Stock Options may be granted only to Employees of the Company or a “parent corporation” or “subsidiary corporation” thereof (as such terms are defined in Sections 424(e) and (f) of the Code).

**(ii) Incentive Stock Option \$100,000 Limitation.** To the extent that the aggregate Fair Market Value (determined at the time of grant) of Common Stock with respect to which Incentive Stock Options are exercisable for the first time by any Optionholder during any calendar year (under all plans of the Company and any Affiliates) exceeds \$100,000 (or such

other limit established in the Code) or otherwise does not comply with the rules governing Incentive Stock Options, the Options or portions thereof that exceed such limit (according to the order in which they were granted) or otherwise do not comply with such rules will be treated as Nonstatutory Stock Options, notwithstanding any contrary provision of the applicable Option Agreement(s).

**(iii) Limitations on Incentive Stock Options Granted to Ten Percent Stockholders.** A Ten Percent Stockholder may not be granted an Incentive Stock Option unless (i) the exercise price of such Option is at least 110% of the Fair Market Value on the date of grant of such Option and (ii) the Option is not exercisable after the expiration of five years from the date of grant of such Option.

**(iv) Limitations on Nonstatutory Stock Options and SARs.** Nonstatutory Stock Options and SARs may not be granted to Employees, Directors and Consultants who are providing Continuous Service only to any “parent” of the Company (as such term is defined in Rule 405) unless the stock underlying such Awards is treated as “service recipient stock” under Section 409A because the Awards are granted pursuant to a corporate transaction (such as a spin off transaction) or unless such Awards otherwise comply with the distribution requirements of Section 409A.

**(c) Aggregate Incentive Stock Option Limit.** The aggregate maximum number of shares of Common Stock that may be issued pursuant to the exercise of Incentive Stock Options is the number of shares specified in Section 2(b).

**(d) Non-Employee Director Compensation Limit.** The aggregate value of all compensation granted or paid, as applicable, to any individual for service as a Non-Employee Director with respect to any calendar year that follows the calendar year in which such individual is first appointed or elected to the Board, including Awards granted and cash fees paid by the Company to such Non-Employee Director, will not exceed \$750,000 in total value, and with respect to the calendar year in which a Non-Employee Director is first appointed or elected to the Board, will not exceed \$1,000,000 in total value, in each case calculating the value of any equity awards based on the grant date fair value of such equity awards for financial reporting purposes.

#### **4. OPTIONS AND STOCK APPRECIATION RIGHTS.**

Each Option and SAR will have such terms and conditions as determined by the Board. Each Option will be designated in writing as an Incentive Stock Option or Nonstatutory Stock Option at the time of grant; *provided, however*, that if an Option is not so designated, then such Option will be a Nonstatutory Stock Option, and the shares purchased upon exercise of each type of Option will be separately accounted for. Each SAR will be denominated in shares of Common Stock equivalents. The terms and conditions of separate Options and SARs need not be identical; *provided, however*, that each Option Agreement and SAR Agreement will conform (through incorporation of provisions hereof by reference in the Award Agreement or otherwise) to the substance of each of the following provisions:

**(a) Term.** Subject to Section 3(b) regarding Ten Percent Stockholders, no Option or SAR will be exercisable after the expiration of ten years from the date of grant of such Award or such shorter period specified in the Award Agreement.

**(b) Exercise or Strike Price.** Subject to Section 3(b) regarding Ten Percent Stockholders, the exercise or strike price of each Option or SAR will not be less than 100% of the Fair Market Value on the date of grant of such Award. Notwithstanding the foregoing, an Option or SAR may be granted with an exercise or strike price lower than 100% of the Fair Market Value on the date of grant of such Award if such Award is granted pursuant to an assumption of or substitution for another option or stock appreciation right pursuant to a Corporate Transaction and in a manner consistent with the provisions of Sections 409A and, if applicable, 424(a) of the Code.

**(c) Exercise Procedure and Payment of Exercise Price for Options.** In order to exercise an Option, the Participant must provide notice of exercise to the Plan Administrator in accordance with the procedures specified in the Option Agreement or otherwise provided by the Company. The Board has the authority to grant Options that do not permit all of the following methods of payment (or otherwise restrict the ability to use certain methods) and to grant Options that require the consent of the Company to utilize a particular method of payment. The exercise price of an Option may be paid, to the extent permitted by Applicable Law and as determined by the Board, by one or more of the following methods of payment to the extent set forth in the Option Agreement:

**(i)** by cash or check, bank draft or money order payable to the Company;

**(ii)** pursuant to a “cashless exercise” program developed under Regulation T as promulgated by the Federal Reserve Board that, prior to the issuance of the Common Stock subject to the Option, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the exercise price to the Company from the sales proceeds;

**(iii)** by delivery to the Company (either by actual delivery or attestation) of shares of Common Stock that are already owned by the Participant free and clear of any liens, claims, encumbrances or security interests, with a Fair Market Value on the date of exercise that does not exceed the exercise price, provided that (1) at the time of exercise the Common Stock is publicly traded, (2) any remaining balance of the exercise price not satisfied by such delivery is paid by the Participant in cash or other permitted form of payment, (3) such delivery would not violate any Applicable Law or agreement restricting the redemption of the Common Stock, (4) any certificated shares are endorsed or accompanied by an executed assignment separate from certificate, and (5) such shares have been held by the Participant for any minimum period necessary to avoid adverse accounting treatment as a result of such delivery;

**(iv)** if the Option is a Nonstatutory Stock Option, by a “net exercise” arrangement pursuant to which the Company will reduce the number of shares of Common Stock issuable upon exercise by the largest whole number of shares with a Fair Market Value on the date of exercise that does not exceed the exercise price, provided that (1) such shares used to pay the exercise price will not be exercisable thereafter and (2) any remaining balance of the exercise price not satisfied by such net exercise is paid by the Participant in cash or other permitted form of payment; or

(v) in any other form of consideration that may be acceptable to the Board and permissible under Applicable Law.

**(d) Exercise Procedure and Payment of Appreciation Distribution for SARs.** In order to exercise any SAR, the Participant must provide notice of exercise to the Plan Administrator in accordance with the SAR Agreement. The appreciation distribution payable to a Participant upon the exercise of a SAR will not be greater than an amount equal to the excess of (i) the aggregate Fair Market Value on the date of exercise of a number of shares of Common Stock equal to the number of Common Stock equivalents that are vested and being exercised under such SAR, over (ii) the strike price of such SAR. Such appreciation distribution may be paid to the Participant in the form of Common Stock or cash (or any combination of Common Stock and cash) or in any other form of payment, as determined by the Board and specified in the SAR Agreement.

**(e) Transferability.** Options and SARs may not be transferred to third party financial institutions for value. The Board may impose such additional limitations on the transferability of an Option or SAR as it determines. In the absence of any such determination by the Board, the following restrictions on the transferability of Options and SARs will apply, provided that except as explicitly provided herein, neither an Option nor a SAR may be transferred for consideration and *provided, further*, that if an Option is an Incentive Stock Option, such Option may be deemed to be a Nonstatutory Stock Option as a result of such transfer:

**(i) Restrictions on Transfer.** An Option or SAR will not be transferable, except by will or by the laws of descent and distribution, and will be exercisable during the lifetime of the Participant only by the Participant; *provided, however*, that the Board may permit transfer of an Option or SAR in a manner that is not prohibited by applicable tax and securities laws upon the Participant's request, including to a trust if the Participant is considered to be the sole beneficial owner of such trust (as determined under Section 671 of the Code and applicable state law) while such Option or SAR is held in such trust, provided that the Participant and the trustee enter into a transfer and other agreements required by the Company.

**(ii) Domestic Relations Orders.** Notwithstanding the foregoing, subject to the execution of transfer documentation in a format acceptable to the Company and subject to the approval of the Board or a duly authorized Officer, an Option or SAR may be transferred pursuant to a domestic relations order.

**(f) Vesting.** The Board may impose such restrictions on or conditions to the vesting and/or exercisability of an Option or SAR as determined by the Board. Except as otherwise provided in the Award Agreement or other written agreement between a Participant and the Company or an Affiliate, vesting of Options and SARs will cease upon termination of the Participant's Continuous Service.

**(g) Termination of Continuous Service for Cause.** Except as explicitly otherwise provided in the Award Agreement or other written agreement between a Participant and the Company or an Affiliate, if a Participant's Continuous Service is terminated for Cause, the Participant's Options and SARs will terminate and be forfeited immediately upon such termination of Continuous Service, and the Participant will be prohibited from exercising any portion (including any vested portion) of such Awards on and after the date of such termination of Continuous Service and the Participant will have no further right, title or interest in such forfeited Award, the shares of Common Stock subject to the forfeited Award, or any consideration in respect of the forfeited Award.

**(h) Post-Termination Exercise Period Following Termination of Continuous Service for Reasons Other than Cause.** Subject to Section 4(i), if a Participant's Continuous Service terminates for any reason other than for Cause, the Participant may exercise his or her Option or SAR to the extent vested, but only within the following period of time or, if applicable, such other period of time provided in the Award Agreement or other written agreement between a Participant and the Company or an Affiliate; *provided, however*, that in no event may such Award be exercised after the expiration of its maximum term (as set forth in Section 4(a)):

**(i)** three months following the date of such termination if such termination is a termination without Cause (other than any termination due to the Participant's Disability or death);

**(ii)** 12 months following the date of such termination if such termination is due to the Participant's Disability;

**(iii)** 18 months following the date of such termination if such termination is due to the Participant's death; or

**(iv)** 18 months following the date of the Participant's death if such death occurs following the date of such termination but during the period such Award is otherwise exercisable (as provided in (i) or (ii) above).

Following the date of such termination, to the extent the Participant does not exercise such Award within the applicable Post-Termination Exercise Period (or, if earlier, prior to the expiration of the maximum term of such Award), such unexercised portion of the Award will terminate, and the Participant will have no further right, title or interest in terminated Award, the shares of Common Stock subject to the terminated Award, or any consideration in respect of the terminated Award.

**(i) Restrictions on Exercise; Extension of Exercisability.** A Participant may not exercise an Option or SAR at any time that the issuance of shares of Common Stock upon such exercise would violate Applicable Law. Except as otherwise provided in the Award Agreement or other written agreement between a Participant and the Company or an Affiliate, if a Participant's Continuous Service terminates for any reason other than for Cause and, at any time during the last thirty days of the applicable Post-Termination Exercise Period: (i) the exercise of the Participant's Option or SAR would be prohibited solely because the issuance of shares of Common Stock upon such exercise would violate Applicable Law, or (ii) the immediate sale of

any shares of Common Stock issued upon such exercise would violate the Company's Trading Policy, then the applicable Post-Termination Exercise Period will be extended to the last day of the calendar month that commences following the date the Award would otherwise expire, with an additional extension of the exercise period to the last day of the next calendar month to apply if any of the foregoing restrictions apply at any time during such extended exercise period, generally without limitation as to the maximum permitted number of extensions; *provided, however*, that in no event may such Award be exercised after the expiration of its maximum term (as set forth in Section 4(a)).

**(j) Non-Exempt Employees.** No Option or SAR, whether or not vested, granted to an Employee who is a non-exempt employee for purposes of the Fair Labor Standards Act of 1938, as amended, will be first exercisable for any shares of Common Stock until at least six months following the date of grant of such Award. Notwithstanding the foregoing, in accordance with the provisions of the Worker Economic Opportunity Act, any vested portion of such Award may be exercised earlier than six months following the date of grant of such Award in the event of (i) such Participant's death or Disability, (ii) a Corporate Transaction in which such Award is not assumed, continued or substituted, (iii) a Change in Control, or (iv) such Participant's retirement (as such term may be defined in the Award Agreement or another applicable agreement or, in the absence of any such definition, in accordance with the Company's then current employment policies and guidelines). This Section 4(j) is intended to operate so that any income derived by a non-exempt employee in connection with the exercise or vesting of an Option or SAR will be exempt from his or her regular rate of pay.

**(k) Whole Shares.** Options and SARs may be exercised only with respect to whole shares of Common Stock or their equivalents.

#### **5. AWARDS OTHER THAN OPTIONS AND STOCK APPRECIATION RIGHTS.**

**(a) Restricted Stock Awards and RSU Awards.** Each Restricted Stock Award and RSU Award will have such terms and conditions as determined by the Board; *provided, however*, that each Restricted Stock Award Agreement and RSU Award Agreement will conform (through incorporation of the provisions hereof by reference in the Award Agreement or otherwise) to the substance of each of the following provisions:

**(i) Form of Award.**

**(1) RSAs:** To the extent consistent with the Company's Bylaws, at the Board's election, shares of Common Stock subject to a Restricted Stock Award may be (i) held in book entry form subject to the Company's instructions until such shares become vested or any other restrictions lapse, or (ii) evidenced by a certificate, which certificate will be held in such form and manner as determined by the Board. Unless otherwise determined by the Board, a Participant will have voting and other rights as a stockholder of the Company with respect to any shares subject to a Restricted Stock Award.

**(2) RSUs:** A RSU Award represents a Participant's right to be issued on a future date the number of shares of Common Stock that is equal to the number of restricted stock units subject to the RSU Award. As a holder of a RSU Award, a Participant is an unsecured creditor of the Company with respect to the Company's unfunded obligation, if any, to issue shares of Common Stock in settlement of such Award and nothing contained in the Plan or any RSU Agreement, and no action taken pursuant to its provisions, will create or be construed to create a trust of any kind or a fiduciary relationship between a Participant and the Company or an Affiliate or any other person. A Participant will not have voting or any other rights as a stockholder of the Company with respect to any RSU Award (unless and until shares are actually issued in settlement of a vested RSU Award).

**(ii) Consideration.**

**(1) RSA:** A Restricted Stock Award may be granted in consideration for (A) cash or check, bank draft or money order payable to the Company, (B) past services to the Company or an Affiliate, or (C) any other form of consideration (including future services) as the Board may determine and permissible under Applicable Law.

**(2) RSU:** Unless otherwise determined by the Board at the time of grant, a RSU Award will be granted in consideration for the Participant's services to the Company or an Affiliate, such that the Participant will not be required to make any payment to the Company (other than such services) with respect to the grant or vesting of the RSU Award, or the issuance of any shares of Common Stock pursuant to the RSU Award. If, at the time of grant, the Board determines that any consideration must be paid by the Participant (in a form other than the Participant's services to the Company or an Affiliate) upon the issuance of any shares of Common Stock in settlement of the RSU Award, such consideration may be paid in any form of consideration as the Board may determine and permissible under Applicable Law.

**(iii) Vesting.** The Board may impose such restrictions on or conditions to the vesting of a Restricted Stock Award or RSU Award as determined by the Board and which may vary. Except as otherwise provided in the Award Agreement or other written agreement between a Participant and the Company or an Affiliate, vesting of Restricted Stock Awards and RSU Awards will cease upon termination of the Participant's Continuous Service.

**(iv) Termination of Continuous Service.** Except as otherwise provided in the Award Agreement or other written agreement between a Participant and the Company or an Affiliate, if a Participant's Continuous Service terminates for any reason, (i) the Company may receive through a forfeiture condition or a repurchase right any or all of the shares of Common Stock held by the Participant under his or her Restricted Stock Award that have not vested as of the date of such termination as set forth in the Restricted Stock Award Agreement and (ii) any portion of his or her RSU Award that has not vested will be forfeited upon such termination and the Participant will have no further right, title or interest in the RSU Award, the shares of Common Stock issuable pursuant to the RSU Award, or any consideration in respect of the RSU Award.

**(v) Dividends and Dividend Equivalents.** Dividends or dividend equivalents may be paid or credited, as applicable, with respect to any shares of Common Stock subject to a Restricted Stock Award or RSU Award, as determined by the Board and specified in the Award Agreement).

**(vi) Settlement of RSU Awards.** A RSU Award may be settled by the issuance of shares of Common Stock or cash (or any combination thereof) or in any other form of payment, as determined by the Board and specified in the RSU Award Agreement. At the time of grant, the Board may determine to impose such restrictions or conditions that delay such delivery to a date following the vesting of the RSU Award.

**(b) Performance Awards.** With respect to any Performance Award, the length of any Performance Period, the Performance Goals to be achieved during the Performance Period, the other terms and conditions of such Award, and the measure of whether and to what degree such Performance Goals have been attained will be determined by the Board.

**(c) Other Awards.** Other forms of Awards valued in whole or in part by reference to, or otherwise based on, Common Stock, including the appreciation in value thereof (e.g., options or stock rights with an exercise price or strike price less than 100% of the Fair Market Value at the time of grant) may be granted either alone or in addition to Awards provided for under Section 4 and the preceding provisions of this Section 5. Subject to the provisions of the Plan, the Board will have sole and complete discretion to determine the persons to whom and the time or times at which such Other Awards will be granted, the number of shares of Common Stock (or the cash equivalent thereof) to be granted pursuant to such Other Awards and all other terms and conditions of such Other Awards.

## **6. ADJUSTMENTS UPON CHANGES IN COMMON STOCK; OTHER CORPORATE EVENTS.**

**(a) Capitalization Adjustments.** In the event of a Capitalization Adjustment, the Board shall appropriately and proportionately adjust: (i) the class(es) and maximum number of shares of Common Stock subject to the Plan and the maximum number of shares by which the Share Reserve may annually increase pursuant to Section 2(a), (ii) the class(es) and maximum number of shares that may be issued pursuant to the exercise of Incentive Stock Options pursuant to Section 2(a), and (iii) the class(es) and number of securities and exercise price, strike price or purchase price of Common Stock subject to outstanding Awards. The Board shall make such adjustments, and its determination shall be final, binding and conclusive. Notwithstanding the foregoing, no fractional shares or rights for fractional shares of Common Stock shall be created in order to implement any Capitalization Adjustment. The Board shall determine an equivalent benefit for any fractional shares or fractional shares that might be created by the adjustments referred to in the preceding provisions of this Section.

**(b) Dissolution or Liquidation.** Except as otherwise provided in the Award Agreement, in the event of a dissolution or liquidation of the Company, all outstanding Awards (other than Awards consisting of vested and outstanding shares of Common Stock not subject to a forfeiture condition or the Company's right of repurchase) will terminate immediately prior to the completion of such dissolution or liquidation, and the shares of Common Stock subject to the Company's repurchase rights or subject to a forfeiture condition may be repurchased or reacquired by the Company notwithstanding the fact that the holder of such Award is providing Continuous Service, *provided, however*, that the Board may determine to cause some or all Awards to become fully vested, exercisable and/or no longer subject to repurchase or forfeiture (to the extent such Awards have not previously expired or terminated) before the dissolution or liquidation is completed but contingent on its completion.

**(c) Corporate Transaction.** The following provisions will apply to Awards in the event of a Corporate Transaction unless otherwise provided in the instrument evidencing the Award or any other written agreement between the Company or any Affiliate and the Participant or unless otherwise expressly provided by the Board. The Board has sole and complete discretion to determine to accelerate the vesting and exercisability of all or any Awards in the event of a Corporate Transaction.

**(i) Awards May Be Assumed.** In the event of a Corporate Transaction, any surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company) may assume or continue any or all Awards outstanding under the Plan or may substitute similar awards for Awards outstanding under the Plan (including but not limited to, awards to acquire the same consideration paid to the stockholders of the Company pursuant to the Corporate Transaction), and any reacquisition or repurchase rights held by the Company in respect of Common Stock issued pursuant to Awards may be assigned by the Company to the successor of the Company (or the successor's parent company, if any), in connection with such Corporate Transaction. A surviving corporation or acquiring corporation (or its parent) may choose to assume or continue only a portion of an Award or substitute a similar award for only a portion of an Award, or may choose to assume or continue the Awards held by some, but not all Participants. The terms of any assumption, continuation or substitution will be set by the Board.

**(ii) Awards Held by Current Participants.** In the event of a Corporate Transaction in which the surviving corporation or acquiring corporation (or its parent company) does not assume or continue such outstanding Awards or substitute similar awards for such outstanding Awards, then with respect to Awards that have not been assumed, continued or substituted and that are held by Participants whose Continuous Service has not terminated prior to the effective time of the Corporate Transaction (referred to as the "**Current Participants**"), the vesting of such Awards (and, with respect to Options and Stock Appreciation Rights, the time when such Awards may be exercised) will be accelerated in full to a date prior to the effective time of such Corporate Transaction (contingent upon the effectiveness of the Corporate Transaction) as the Board determines (or, if the Board does not determine such a date, to the date that is five (5) days prior to the effective time of the Corporate Transaction), and such Awards will terminate if not exercised (if applicable) at or prior to the effective time of the Corporate Transaction, and any reacquisition or repurchase rights held by the Company with respect to such Awards will lapse (contingent upon the effectiveness of the Corporate Transaction). With respect to the vesting of Performance Awards that will accelerate upon the occurrence of a Corporate Transaction pursuant to this subsection (ii) and that have multiple vesting levels depending on the level of performance, unless otherwise provided in the Award Agreement, the vesting of such Performance Awards will accelerate at 100% of the target level upon the occurrence of the Corporate Transaction. With respect to the vesting of Awards that will accelerate upon the occurrence of a Corporate Transaction pursuant to this subsection (ii) and are settled in the form of a cash payment, such cash payment will be made no later than 30 days following the occurrence of the Corporate Transaction..

**(iii) Awards Held by Persons other than Current Participants.** In the event of a Corporate Transaction in which the surviving corporation or acquiring corporation (or its parent company) does not assume or continue such outstanding Awards or substitute similar awards for such outstanding Awards, then with respect to Awards that have not been

assumed, continued or substituted and that are held by persons other than Current Participants, such Awards will terminate if not exercised (if applicable) prior to the occurrence of the Corporate Transaction; *provided, however*, that any reacquisition or repurchase rights held by the Company with respect to such Awards will not terminate and may continue to be exercised notwithstanding the Corporate Transaction.

**(iv) Payment for Awards in Lieu of Exercise.** Notwithstanding the foregoing, in the event an Award will terminate if not exercised prior to the effective time of a Corporate Transaction, the Board may provide, in its sole discretion, that the holder of such Award may not exercise such Award but will receive a payment, in such form as may be determined by the Board, equal in value, at the effective time, to the excess, if any, of (1) the value of the property the Participant would have received upon the exercise of the Award (including, at the discretion of the Board, any unvested portion of such Award), over (2) any exercise price payable by such holder in connection with such exercise.

**(d) Appointment of Stockholder Representative.** As a condition to the receipt of an Award under this Plan, a Participant will be deemed to have agreed that the Award will be subject to the terms of any agreement governing a Corporate Transaction involving the Company, including, without limitation, a provision for the appointment of a stockholder representative that is authorized to act on the Participant's behalf with respect to any escrow, indemnities and any contingent consideration.

**(e) No Restriction on Right to Undertake Transactions.** The grant of any Award under the Plan and the issuance of shares pursuant to any Award does not affect or restrict in any way the right or power of the Company or the stockholders of the Company to make or authorize any adjustment, recapitalization, reorganization or other change in the Company's capital structure or its business, any merger or consolidation of the Company, any issue of stock or of options, rights or options to purchase stock or of bonds, debentures, preferred or prior preference stocks whose rights are superior to or affect the Common Stock or the rights thereof or which are convertible into or exchangeable for Common Stock, or the dissolution or liquidation of the Company, or any sale or transfer of all or any part of its assets or business, or any other corporate act or proceeding, whether of a similar character or otherwise.

## 7. ADMINISTRATION.

**(a) Administration by Board.** The Board will administer the Plan unless and until the Board delegates administration of the Plan to a Committee or Committees, as provided in subsection (c) below.

**(b) Powers of Board.** The Board will have the power, subject to, and within the limitations of, the express provisions of the Plan:

**(i)** To determine from time to time (1) which of the persons eligible under the Plan will be granted Awards; (2) when and how each Award will be granted; (3) what type or combination of types of Award will be granted; (4) the provisions of each Award granted (which need not be identical), including the time or times when a person will be permitted to receive an issuance of Common Stock or other payment pursuant to an Award; (5) the number

of shares of Common Stock or cash equivalent with respect to which an Award will be granted to each such person; (6) the Fair Market Value applicable to an Award; and (7) the terms of any Performance Award that is not valued in whole or in part by reference to, or otherwise based on, the Class A Common Stock, including the amount of cash payment or other property that may be earned and the timing of payment.

**(ii)** To construe and interpret the Plan and Awards granted under it, and to establish, amend and revoke rules and regulations for its administration. The Board, in the exercise of this power, may correct any defect, omission or inconsistency in the Plan or in any Award Agreement, in a manner and to the extent it deems necessary or expedient to make the Plan or Award fully effective.

**(iii)** To settle all controversies regarding the Plan and Awards granted under it.

**(iv)** To accelerate the time at which an Award may first be exercised or the time during which an Award or any part thereof will vest, notwithstanding the provisions in the Award Agreement stating the time at which it may first be exercised or the time during which it will vest.

**(v)** To prohibit the exercise of any Option, SAR or other exercisable Award during a period of up to 30 days prior to the consummation of any pending stock dividend, stock split, combination or exchange of shares, merger, consolidation or other distribution (other than normal cash dividends) of Company assets to stockholders, or any other change affecting the shares of Common Stock or the share price of the Common Stock including any Corporate Transaction, for reasons of administrative convenience.

**(vi)** To suspend or terminate the Plan at any time. Suspension or termination of the Plan will not Materially Impair rights and obligations under any Award granted while the Plan is in effect except with the written consent of the affected Participant.

**(vii)** To amend the Plan in any respect the Board deems necessary or advisable; *provided, however*, that stockholder approval will be required for any amendment to the extent required by Applicable Law. Except as provided above, rights under any Award granted before amendment of the Plan will not be Materially Impaired by any amendment of the Plan unless (1) the Company requests the consent of the affected Participant, and (2) such Participant consents in writing.

**(viii)** To submit any amendment to the Plan for stockholder approval.

**(ix)** To approve forms of Award Agreements for use under the Plan and to amend the terms of any one or more Awards, including, but not limited to, amendments to provide terms more favorable to the Participant than previously provided in the Award Agreement, subject to any specified limits in the Plan that are not subject to Board discretion; *provided however*, that, a Participant's rights under any Award will not be Materially Impaired by any such amendment unless (1) the Company requests the consent of the affected Participant, and (2) such Participant consents in writing.

(x) Generally, to exercise such powers and to perform such acts as the Board deems necessary or expedient to promote the best interests of the Company and that are not in conflict with the provisions of the Plan or Awards.

(xi) To adopt such procedures and sub-plans as are necessary or appropriate to permit and facilitate participation in the Plan by, or take advantage of specific tax treatment for Awards granted to, Employees, Directors or Consultants who are foreign nationals or employed outside the United States (provided that Board approval will not be necessary for immaterial modifications to the Plan or any Award Agreement to ensure or facilitate compliance with the laws of the relevant foreign jurisdiction).

(xii) To effect, at any time and from time to time, subject to the consent of any Participant whose Award is Materially Impaired by such action, (1) the reduction of the exercise price (or strike price) of any outstanding Option or SAR; (2) the cancellation of any outstanding Option or SAR and the grant in substitution thereof of (A) a new Option, SAR, Restricted Stock Award, RSU Award or Other Award, under the Plan or another equity plan of the Company, covering the same or a different number of shares of Common Stock, (B) cash and/or (C) other valuable consideration (as determined by the Board); or (3) any other action that is treated as a repricing under generally accepted accounting principles.

**(c) Delegation to Committee.**

**(i) General.** The Board may delegate some or all of the administration of the Plan to a Committee or Committees. If administration of the Plan is delegated to a Committee, the Committee will have, in connection with the administration of the Plan, the powers theretofore possessed by the Board that have been delegated to the Committee, including the power to delegate to another Committee or a subcommittee of the Committee any of the administrative powers the Committee is authorized to exercise (and references in this Plan to the Board will thereafter be to the Committee or subcommittee), subject, however, to such resolutions, not inconsistent with the provisions of the Plan, as may be adopted from time to time by the Board. Each Committee may retain the authority to concurrently administer the Plan with Committee or subcommittee to which it has delegated its authority hereunder and may, at any time, revert in such Committee some or all of the powers previously delegated. The Board may retain the authority to concurrently administer the Plan with any Committee and may, at any time, revert in the Board some or all of the powers previously delegated.

**(ii) Rule 16b-3 Compliance.** To the extent an Award is intended to qualify for the exemption from Section 16(b) of the Exchange Act that is available under Rule 16b-3 of the Exchange Act, the Award will be granted by the Board or a Committee that consists solely of two or more Non-Employee Directors, as determined under Rule 16b-3(b)(3) of the Exchange Act and thereafter any action establishing or modifying the terms of the Award will be approved by the Board or a Committee meeting such requirements to the extent necessary for such exemption to remain available.

**(d) Effect of Board's Decision.** All determinations, interpretations and constructions made by the Board or any Committee in good faith will not be subject to review by any person and will be final, binding and conclusive on all persons.

**(e) Delegation to an Officer.** The Board or any Committee may delegate to one or more Officers the authority to do one or both of the following (i) designate Employees who are not Officers to be recipients of Options and SARs (and, to the extent permitted by Applicable Law, other types of Awards) and, to the extent permitted by Applicable Law, the terms thereof, and (ii) determine the number of shares of Common Stock to be subject to such Awards granted to such Employees; provided, however, that the resolutions or charter adopted by the Board or any Committee evidencing such delegation will specify the total number of shares of Common Stock that may be subject to the Awards granted by such Officer and that such Officer may not grant an Award to himself or herself. Any such Awards will be granted on the applicable form of Award Agreement most recently approved for use by the Board or the Committee, unless otherwise provided in the resolutions approving the delegation authority. Notwithstanding anything to the contrary herein, neither the Board nor any Committee may delegate to an Officer who is acting solely in the capacity of an Officer (and not also as a Director) the authority to determine the Fair Market Value.

## **8. TAX WITHHOLDING**

**(a) Withholding Authorization.** As a condition to acceptance of any Award under the Plan, a Participant authorizes withholding from payroll and any other amounts payable to such Participant, and otherwise agree to make adequate provision for (including), any sums required to satisfy any U.S. federal, state, local and/or foreign tax or social insurance contribution withholding obligations of the Company or an Affiliate, if any, which arise in connection with the exercise, vesting or settlement of such Award, as applicable. Accordingly, a Participant may not be able to exercise an Award even though the Award is vested, and the Company shall have no obligation to issue shares of Common Stock subject to an Award, unless and until such obligations are satisfied.

**(b) Satisfaction of Withholding Obligation.** To the extent permitted by the terms of an Award Agreement, the Company may, in its sole discretion, satisfy any U.S. federal, state, local and/or foreign tax or social insurance withholding obligation relating to an Award by any of the following means or by a combination of such means: (i) causing the Participant to tender a cash payment; (ii) withholding shares of Common Stock from the shares of Common Stock issued or otherwise issuable to the Participant in connection with the Award; (iii) withholding cash from an Award settled in cash; (iv) withholding payment from any amounts otherwise payable to the Participant; (v) by allowing a Participant to effectuate a “cashless exercise” pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board, or (vi) by such other method as may be set forth in the Award Agreement.

**(c) No Obligation to Notify or Minimize Taxes; No Liability to Claims.** Except as required by Applicable Law the Company has no duty or obligation to any Participant to advise such holder as to the time or manner of exercising such Award. Furthermore, the Company has no duty or obligation to warn or otherwise advise such holder of a pending termination or expiration of an Award or a possible period in which the Award may not be exercised. The Company has no duty or obligation to minimize the tax consequences of an Award to the holder of such Award and will not be liable to any holder of an Award for any adverse tax consequences to such holder in connection with an Award. As a condition to accepting an Award under the Plan, each Participant (i) agrees to not make any claim against the Company, or any of its

Officers, Directors, Employees or Affiliates related to tax liabilities arising from such Award or other Company compensation and (ii) acknowledges that such Participant was advised to consult with his or her own personal tax, financial and other legal advisors regarding the tax consequences of the Award and has either done so or knowingly and voluntarily declined to do so. Additionally, each Participant acknowledges any Option or SAR granted under the Plan is exempt from Section 409A only if the exercise or strike price is at least equal to the "fair market value" of the Common Stock on the date of grant as determined by the Internal Revenue Service and there is no other impermissible deferral of compensation associated with the Award. Additionally, as a condition to accepting an Option or SAR granted under the Plan, each Participant agrees not make any claim against the Company, or any of its Officers, Directors, Employees or Affiliates in the event that the Internal Revenue Service asserts that such exercise price or strike price is less than the "fair market value" of the Common Stock on the date of grant as subsequently determined by the Internal Revenue Service.

**(d) Withholding Indemnification.** As a condition to accepting an Award under the Plan, in the event that the amount of the Company's and/or its Affiliate's withholding obligation in connection with such Award was greater than the amount actually withheld by the Company and/or its Affiliates, each Participant agrees to indemnify and hold the Company and/or its Affiliates harmless from any failure by the Company and/or its Affiliates to withhold the proper amount.

## **9. MISCELLANEOUS.**

**(a) Source of Shares.** The stock issuable under the Plan will be shares of authorized but unissued or reacquired Common Stock, including shares repurchased by the Company on the open market or otherwise.

**(b) Use of Proceeds from Sales of Common Stock.** Proceeds from the sale of shares of Common Stock pursuant to Awards will constitute general funds of the Company.

**(c) Corporate Action Constituting Grant of Awards.** Corporate action constituting a grant by the Company of an Award to any Participant will be deemed completed as of the date of such corporate action, unless otherwise determined by the Board, regardless of when the instrument, certificate, or letter evidencing the Award is communicated to, or actually received or accepted by, the Participant. In the event that the corporate records (e.g., Board consents, resolutions or minutes) documenting the corporate action approving the grant contain terms (e.g., exercise price, vesting schedule or number of shares) that are inconsistent with those in the Award Agreement or related grant documents as a result of a clerical error in the Award Agreement or related grant documents, the corporate records will control and the Participant will have no legally binding right to the incorrect term in the Award Agreement or related grant documents.

**(d) Stockholder Rights.** No Participant will be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Common Stock subject to such Award unless and until (i) such Participant has satisfied all requirements for exercise of the Award pursuant to its terms, if applicable, and (ii) the issuance of the Common Stock subject to such Award is reflected in the records of the Company.

**(e) No Employment or Other Service Rights.** Nothing in the Plan, any Award Agreement or any other instrument executed thereunder or in connection with any Award granted pursuant thereto will confer upon any Participant any right to continue to serve the Company or an Affiliate in the capacity in effect at the time the Award was granted or affect the right of the Company or an Affiliate to terminate at will and without regard to any future vesting opportunity that a Participant may have with respect to any Award (i) the employment of an Employee with or without notice and with or without cause, (ii) the service of a Consultant pursuant to the terms of such Consultant's agreement with the Company or an Affiliate, or (iii) the service of a Director pursuant to the Bylaws of the Company or an Affiliate, and any applicable provisions of the corporate law of the state or foreign jurisdiction in which the Company or the Affiliate is incorporated, as the case may be. Further, nothing in the Plan, any Award Agreement or any other instrument executed thereunder or in connection with any Award will constitute any promise or commitment by the Company or an Affiliate regarding the fact or nature of future positions, future work assignments, future compensation or any other term or condition of employment or service or confer any right or benefit under the Award or the Plan unless such right or benefit has specifically accrued under the terms of the Award Agreement and/or Plan.

**(f) Change in Time Commitment.** In the event a Participant's regular level of time commitment in the performance of his or her services for the Company and any Affiliates is reduced (for example, and without limitation, if the Participant is an Employee of the Company and the Employee has a change in status from a full-time Employee to a part-time Employee or takes an extended leave of absence) after the date of grant of any Award to the Participant, the Board may determine, to the extent permitted by Applicable Law, to (i) make a corresponding reduction in the number of shares or cash amount subject to any portion of such Award that is scheduled to vest or become payable after the date of such change in time commitment, and (ii) in lieu of or in combination with such a reduction, extend the vesting or payment schedule applicable to such Award. In the event of any such reduction, the Participant will have no right with respect to any portion of the Award that is so reduced or extended.

**(g) Execution of Additional Documents.** As a condition to accepting an Award under the Plan, the Participant agrees to execute any additional documents or instruments necessary or desirable, as determined in the Plan Administrator's sole discretion, to carry out the purposes or intent of the Award, or facilitate compliance with securities and/or other regulatory requirements, in each case at the Plan Administrator's request.

**(h) Electronic Delivery and Participation.** Any reference herein or in an Award Agreement to a "written" agreement or document will include any agreement or document delivered electronically, filed publicly at [www.sec.gov](http://www.sec.gov) (or any successor website thereto) or posted on the Company's intranet (or other shared electronic medium controlled by the Company to which the Participant has access). By accepting any Award the Participant consents to receive documents by electronic delivery and to participate in the Plan through any on-line electronic system established and maintained by the Plan Administrator or another third party selected by the Plan Administrator. The form of delivery of any Common Stock (*e.g.*, a stock certificate or electronic entry evidencing such shares) shall be determined by the Company.

**(i) Clawback/Recovery.** All Awards granted under the Plan will be subject to recoupment in accordance with any clawback policy that the Company is required to adopt pursuant to the listing standards of any national securities exchange or association on which the Company's securities are listed or as is otherwise required by the Dodd-Frank Wall Street Reform and Consumer Protection Act or other Applicable Law and any clawback policy that the Company otherwise adopts, to the extent applicable and permissible under Applicable Law. In addition, the Board may impose such other clawback, recovery or recoupment provisions in an Award Agreement as the Board determines necessary or appropriate, including but not limited to a reacquisition right in respect of previously acquired shares of Common Stock or other cash or property upon the occurrence of Cause. No recovery of compensation under such a clawback policy will be an event giving rise to a Participant's right to voluntarily terminate employment upon a "resignation for good reason," or for a "constructive termination" or any similar term under any plan of or agreement with the Company.

**(j) Securities Law Compliance.** A Participant will not be issued any shares in respect of an Award unless either (i) the shares are registered under the Securities Act; or (ii) the Company has determined that such issuance would be exempt from the registration requirements of the Securities Act. Each Award also must comply with other Applicable Law governing the Award, and a Participant will not receive such shares if the Company determines that such receipt would not be in material compliance with Applicable Law.

**(k) Transfer or Assignment of Awards; Issued Shares.** Except as expressly provided in the Plan or the form of Award Agreement, Awards granted under the Plan may not be transferred or assigned by the Participant. After the vested shares subject to an Award have been issued, or in the case of Restricted Stock and similar awards, after the issued shares have vested, the holder of such shares is free to assign, hypothecate, donate, encumber or otherwise dispose of any interest in such shares provided that any such actions are in compliance with the provisions herein, the terms of the Trading Policy and Applicable Law.

**(l) Effect on Other Employee Benefit Plans.** The value of any Award granted under the Plan, as determined upon grant, vesting or settlement, shall not be included as compensation, earnings, salaries, or other similar terms used when calculating any Participant's benefits under any employee benefit plan sponsored by the Company or any Affiliate, except as such plan otherwise expressly provides. The Company expressly reserves its rights to amend, modify, or terminate any of the Company's or any Affiliate's employee benefit plans.

**(m) Deferrals.** To the extent permitted by Applicable Law, the Board, in its sole discretion, may determine that the delivery of Common Stock or the payment of cash, upon the exercise, vesting or settlement of all or a portion of any Award may be deferred and may also establish programs and procedures for deferral elections to be made by Participants. Deferrals will be made in accordance with the requirements of Section 409A.

**(n) Section 409A.** Unless otherwise expressly provided for in an Award Agreement, the Plan and Award Agreements will be interpreted to the greatest extent possible in a manner that makes the Plan and the Awards granted hereunder exempt from Section 409A, and, to the extent not so exempt, in compliance with the requirements of Section 409A. If the Board determines that any Award granted hereunder is not exempt from and is therefore subject to

Section 409A, the Award Agreement evidencing such Award will incorporate the terms and conditions necessary to avoid the consequences specified in Section 409A(a)(1) of the Code, and to the extent an Award Agreement is silent on terms necessary for compliance, such terms are hereby incorporated by reference into the Award Agreement. Notwithstanding anything to the contrary in this Plan (and unless the Award Agreement specifically provides otherwise), if the shares of Common Stock are publicly traded, and if a Participant holding an Award that constitutes “deferred compensation” under Section 409A is a “specified employee” for purposes of Section 409A, no distribution or payment of any amount that is due because of a “separation from service” (as defined in Section 409A without regard to alternative definitions thereunder) will be issued or paid before the date that is six months and one day following the date of such Participant’s “separation from service” or, if earlier, the date of the Participant’s death, unless such distribution or payment can be made in a manner that complies with Section 409A, and any amounts so deferred will be paid in a lump sum on the day after such six month period elapses, with the balance paid thereafter on the original schedule.

**(o) CHOICE OF LAW.** This Plan and any controversy arising out of or relating to this Plan shall be governed by, and construed in accordance with, the internal laws of the State of Delaware, without regard to conflict of law principles that would result in any application of any law other than the law of the State of Delaware.

#### **10. COVENANTS OF THE COMPANY.**

**(a) Compliance with Law.** The Company will seek to obtain from each regulatory commission or agency, as may be deemed to be necessary, having jurisdiction over the Plan such authority as may be required to grant Awards and to issue and sell shares of Common Stock upon exercise or vesting of the Awards; *provided, however,* that this undertaking will not require the Company to register under the Securities Act the Plan, any Award or any Common Stock issued or issuable pursuant to any such Award. If, after reasonable efforts and at a reasonable cost, the Company is unable to obtain from any such regulatory commission or agency the authority that counsel for the Company deems necessary or advisable for the lawful issuance and sale of Common Stock under the Plan, the Company will be relieved from any liability for failure to issue and sell Common Stock upon exercise or vesting of such Awards unless and until such authority is obtained. A Participant is not eligible for the grant of an Award or the subsequent issuance of Common Stock pursuant to the Award if such grant or issuance would be in violation of any Applicable Law.

#### **11. ADDITIONAL RULES FOR AWARDS SUBJECT TO SECTION 409A.**

**(a) Application.** Unless the provisions of this Section of the Plan are expressly superseded by the provisions in the form of Award Agreement, the provisions of this Section shall apply and shall supersede anything to the contrary set forth in the Award Agreement for a Non-Exempt Award.

**(b) Non-Exempt Awards Subject to Non-Exempt Severance Arrangements.** To the extent a Non-Exempt Award is subject to Section 409A due to application of a Non-Exempt Severance Arrangement, the following provisions of this subsection (b) apply.

(i) If the Non-Exempt Award vests in the ordinary course during the Participant's Continuous Service in accordance with the vesting schedule set forth in the Award Agreement, and does not accelerate vesting under the terms of a Non-Exempt Severance Arrangement, in no event will the shares be issued in respect of such Non-Exempt Award any later than the later of: (i) December 31<sup>st</sup> of the calendar year that includes the applicable vesting date, or (ii) the 60<sup>th</sup> day that follows the applicable vesting date.

(ii) If vesting of the Non-Exempt Award accelerates under the terms of a Non-Exempt Severance Arrangement in connection with the Participant's Separation from Service, and such vesting acceleration provisions were in effect as of the date of grant of the Non-Exempt Award and, therefore, are part of the terms of such Non-Exempt Award as of the date of grant, then the shares will be earlier issued in settlement of such Non-Exempt Award upon the Participant's Separation from Service in accordance with the terms of the Non-Exempt Severance Arrangement, but in no event later than the 60<sup>th</sup> day that follows the date of the Participant's Separation from Service. However, if at the time the shares would otherwise be issued the Participant is subject to the distribution limitations contained in Section 409A applicable to "specified employees," as defined in Section 409A(a)(2)(B)(i) of the Code, such shares shall not be issued before the date that is six months following the date of such Participant's Separation from Service, or, if earlier, the date of the Participant's death that occurs within such six month period.

(iii) If vesting of a Non-Exempt Award accelerates under the terms of a Non-Exempt Severance Arrangement in connection with a Participant's Separation from Service, and such vesting acceleration provisions were not in effect as of the date of grant of the Non-Exempt Award and, therefore, are not a part of the terms of such Non-Exempt Award on the date of grant, then such acceleration of vesting of the Non-Exempt Award shall not accelerate the issuance date of the shares, but the shares shall instead be issued on the same schedule as set forth in the Grant Notice as if they had vested in the ordinary course during the Participant's Continuous Service, notwithstanding the vesting acceleration of the Non-Exempt Award. Such issuance schedule is intended to satisfy the requirements of payment on a specified date or pursuant to a fixed schedule, as provided under Treasury Regulations Section 1.409A-3(a)(4).

**(c) Treatment of Non-Exempt Awards Upon a Corporate Transaction for Employees and Consultants.** The provisions of this subsection (c) shall apply and shall supersede anything to the contrary set forth in the Plan with respect to the permitted treatment of any Non-Exempt Award in connection with a Corporate Transaction if the Participant was either an Employee or Consultant upon the applicable date of grant of the Non-Exempt Award.

**(i) Vested Non-Exempt Awards.** The following provisions shall apply to any Vested Non-Exempt Award in connection with a Corporate Transaction:

**(1)** If the Corporate Transaction is also a Section 409A Change in Control then the Acquiring Entity may not assume, continue or substitute the Vested Non-Exempt Award. Upon the Section 409A Change of Control the settlement of the Vested Non-Exempt Award will automatically be accelerated and the shares will be immediately issued in respect of the Vested Non-Exempt Award. Alternatively, the Company may instead provide that the Participant will receive a cash settlement equal to the Fair Market Value of the shares that would otherwise be issued to the Participant upon the Section 409A Change of Control.

(2) If the Corporate Transaction is not also a Section 409A Change of Control, then the Acquiring Entity must either assume, continue or substitute each Vested Non-Exempt Award. The shares to be issued in respect of the Vested Non-Exempt Award shall be issued to the Participant by the Acquiring Entity on the same schedule that the shares would have been issued to the Participant if the Corporate Transaction had not occurred. In the Acquiring Entity's discretion, in lieu of an issuance of shares, the Acquiring Entity may instead substitute a cash payment on each applicable issuance date, equal to the Fair Market Value of the shares that would otherwise be issued to the Participant on such issuance dates, with the determination of the Fair Market Value of the shares made on the date of the Corporate Transaction.

**(ii) Unvested Non-Exempt Awards.** The following provisions shall apply to any Unvested Non-Exempt Award unless otherwise determined by the Board pursuant to subsection (e) of this Section.

(1) In the event of a Corporate Transaction, the Acquiring Entity shall assume, continue or substitute any Unvested Non-Exempt Award. Unless otherwise determined by the Board, any Unvested Non-Exempt Award will remain subject to the same vesting and forfeiture restrictions that were applicable to the Award prior to the Corporate Transaction. The shares to be issued in respect of any Unvested Non-Exempt Award shall be issued to the Participant by the Acquiring Entity on the same schedule that the shares would have been issued to the Participant if the Corporate Transaction had not occurred. In the Acquiring Entity's discretion, in lieu of an issuance of shares, the Acquiring Entity may instead substitute a cash payment on each applicable issuance date, equal to the Fair Market Value of the shares that would otherwise be issued to the Participant on such issuance dates, with the determination of Fair Market Value of the shares made on the date of the Corporate Transaction.

(2) If the Acquiring Entity will not assume, substitute or continue any Unvested Non-Exempt Award in connection with a Corporate Transaction, then such Award shall automatically terminate and be forfeited upon the Corporate Transaction with no consideration payable to any Participant in respect of such forfeited Unvested Non-Exempt Award. Notwithstanding the foregoing, to the extent permitted and in compliance with the requirements of Section 409A, the Board may in its discretion determine to elect to accelerate the vesting and settlement of the Unvested Non-Exempt Award upon the Corporate Transaction, or instead substitute a cash payment equal to the Fair Market Value of such shares that would otherwise be issued to the Participant, as further provided in subsection (e)(ii) below. In the absence of such discretionary election by the Board, any Unvested Non-Exempt Award shall be forfeited without payment of any consideration to the affected Participants if the Acquiring Entity will not assume, substitute or continue the Unvested Non-Exempt Awards in connection with the Corporate Transaction.

(3) The foregoing treatment shall apply with respect to all Unvested Non-Exempt Awards upon any Corporate Transaction, and regardless of whether or not such Corporate Transaction is also a Section 409A Change of Control.

**(d) Treatment of Non-Exempt Awards Upon a Corporate Transaction for Non-Employee Directors.** The following provisions of this subsection (d) shall apply and shall supersede anything to the contrary that may be set forth in the Plan with respect to the permitted treatment of a Non-Exempt Director Award in connection with a Corporate Transaction.

**(i)** If the Corporate Transaction is also a Section 409A Change of Control then the Acquiring Entity may not assume, continue or substitute the Non-Exempt Director Award. Upon the Section 409A Change of Control the vesting and settlement of any Non-Exempt Director Award will automatically be accelerated and the shares will be immediately issued to the Participant in respect of the Non-Exempt Director Award. Alternatively, the Company may provide that the Participant will instead receive a cash settlement equal to the Fair Market Value of the shares that would otherwise be issued to the Participant upon the Section 409A Change of Control pursuant to the preceding provision.

**(ii)** If the Corporate Transaction is not also a Section 409A Change of Control, then the Acquiring Entity must either assume, continue or substitute the Non-Exempt Director Award. Unless otherwise determined by the Board, the Non-Exempt Director Award will remain subject to the same vesting and forfeiture restrictions that were applicable to the Award prior to the Corporate Transaction. The shares to be issued in respect of the Non-Exempt Director Award shall be issued to the Participant by the Acquiring Entity on the same schedule that the shares would have been issued to the Participant if the Corporate Transaction had not occurred. In the Acquiring Entity's discretion, in lieu of an issuance of shares, the Acquiring Entity may instead substitute a cash payment on each applicable issuance date, equal to the Fair Market Value of the shares that would otherwise be issued to the Participant on such issuance dates, with the determination of Fair Market Value made on the date of the Corporate Transaction.

**(e)** If the RSU Award is a Non-Exempt Award, then the provisions in this Section 11(e) shall apply and supersede anything to the contrary that may be set forth in the Plan or the Award Agreement with respect to the permitted treatment of such Non-Exempt Award:

**(i)** Any exercise by the Board of discretion to accelerate the vesting of a Non-Exempt Award shall not result in any acceleration of the scheduled issuance dates for the shares in respect of the Non-Exempt Award unless earlier issuance of the shares upon the applicable vesting dates would be in compliance with the requirements of Section 409A.

**(ii)** The Company explicitly reserves the right to earlier settle any Non-Exempt Award to the extent permitted and in compliance with the requirements of Section 409A, including pursuant to any of the exemptions available in Treasury Regulations Section 1.409A-3(j)(4)(ix).

**(iii)** To the extent the terms of any Non-Exempt Award provide that it will be settled upon a Change in Control or Corporate Transaction, to the extent it is required for compliance with the requirements of Section 409A, the Change in Control or Corporate Transaction event triggering settlement must also constitute a Section 409A Change of Control. To the extent the terms of a Non-Exempt Award provides that it will be settled upon a termination of employment or termination of Continuous Service, to the extent it is required for

compliance with the requirements of Section 409A, the termination event triggering settlement must also constitute a Separation From Service. However, if at the time the shares would otherwise be issued to a Participant in connection with a "separation from service" such Participant is subject to the distribution limitations contained in Section 409A applicable to "specified employees," as defined in Section 409A(a)(2)(B)(i) of the Code, such shares shall not be issued before the date that is six months following the date of the Participant's Separation From Service, or, if earlier, the date of the Participant's death that occurs within such six month period.

(iv) The provisions in this subsection (e) for delivery of the shares in respect of the settlement of a RSU Award that is a Non-Exempt Award are intended to comply with the requirements of Section 409A so that the delivery of the shares to the Participant in respect of such Non-Exempt Award will not trigger the additional tax imposed under Section 409A, and any ambiguities herein will be so interpreted.

## **12. SEVERABILITY.**

If all or any part of the Plan or any Award Agreement is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity shall not invalidate any portion of the Plan or such Award Agreement not declared to be unlawful or invalid. Any Section of the Plan or any Award Agreement (or part of such a Section) so declared to be unlawful or invalid shall, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

## **13. TERMINATION OF THE PLAN.**

The Board may suspend or terminate the Plan at any time.

No Incentive Stock Options may be granted after the tenth anniversary of the earlier of: (i) the Adoption Date, or (ii) the date the Plan is approved by the Company's stockholders. No Awards may be granted under the Plan while the Plan is suspended or after it is terminated.

#### 14. DEFINITIONS.

As used in the Plan, the following definitions apply to the capitalized terms indicated below:

(a) **“Acquiring Entity”** means the surviving or acquiring corporation (or its parent company) in connection with a Corporate Transaction.

(b) **“Adoption Date”** means the date the Plan is first approved by the Board or Compensation Committee.

(c) **“Affiliate”** means, at the time of determination, any “parent” or “subsidiary” of the Company as such terms are defined in Rule 405 promulgated under the Securities Act. The Board may determine the time or times at which “parent” or “subsidiary” status is determined within the foregoing definition.

(d) **“Applicable Law”** means shall mean any applicable securities, federal, state, foreign, material local or municipal or other law, statute, constitution, principle of common law, resolution, ordinance, code, edict, decree, rule, listing rule, regulation, judicial decision, ruling or requirement issued, enacted, adopted, promulgated, implemented or otherwise put into effect by or under the authority of any Governmental Body (including under the authority of any applicable self-regulating organization such as the Nasdaq Stock Market, New York Stock Exchange, or the Financial Industry Regulatory Authority).

(e) **“Award”** means any right to receive Common Stock, cash or other property granted under the Plan (including an Incentive Stock Option, a Nonstatutory Stock Option, a Restricted Stock Award, a RSU Award, a SAR, a Performance Award or any Other Award).

(f) **“Award Agreement”** means a written agreement between the Company and a Participant evidencing the terms and conditions of an Award. The Award Agreement generally consists of the Grant Notice and the agreement containing the written summary of the general terms and conditions applicable to the Award and which is provided to a Participant along with the Grant Notice.

(g) **“Board”** means the Board of Directors of the Company (or its designee). Any decision or determination made by the Board shall be a decision or determination that is made in the sole discretion of the Board (or its designee), and such decision or determination shall be final and binding on all Participants.

(h) **“Capitalization Adjustment”** means any change that is made in, or other events that occur with respect to, the Common Stock subject to the Plan or subject to any Award after the Effective Date without the receipt of consideration by the Company through merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, stock split, reverse stock split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or any similar equity restructuring transaction, as that term is used in Statement of Financial Accounting Standards Board Accounting Standards Codification Topic 718 (or any successor thereto). Notwithstanding the foregoing, the conversion of any convertible securities of the Company will not be treated as a Capitalization Adjustment.

(i) **“Cause”** has the meaning ascribed to such term in any written agreement between the Participant and the Company defining such term and, in the absence of such agreement, such term means, with respect to a Participant, the occurrence of any of the following events: (i) such Participant’s commission of any crime involving fraud, dishonesty or moral turpitude or attempted commission of, or participation in, a fraud or act of dishonesty against the Company; (ii) such Participant’s intentional, material violation of any contract or agreement between the Participant and the Company or of any statutory duty owed to the Company; (iii) such Participant’s unauthorized use or disclosure of the Company’s confidential information or trade secrets; or (iv) such Participant’s gross misconduct, conduct that constitutes gross insubordination, incompetence or habitual neglect of duties and that results in (or might have reasonably resulted in) material harm to the business of the Company. The determination that a termination of the Participant’s Continuous Service is either for Cause or without Cause will be made by the Board with respect to Participants who are executive officers of the Company and by the Company’s Chief Executive Officer with respect to Participants who are not executive officers of the Company. Any determination by the Company that the Continuous Service of a Participant was terminated with or without Cause for the purposes of outstanding Awards held by such Participant will have no effect upon any determination of the rights or obligations of the Company or such Participant for any other purpose.

(j) **“Change in Control”** or **“Change of Control”** means the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events; provided, however, to the extent necessary to avoid adverse personal income tax consequences to the Participant in connection with an Award, also constitutes a Section 409A Change of Control:

(i) any Exchange Act Person becomes the Owner, directly or indirectly, of securities of the Company representing more than 50% of the combined voting power of the Company’s then outstanding securities other than by virtue of a merger, consolidation or similar transaction. Notwithstanding the foregoing, a Change in Control shall not be deemed to occur (A) on account of the acquisition of securities of the Company directly from the Company, (B) on account of the acquisition of securities of the Company by an investor, any affiliate thereof or any other Exchange Act Person that acquires the Company’s securities in a transaction or series of related transactions the primary purpose of which is to obtain financing for the Company through the issuance of equity securities, or (C) solely because the level of Ownership held by any Exchange Act Person (the *“Subject Person”*) exceeds the designated percentage threshold of the outstanding voting securities as a result of a repurchase or other acquisition of voting securities by the Company reducing the number of shares outstanding, provided that if a Change in Control would occur (but for the operation of this sentence) as a result of the acquisition of voting securities by the Company, and after such share acquisition, the Subject Person becomes the Owner of any additional voting securities that, assuming the repurchase or other acquisition had not occurred, increases the percentage of the then outstanding voting securities Owned by the Subject Person over the designated percentage threshold, then a Change in Control shall be deemed to occur;

(ii) there is consummated a merger, consolidation or similar transaction involving (directly or indirectly) the Company and, immediately after the consummation of such merger, consolidation or similar transaction, the stockholders of the Company immediately prior thereto do not Own, directly or indirectly, either (A) outstanding voting securities representing more than 50% of the combined outstanding voting power of the surviving Entity in such merger, consolidation or similar transaction or (B) more than 50% of the combined outstanding voting power of the parent of the surviving Entity in such merger, consolidation or similar transaction, in each case in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such transaction;

(iii) the stockholders of the Company approve or the Board approves a plan of complete dissolution or liquidation of the Company, or a complete dissolution or liquidation of the Company shall otherwise occur, except for a liquidation into a parent corporation;

(iv) there is consummated a sale, lease, exclusive license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries, other than a sale, lease, license or other disposition of all or substantially all of the consolidated assets of the Company and its Subsidiaries to an Entity, more than 50% of the combined voting power of the voting securities of which are Owned by stockholders of the Company in substantially the same proportions as their Ownership of the outstanding voting securities of the Company immediately prior to such sale, lease, license or other disposition; or

(v) individuals who, on the date the Plan is adopted by the Board, are members of the Board (the “**Incumbent Board**”) cease for any reason to constitute at least a majority of the members of the Board; *provided, however*, that if the appointment or election (or nomination for election) of any new Board member was approved or recommended by a majority vote of the members of the Incumbent Board then still in office, such new member shall, for purposes of this Plan, be considered as a member of the Incumbent Board.

Notwithstanding the foregoing or any other provision of this Plan, (A) the term Change in Control shall not include a sale of assets, merger or other transaction effected exclusively for the purpose of changing the domicile of the Company, and (B) the definition of Change in Control (or any analogous term) in an individual written agreement between the Company or any Affiliate and the Participant shall supersede the foregoing definition with respect to Awards subject to such agreement; *provided, however*, that if no definition of Change in Control or any analogous term is set forth in such an individual written agreement, the foregoing definition shall apply.

(k) “**Code**” means the Internal Revenue Code of 1986, as amended, including any applicable regulations and guidance thereunder.

(l) “**Committee**” means the Compensation Committee and any other committee of Directors to whom authority has been delegated by the Board or Compensation Committee in accordance with the Plan.

(m) “**Common Stock**” means the common stock of the Company.

(n) “**Company**” means Oncorus, Inc., a Delaware corporation.

(o) “**Compensation Committee**” means the Compensation Committee of the Board.

(p) “**Consultant**” means any person, including an advisor, who is (i) engaged by the Company or an Affiliate to render consulting or advisory services and is compensated for such services, or (ii) serving as a member of the board of directors of an Affiliate and is compensated for such services. However, service solely as a Director, or payment of a fee for such service, will not cause a Director to be considered a “Consultant” for purposes of the Plan. Notwithstanding the foregoing, a person is treated as a Consultant under this Plan only if a Form S-8 Registration Statement under the Securities Act is available to register either the offer or the sale of the Company’s securities to such person.

(q) “**Continuous Service**” means that the Participant’s service with the Company or an Affiliate, whether as an Employee, Director or Consultant, is not interrupted or terminated. A change in the capacity in which the Participant renders service to the Company or an Affiliate as an Employee, Director or Consultant or a change in the Entity for which the Participant renders such service, provided that there is no interruption or termination of the Participant’s service with the Company or an Affiliate, will not terminate a Participant’s Continuous Service; *provided, however*, that if the Entity for which a Participant is rendering services ceases to qualify as an Affiliate, as determined by the Board, such Participant’s Continuous Service will be considered to have terminated on the date such Entity ceases to qualify as an Affiliate. For example, a change in status from an Employee of the Company to a Consultant of an Affiliate or to a Director will not constitute an interruption of Continuous Service. To the extent permitted by law, the Board or the chief executive officer of the Company, in that party’s sole discretion, may determine whether Continuous Service will be considered interrupted in the case of (i) any leave of absence approved by the Board or chief executive officer, including sick leave, military leave or any other personal leave, or (ii) transfers between the Company, an Affiliate, or their successors. Notwithstanding the foregoing, a leave of absence will be treated as Continuous Service for purposes of vesting in an Award only to such extent as may be provided in the Company’s leave of absence policy, in the written terms of any leave of absence agreement or policy applicable to the Participant, or as otherwise required by law. In addition, to the extent required for exemption from or compliance with Section 409A, the determination of whether there has been a termination of Continuous Service will be made, and such term will be construed, in a manner that is consistent with the definition of “separation from service” as defined under Treasury Regulation Section 1.409A-1(h) (without regard to any alternative definition thereunder).

(r) “**Corporate Transaction**” means the consummation, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) a sale or other disposition of all or substantially all, as determined by the Board, of the consolidated assets of the Company and its Subsidiaries;

(ii) a sale or other disposition of at least 50% of the outstanding securities of the Company;

(iii) a merger, consolidation or similar transaction following which the Company is not the surviving corporation; or

(iv) a merger, consolidation or similar transaction following which the Company is the surviving corporation but the shares of Common Stock outstanding immediately preceding the merger, consolidation or similar transaction are converted or exchanged by virtue of the merger, consolidation or similar transaction into other property, whether in the form of securities, cash or otherwise.

(s) “**Director**” means a member of the Board.

(t) “**determine**” or “**determined**” means as determined by the Board or the Committee (or its designee) in its sole discretion.

(u) “**Disability**” means, with respect to a Participant, such Participant is unable to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment which can be expected to result in death or which has lasted or can be expected to last for a continuous period of not less than 12 months, as provided in Section 22(e)(3) of the Code, and will be determined by the Board on the basis of such medical evidence as the Board deems warranted under the circumstances.

(v) “**Effective Date**” means the IPO Date, provided this Plan is approved by the Company’s stockholders prior to the IPO Date.

(w) “**Employee**” means any person employed by the Company or an Affiliate. However, service solely as a Director, or payment of a fee for such services, will not cause a Director to be considered an “Employee” for purposes of the Plan.

(x) “**Employer**” means the Company or the Affiliate of the Company that employs the Participant.

(y) “**Entity**” means a corporation, partnership, limited liability company or other entity.

(z) “**Exchange Act**” means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

(aa) “**Exchange Act Person**” means any natural person, Entity or “group” (within the meaning of Section 13(d) or 14(d) of the Exchange Act), except that “Exchange Act Person” will not include (i) the Company or any Subsidiary of the Company, (ii) any employee benefit plan of the Company or any Subsidiary of the Company or any trustee or other fiduciary holding securities under an employee benefit plan of the Company or any Subsidiary of the Company, (iii) an underwriter temporarily holding securities pursuant to a registered public offering of such securities, (iv) an Entity Owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their Ownership of stock of the Company; or (v) any natural person, Entity or “group” (within the meaning of Section 13(d) or 14(d) of the Exchange Act) that, as of the Effective Date, is the Owner, directly or indirectly, of securities of the Company representing more than 50% of the combined voting power of the Company’s then outstanding securities.

**(bb) “Fair Market Value”** means, as of any date, unless otherwise determined by the Board, the value of the Common Stock (as determined on a per share or aggregate basis, as applicable) determined as follows:

**(i)** If the Common Stock is listed on any established stock exchange or traded on any established market, the Fair Market Value will be the closing sales price for such stock as quoted on such exchange or market (or the exchange or market with the greatest volume of trading in the Common Stock) on the date of determination, as reported in a source the Board deems reliable.

**(ii)** If there is no closing sales price for the Common Stock on the date of determination, then the Fair Market Value will be the closing selling price on the last preceding date for which such quotation exists.

**(iii)** In the absence of such markets for the Common Stock, or if otherwise determined by the Board, the Fair Market Value will be determined by the Board in good faith and in a manner that complies with Sections 409A and 422 of the Code.

**(cc) “Governmental Body”** means any: (a) nation, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (b) federal, state, local, municipal, foreign or other government; (c) governmental or regulatory body, or quasi-governmental body of any nature (including any governmental division, department, administrative agency or bureau, commission, authority, instrumentality, official, ministry, fund, foundation, center, organization, unit, body or Entity and any court or other tribunal, and for the avoidance of doubt, any Tax authority) or other body exercising similar powers or authority; or (d) self-regulatory organization (including the Nasdaq Stock Market, New York Stock Exchange, and the Financial Industry Regulatory Authority).

**(dd) “Grant Notice”** means the notice provided to a Participant that he or she has been granted an Award under the Plan and which includes the name of the Participant, the type of Award, the date of grant of the Award, number of shares of Common Stock subject to the Award or potential cash payment right, (if any), the vesting schedule for the Award (if any) and other key terms applicable to the Award.

**(ee) “Incentive Stock Option”** means an option granted pursuant to Section 4 of the Plan that is intended to be, and qualifies as, an “incentive stock option” within the meaning of Section 422 of the Code.

**(ff) “IPO Date”** means the date of the underwriting agreement between the Company and the underwriter(s) managing the initial public offering of the Common Stock, pursuant to which the Common Stock is priced for the initial public offering.

**(gg) “Materially Impair”** means any amendment to the terms of the Award that materially adversely affects the Participant’s rights under the Award. A Participant’s rights under an Award will not be deemed to have been Materially Impaired by any such amendment if the Board, in its sole discretion, determines that the amendment, taken as a whole, does not materially impair the Participant’s rights. For example, the following types of amendments to the terms of an Award do not Materially Impair the Participant’s rights under the Award: (i)

imposition of reasonable restrictions on the minimum number of shares subject to an Option that may be exercised, (ii) to maintain the qualified status of the Award as an Incentive Stock Option under Section 422 of the Code; (iii) to change the terms of an Incentive Stock Option in a manner that disqualifies, impairs or otherwise affects the qualified status of the Award as an Incentive Stock Option under Section 422 of the Code; (iv) to clarify the manner of exemption from, or to bring the Award into compliance with or qualify it for an exemption from, Section 409A; or (v) to comply with other Applicable Laws.

**(hh) “Non-Employee Director”** means a Director who either (i) is not a current employee or officer of the Company or an Affiliate, does not receive compensation, either directly or indirectly, from the Company or an Affiliate for services rendered as a consultant or in any capacity other than as a Director (except for an amount as to which disclosure would not be required under Item 404(a) of Regulation S-K promulgated pursuant to the Securities Act (“**Regulation S-K**”)), does not possess an interest in any other transaction for which disclosure would be required under Item 404(a) of Regulation S-K, and is not engaged in a business relationship for which disclosure would be required pursuant to Item 404(b) of Regulation S-K; or (ii) is otherwise considered a “non-employee director” for purposes of Rule 16b-3.

**(ii) “Non-Exempt Award”** means any Award that is subject to, and not exempt from, Section 409A, including as the result of (i) a deferral of the issuance of the shares subject to the Award which is elected by the Participant or imposed by the Company, (ii) the terms of any Non-Exempt Severance Agreement.

**(jj) “Non-Exempt Director Award”** means a Non-Exempt Award granted to a Participant who was a Director but not an Employee on the applicable grant date.

**(kk) “Non-Exempt Severance Arrangement”** means a severance arrangement or other agreement between the Participant and the Company that provides for acceleration of vesting of an Award and issuance of the shares in respect of such Award upon the Participant’s termination of employment or separation from service (as such term is defined in Section 409A(a)(2)(A)(i) of the Code (and without regard to any alternative definition thereunder) (“**Separation from Service**”)) and such severance benefit does not satisfy the requirements for an exemption from application of Section 409A provided under Treasury Regulations Section 1.409A-1(b)(4), 1.409A-1(b)(9) or otherwise.

**(ll) “Nonstatutory Stock Option”** means any option granted pursuant to Section 4 of the Plan that does not qualify as an Incentive Stock Option.

**(mm) “Officer”** means a person who is an officer of the Company within the meaning of Section 16 of the Exchange Act.

**(nn) “Option”** means an Incentive Stock Option or a Nonstatutory Stock Option to purchase shares of Common Stock granted pursuant to the Plan.

**(oo) “Option Agreement”** means a written agreement between the Company and the Optionholder evidencing the terms and conditions of the Option grant. The Option Agreement includes the Grant Notice for the Option and the agreement containing the written summary of the general terms and conditions applicable to the Option and which is provided to a Participant along with the Grant Notice. Each Option Agreement will be subject to the terms and conditions of the Plan.

(pp) “**Optionholder**” means a person to whom an Option is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Option.

(qq) “**Other Award**” means an award based in whole or in part by reference to the Common Stock which is granted pursuant to the terms and conditions of Section 5(c).

(rr) “**Other Award Agreement**” means a written agreement between the Company and a holder of an Other Award evidencing the terms and conditions of an Other Award grant. Each Other Award Agreement will be subject to the terms and conditions of the Plan.

(ss) “**Own,**” “**Owned,**” “**Owner,**” “**Ownership**” means that a person or Entity will be deemed to “Own,” to have “Owned,” to be the “Owner” of, or to have acquired “Ownership” of securities if such person or Entity, directly or indirectly, through any contract, arrangement, understanding, relationship or otherwise, has or shares voting power, which includes the power to vote or to direct the voting, with respect to such securities.

(tt) “**Participant**” means an Employee, Director or Consultant to whom an Award is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Award.

(uu) “**Performance Award**” means an Award that may vest or may be exercised or a cash award that may vest or become earned and paid contingent upon the attainment during a Performance Period of certain Performance Goals and which is granted under the terms and conditions of Section 5(b) pursuant to such terms as are approved by the Board. In addition, to the extent permitted by Applicable Law and set forth in the applicable Award Agreement, the Board may determine that cash or other property may be used in payment of Performance Awards. Performance Awards that are settled in cash or other property are not required to be valued in whole or in part by reference to, or otherwise based on, the Common Stock.

(vv) “**Performance Criteria**” means the one or more criteria that the Board will select for purposes of establishing the Performance Goals for a Performance Period. The Performance Criteria that will be used to establish such Performance Goals may be based on any measure of performance selected by the Board.

(ww) “**Performance Goals**” means, for a Performance Period, the one or more goals established by the Board for the Performance Period based upon the Performance Criteria. Performance Goals may be based on a Company-wide basis, with respect to one or more business units, divisions, Affiliates, or business segments, and in either absolute terms or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise by the Board (i) in the Award Agreement at the time the Award is granted or (ii) in such other document setting forth the Performance Goals at the time the Performance Goals are established, the Board will appropriately make adjustments in the method of calculating the attainment of Performance Goals for a Performance Period as follows: (1) to exclude restructuring and/or other nonrecurring charges; (2) to exclude exchange rate effects; (3) to exclude the effects of changes to generally accepted accounting principles; (4)

to exclude the effects of any statutory adjustments to corporate tax rates; (5) to exclude the effects of items that are “unusual” in nature or occur “infrequently” as determined under generally accepted accounting principles; (6) to exclude the dilutive effects of acquisitions or joint ventures; (7) to assume that any business divested by the Company achieved performance objectives at targeted levels during the balance of a Performance Period following such divestiture; (8) to exclude the effect of any change in the outstanding shares of common stock of the Company by reason of any stock dividend or split, stock repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination or exchange of shares or other similar corporate change, or any distributions to common stockholders other than regular cash dividends; (9) to exclude the effects of stock based compensation and the award of bonuses under the Company’s bonus plans; (10) to exclude costs incurred in connection with potential acquisitions or divestitures that are required to be expensed under generally accepted accounting principles; and (11) to exclude the goodwill and intangible asset impairment charges that are required to be recorded under generally accepted accounting principles. In addition, the Board retains the discretion to reduce or eliminate the compensation or economic benefit due upon attainment of Performance Goals and to define the manner of calculating the Performance Criteria it selects to use for such Performance Period. Partial achievement of the specified criteria may result in the payment or vesting corresponding to the degree of achievement as specified in the Award Agreement or the written terms of a Performance Cash Award.

**(xx) “Performance Period”** means the period of time selected by the Board over which the attainment of one or more Performance Goals will be measured for the purpose of determining a Participant’s right to vesting or exercise of an Award. Performance Periods may be of varying and overlapping duration, at the sole discretion of the Board.

**(yy) “Plan”** means this Oncorus, Inc. 2020 Equity Incentive Plan, as amended from time to time.

**(zz) “Plan Administrator”** means the person, persons, and/or third-party administrator designated by the Company to administer the day to day operations of the Plan and the Company’s other equity incentive programs.

**(aaa) “Post-Termination Exercise Period”** means the period following termination of a Participant’s Continuous Service within which an Option or SAR is exercisable, as specified in Section 4(h).

**(bbb) “Prior Plan’s Available Reserve”** means the number of shares available for the grant of new awards under the Prior Plan, to the extent applicable, as of immediately prior to the Effective Date.

**(ccc) “Prior Plan”** means the Oncorus, Inc. 2016 Equity Incentive Plan, as amended.

**(ddd) “Prospectus”** means the document containing the Plan information specified in Section 10(a) of the Securities Act.

**(eee) “Restricted Stock Award” or “RSA”** means an Award of shares of Common Stock which is granted pursuant to the terms and conditions of Section 5(a).

**(fff) “Restricted Stock Award Agreement”** means a written agreement between the Company and a holder of a Restricted Stock Award evidencing the terms and conditions of a Restricted Stock Award grant. The Restricted Stock Award Agreement includes the Grant Notice for the Restricted Stock Award and the agreement containing the written summary of the general terms and conditions applicable to the Restricted Stock Award and which is provided to a Participant along with the Grant Notice. Each Restricted Stock Award Agreement will be subject to the terms and conditions of the Plan.

**(ggg) “Returning Shares”** means shares subject to outstanding stock awards granted under the Prior Plan and that following the Effective Date: (A) are not issued because such stock award or any portion thereof expires or otherwise terminates without all of the shares covered by such stock award having been issued; (B) are not issued because such stock award or any portion thereof is settled in cash; (C) are forfeited back to or repurchased by the Company because of the failure to meet a contingency or condition required for the vesting of such shares; (D) are withheld or reacquired to satisfy the exercise, strike or purchase price; or (E) are withheld or reacquired to satisfy a tax withholding obligation.

**(hhh) “RSU Award” or “RSU”** means an Award of restricted stock units representing the right to receive an issuance of shares of Common Stock which is granted pursuant to the terms and conditions of Section 5(a).

**(iii) “RSU Award Agreement”** means a written agreement between the Company and a holder of a RSU Award evidencing the terms and conditions of a RSU Award grant. The RSU Award Agreement includes the Grant Notice for the RSU Award and the agreement containing the written summary of the general terms and conditions applicable to the RSU Award and which is provided to a Participant along with the Grant Notice. Each RSU Award Agreement will be subject to the terms and conditions of the Plan.

**(jjj) “Rule 16b-3”** means Rule 16b-3 promulgated under the Exchange Act or any successor to Rule 16b-3, as in effect from time to time.

**(kkk) “Rule 405”** means Rule 405 promulgated under the Securities Act.

**(lll) “Section 409A”** means Section 409A of the Code and the regulations and other guidance thereunder.

**(mmm) “Section 409A Change of Control”** means a change in the ownership or effective control of the Company, or in the ownership of a substantial portion of the Company’s assets, as provided in Section 409A(a)(2)(A)(v) of the Code and Treasury Regulations Section 1.409A-3(i)(5) (without regard to any alternative definition thereunder).

**(nnn) “Securities Act”** means the Securities Act of 1933, as amended.

**(ooo) “Share Reserve”** means the number of shares available for issuance under the Plan as set forth in Section 2(a).

**(ppp) “Stock Appreciation Right” or “SAR”** means a right to receive the appreciation on Common Stock that is granted pursuant to the terms and conditions of Section 4.

**(qqq) “SAR Agreement”** means a written agreement between the Company and a holder of a SAR evidencing the terms and conditions of a SAR grant. The SAR Agreement includes the Grant Notice for the SAR and the agreement containing the written summary of the general terms and conditions applicable to the SAR and which is provided to a Participant along with the Grant Notice. Each SAR Agreement will be subject to the terms and conditions of the Plan.

**(rrr) “Subsidiary”** means, with respect to the Company, (i) any corporation of which more than 50% of the outstanding capital stock having ordinary voting power to elect a majority of the board of directors of such corporation (irrespective of whether, at the time, stock of any other class or classes of such corporation will have or might have voting power by reason of the happening of any contingency) is at the time, directly or indirectly, Owned by the Company, and (ii) any partnership, limited liability company or other entity in which the Company has a direct or indirect interest (whether in the form of voting or participation in profits or capital contribution) of more than 50%.

**(sss) “Ten Percent Stockholder”** means a person who Owns (or is deemed to Own pursuant to Section 424(d) of the Code) stock possessing more than 10% of the total combined voting power of all classes of stock of the Company or any Affiliate.

**(ttt) “Trading Policy”** means the Company’s policy permitting certain individuals to sell Company shares only during certain “window” periods and/or otherwise restricts the ability of certain individuals to transfer or encumber Company shares, as in effect from time to time.

**(uuu) “Unvested Non-Exempt Award”** means the portion of any Non-Exempt Award that had not vested in accordance with its terms upon or prior to the date of any Corporate Transaction.

**(vvv) “Vested Non-Exempt Award”** means the portion of any Non-Exempt Award that had vested in accordance with its terms upon or prior to the date of a Corporate Transaction.

## ONCORUS, INC.

## 2020 EMPLOYEE STOCK PURCHASE PLAN

ADOPTED BY THE BOARD OF DIRECTORS: SEPTEMBER 15, 2020

APPROVED BY THE STOCKHOLDERS: SEPTEMBER 25, 2020

IPO DATE: OCTOBER 1, 2020

**1. GENERAL; PURPOSE.**

(a) The Plan provides a means by which Eligible Employees of the Company and certain designated Related Corporations may be given an opportunity to purchase shares of Common Stock. The Plan permits the Company to grant a series of Purchase Rights to Eligible Employees under an Employee Stock Purchase Plan. In addition, the Plan permits the Company to grant a series of Purchase Rights to Eligible Employees that do not meet the requirements of an Employee Stock Purchase Plan.

(b) The Plan includes two components: a 423 Component and a Non-423 Component. The Company intends (but makes no undertaking or representation to maintain) the 423 Component to qualify as an Employee Stock Purchase Plan. The provisions of the 423 Component, accordingly, will be construed in a manner that is consistent with the requirements of Section 423 of the Code. Except as otherwise provided in the Plan or determined by the Board, the Non-423 Component will operate and be administered in the same manner as the 423 Component.

(c) The Company, by means of the Plan, seeks to retain the services of such Employees, to secure and retain the services of new Employees and to provide incentives for such persons to exert maximum efforts for the success of the Company and its Related Corporations.

**2. ADMINISTRATION.**

(a) The Board or the Committee will administer the Plan. References herein to the Board shall be deemed to refer to the Committee except where context dictates otherwise.

(b) The Board will have the power, subject to, and within the limitations of, the express provisions of the Plan:

(i) To determine how and when Purchase Rights will be granted and the provisions of each Offering (which need not be identical).

(ii) To designate from time to time (A) which Related Corporations of the Company will be eligible to participate in the Plan, (B) whether such Related Corporations will participate in the 423 Component or the Non-423 Component, and (C) to the extent that the Company makes separate Offerings under the 423 Component, in which Offering the Related Corporations in the 423 Component will participate.

(iii) To construe and interpret the Plan and Purchase Rights, and to establish, amend and revoke rules and regulations for its administration. The Board, in the exercise of this power, may correct any defect, omission or inconsistency in the Plan, in a manner and to the extent it deems necessary or expedient to make the Plan fully effective.

(iv) To settle all controversies regarding the Plan and Purchase Rights granted under the Plan.

(v) To suspend or terminate the Plan at any time as provided in Section 12.

(vi) To amend the Plan at any time as provided in Section 12.

(vii) Generally, to exercise such powers and to perform such acts as it deems necessary or expedient to promote the best interests of the Company and its Related Corporations and to carry out the intent that the Plan be treated as an Employee Stock Purchase Plan with respect to the 423 Component.

(viii) To adopt such rules, procedures and sub-plans as are necessary or appropriate to permit or facilitate participation in the Plan by Employees who are foreign nationals or employed or located outside the United States. Without limiting the generality of, and consistent with, the foregoing, the Board specifically is authorized to adopt rules, procedures, and sub-plans regarding, without limitation, eligibility to participate in the Plan, the definition of eligible "earnings," handling and making of Contributions, establishment of bank or trust accounts to hold Contributions, payment of interest, conversion of local currency, obligations to pay payroll tax, determination of beneficiary designation requirements, withholding procedures and handling of share issuances, any of which may vary according to applicable requirements, and which, if applicable to a Related Corporation designated for participation in the Non-423 Component, do not have to comply with the requirements of Section 423 of the Code.

(c) The Board may delegate some or all of the administration of the Plan to a Committee or Committees. If administration is delegated to a Committee, the Committee will have, in connection with the administration of the Plan, the powers theretofore possessed by the Board that have been delegated to the Committee, including the power to delegate to a subcommittee any of the administrative powers the Committee is authorized to exercise (and references in this Plan to the Board will thereafter be to the Committee or subcommittee), subject, however, to such resolutions, not inconsistent with the provisions of the Plan, as may be adopted from time to time by the Board. The Board may retain the authority to concurrently administer the Plan with the Committee and may, at any time, revert in the Board some or all of the powers previously delegated. Whether or not the Board has delegated administration of the Plan to a Committee, the Board will have the final power to determine all questions of policy and expediency that may arise in the administration of the Plan.

(d) All determinations, interpretations and constructions made by the Board in good faith will not be subject to review by any person and will be final, binding and conclusive on all persons.

### **3. SHARES OF COMMON STOCK SUBJECT TO THE PLAN.**

(a) Subject to the provisions of Section 11(a) relating to Capitalization Adjustments, the maximum number of shares of Common Stock that may be issued under the Plan will not exceed 280,000 shares of Common Stock, plus the number of shares of Common Stock that are automatically added on January 1<sup>st</sup> of each calendar year for a period of up to ten years, commencing on the first January 1 following the year in which the IPO Date occurs and ending on (and including) January 1, 2030, in an amount equal to the lesser of (i) 1% of the total number of shares of Common Stock outstanding on December 31<sup>st</sup> of the preceding calendar year, and (ii) 560,000 shares of Common Stock. Notwithstanding the foregoing, the Board may act prior to the first day of any calendar year to provide that there will be no January 1<sup>st</sup> increase in the share reserve for such calendar year or that the increase in the share reserve for such calendar year will be a lesser number of shares of Common Stock than would otherwise occur pursuant to the preceding sentence. For the avoidance of doubt, up to the maximum number of shares of Common Stock reserved under this Section 3(a) may be used to satisfy purchases of Common Stock under the 423 Component and any remaining portion of such maximum number of shares may be used to satisfy purchases of Common Stock under the Non-423 Component.

(b) If any Purchase Right granted under the Plan terminates without having been exercised in full, the shares of Common Stock not purchased under such Purchase Right will again become available for issuance under the Plan.

(c) The stock purchasable under the Plan will be shares of authorized but unissued or reacquired Common Stock, including shares repurchased by the Company on the open market.

#### **4. GRANT OF PURCHASE RIGHTS; OFFERING.**

(a) The Board may from time to time grant or provide for the grant of Purchase Rights to Eligible Employees under an Offering (consisting of one or more Purchase Periods) on an Offering Date or Offering Dates selected by the Board. Each Offering will be in such form and will contain such terms and conditions as the Board will deem appropriate, and, with respect to the 423 Component, will comply with the requirement of Section 423(b)(5) of the Code that all Employees granted Purchase Rights will have the same rights and privileges. The terms and conditions of an Offering shall be incorporated by reference into the Plan and treated as part of the Plan. The provisions of separate Offerings need not be identical, but each Offering will include (through incorporation of the provisions of this Plan by reference in the document comprising the Offering or otherwise) the period during which the Offering will be effective, which period will not exceed 27 months beginning with the Offering Date, and the substance of the provisions contained in Sections 5 through 8, inclusive.

(b) If a Participant has more than one Purchase Right outstanding under the Plan, unless he or she otherwise indicates in forms delivered to the Company: (i) each form will apply to all of his or her Purchase Rights under the Plan, and (ii) a Purchase Right with a lower exercise price (or an earlier-granted Purchase Right, if different Purchase Rights have identical exercise prices) will be exercised to the fullest possible extent before a Purchase Right with a higher exercise price (or a later-granted Purchase Right if different Purchase Rights have identical exercise prices) will be exercised.

(c) The Board will have the discretion to structure an Offering so that if the Fair Market Value of a share of Common Stock on the first Trading Day of a new Purchase Period within that Offering is less than or equal to the Fair Market Value of a share of Common Stock on the Offering Date for that Offering, then (i) that Offering will terminate immediately as of that first Trading Day, and (ii) the Participants in such terminated Offering will be automatically enrolled in a new Offering beginning on the first Trading Day of such new Purchase Period.

#### **5. ELIGIBILITY.**

(a) Purchase Rights may be granted only to Employees of the Company or, as the Board may designate in accordance with Section 2(b), to Employees of a Related Corporation. Except as provided in Section 5(b) or as required by Applicable Law, an Employee will not be eligible to be granted Purchase Rights unless, on the Offering Date, the Employee has been in the employ of the Company or the Related Corporation, as the case may be, for such continuous period preceding such Offering Date as the Board may require, but in no event will the required period of continuous employment be equal to or greater than two years. In addition, the Board may (unless prohibited by law) provide that no Employee will be eligible to be granted Purchase Rights under the Plan unless, on the Offering Date, such Employee's customary employment with the Company or the Related Corporation is more than 20 hours per week and more than five months per calendar year or such other criteria as the Board may determine consistent with Section 423 of the Code with respect to the 423 Component. The Board may also exclude from participation in the Plan or any Offering Employees who are "highly compensated employees" (within the meaning of Section 423(b)(4)(D) of the Code) of the Company or a Related Corporation or a subset of such highly compensated employees.

(b) The Board may provide that each person who, during the course of an Offering, first becomes an Eligible Employee will, on a date or dates specified in the Offering which coincides with the day on which such person becomes an Eligible Employee or which occurs thereafter, receive a Purchase Right under that Offering, which Purchase Right will thereafter be deemed to be a part of that Offering. Such Purchase Right will have the same characteristics as any Purchase Rights originally granted under that Offering, as described herein, except that:

(i) the date on which such Purchase Right is granted will be the "Offering Date" of such Purchase Right for all purposes, including determination of the exercise price of such Purchase Right;

(ii) the period of the Offering with respect to such Purchase Right will begin on its Offering Date and end coincident with the end of such Offering; and

(iii) the Board may provide that if such person first becomes an Eligible Employee within a specified period of time before the end of the Offering, he or she will not receive any Purchase Right under that Offering.

(c) No Employee will be eligible for the grant of any Purchase Rights if, immediately after any such Purchase Rights are granted, such Employee owns stock possessing five percent or more of the total combined voting power or value of all classes of stock of the Company or of any Related Corporation. For purposes of this Section 5(c), the rules of Section 424(d) of the Code will apply in determining the stock ownership of any Employee, and stock which such Employee may purchase under all outstanding Purchase Rights and options will be treated as stock owned by such Employee.

(d) As specified by Section 423(b)(8) of the Code, an Eligible Employee may be granted Purchase Rights only if such Purchase Rights, together with any other rights granted under all Employee Stock Purchase Plans of the Company and any Related Corporations, do not permit such Eligible Employee's rights to purchase stock of the Company or any Related Corporation to accrue at a rate which, when aggregated, exceeds US \$25,000 of Fair Market Value of such stock (determined at the time such rights are granted, and which, with respect to the Plan, will be determined as of their respective Offering Dates) for each calendar year in which such rights are outstanding at any time.

(e) Officers of the Company and any designated Related Corporation, if they are otherwise Eligible Employees, will be eligible to participate in Offerings under the Plan. Notwithstanding the foregoing, the Board may (unless prohibited by law) provide in an Offering that Employees who are highly compensated Employees within the meaning of Section 423(b)(4)(D) of the Code will not be eligible to participate.

(f) Notwithstanding anything in this Section 5 to the contrary, in the case of an Offering under the Non-423 Component, an Eligible Employee (or group of Eligible Employees) may be excluded from participation in the Plan or an Offering if the Board has determined, in its sole discretion, that participation of such Eligible Employee(s) is not advisable or practical for any reason.

#### **6. PURCHASE RIGHTS; PURCHASE PRICE.**

(a) On each Offering Date, each Eligible Employee, pursuant to an Offering made under the Plan, will be granted a Purchase Right to purchase up to that number of shares of Common Stock purchasable either with a percentage or with a maximum dollar amount, as designated by the Board, but in either case not exceeding 15% of such Employee's earnings (as defined by the Board in each Offering) during the period that begins on the Offering Date (or such later date as the Board determines for a particular Offering) and ends on the date stated in the Offering, which date will be no later than the end of the Offering.

(b) The Board will establish one or more Purchase Dates during an Offering on which Purchase Rights granted for that Offering will be exercised and shares of Common Stock will be purchased in accordance with such Offering.

(c) In connection with each Offering made under the Plan, the Board may specify (i) a maximum number of shares of Common Stock that may be purchased by any Participant on any Purchase Date during such Offering, (ii) a maximum aggregate number of shares of Common Stock that may be purchased by all Participants pursuant to such Offering and/or (iii) a maximum aggregate number of shares of Common Stock that may be purchased by all Participants on any Purchase Date under the Offering. If the aggregate purchase of shares of Common Stock issuable upon exercise of Purchase Rights granted under the Offering would exceed any such maximum aggregate number, then, in the absence of any Board action otherwise, a pro rata (based on each Participant's accumulated Contributions) allocation of the shares of Common Stock (rounded down to the nearest whole share) available will be made in as nearly a uniform manner as will be practicable and equitable.

(d) The purchase price of shares of Common Stock acquired pursuant to Purchase Rights will be not less than the lesser of:

(i) an amount equal to 85% of the Fair Market Value of the shares of Common Stock on the Offering Date; or

(ii) an amount equal to 85% of the Fair Market Value of the shares of Common Stock on the applicable Purchase Date.

#### **7. PARTICIPATION; WITHDRAWAL; TERMINATION.**

(a) An Eligible Employee may elect to participate in an Offering and authorize payroll deductions as the means of making Contributions by completing and delivering to the Company, within the time specified in the Offering, an enrollment form provided by the Company. The enrollment form will specify the amount of Contributions not to exceed the maximum amount specified by the Board. Each Participant's Contributions will be credited to a bookkeeping account for such Participant under the Plan and will be deposited with the general funds of the Company except where Applicable Law requires that Contributions be deposited with a third party. If permitted in the Offering, a Participant may begin such Contributions with the first payroll occurring on or after the Offering Date (or, in the case of a payroll date that occurs after the end of the prior Offering but before the Offering Date of the next new Offering, Contributions from such payroll will be included in the new Offering). If permitted in the Offering, a Participant may thereafter reduce (including to zero) or increase his or her Contributions. If required under Applicable Law or if specifically provided in the Offering, in addition to or instead of making Contributions by payroll deductions, a Participant may make Contributions through the payment by cash, check or wire transfer prior to a Purchase Date.

(b) During an Offering, a Participant may cease making Contributions and withdraw from the Offering by delivering to the Company a withdrawal form provided by the Company. The Company may impose a deadline before a Purchase Date for withdrawing. Upon such withdrawal, such Participant's Purchase Right in that Offering will immediately terminate and the Company will distribute as soon as practicable to such Participant all of his or her accumulated but unused Contributions and such Participant's Purchase Right in that Offering shall thereupon terminate. A Participant's withdrawal from that Offering will have no effect upon his or her eligibility to participate in any other Offerings under the Plan, but such Participant will be required to deliver a new enrollment form to participate in subsequent Offerings.

(c) Unless otherwise required by Applicable Law, Purchase Rights granted pursuant to any Offering under the Plan will terminate immediately if the Participant either (i) is no longer an Employee for any reason or for no reason (subject to any post-employment participation period required by law) or (ii) is otherwise no longer eligible to participate. The Company will distribute as soon as practicable to such individual all of his or her accumulated but unused Contributions.

(d) Unless otherwise determined by the Board, a Participant whose employment transfers or whose employment terminates with an immediate rehire (with no break in service) by or between the Company and a Related Corporation that has been designated for participation in the Plan will not be treated as having terminated employment for purposes of participating in the Plan or an Offering; however, if a Participant transfers from an Offering under the 423 Component to an Offering under the Non-423 Component, the exercise of the Participant's Purchase Right will be qualified under the 423 Component only to the extent such exercise complies with Section 423 of the Code. If a Participant transfers from an Offering under the Non-423 Component to an Offering under the 423 Component, the exercise of the Purchase Right will remain non-qualified under the Non-423 Component. The Board may establish different and additional rules governing transfers between separate Offerings within the 423 Component and between Offerings under the 423 Component and Offerings under the Non-423 Component.

(e) During a Participant's lifetime, Purchase Rights will be exercisable only by such Participant. Purchase Rights are not transferable by a Participant, except by will, by the laws of descent and distribution, or, if permitted by the Company, by a beneficiary designation as described in Section 10.

(f) Unless otherwise specified in the Offering or as required by Applicable Law, the Company will have no obligation to pay interest on Contributions.

## **8. EXERCISE OF PURCHASE RIGHTS.**

(a) On each Purchase Date, each Participant's accumulated Contributions will be applied to the purchase of shares of Common Stock, up to the maximum number of shares of Common Stock permitted by the Plan and the applicable Offering, at the purchase price specified in the Offering. No fractional shares will be issued unless specifically provided for in the Offering.

(b) Unless otherwise provided in the Offering, if any amount of accumulated Contributions remains in a Participant's account after the purchase of shares of Common Stock on the final Purchase Date of an Offering, then such remaining amount will not roll over to the next Offering and will instead be distributed in full to such Participant after the final Purchase Date of such Offering without interest (unless otherwise required by Applicable Law).

(c) No Purchase Rights may be exercised to any extent unless the shares of Common Stock to be issued upon such exercise under the Plan are covered by an effective registration statement pursuant to the Securities Act and the Plan is in material compliance with all applicable U.S. federal and state, foreign and other securities, exchange control and other laws applicable to the Plan. If on a Purchase Date the shares of Common Stock are not so registered or the Plan is not in such compliance, no Purchase Rights will be exercised on such Purchase Date, and the Purchase Date will be delayed until the shares of Common Stock are subject to such an effective registration statement and the Plan is in material compliance, except that the Purchase Date will in no event be more than 27 months from the Offering Date. If, on the Purchase Date, as delayed to the maximum extent permissible, the shares of Common Stock are not registered and the Plan is not in material compliance with all Applicable Laws, as determined by the Company in its sole discretion, no Purchase Rights will be exercised and all accumulated but unused Contributions will be distributed to the Participants without interest (unless the payment of interest is otherwise required by Applicable Law).

## **9. COVENANTS OF THE COMPANY.**

The Company will seek to obtain from each U.S. federal or state, foreign or other regulatory commission or agency having jurisdiction over the Plan such authority as may be required to grant Purchase Rights and issue and sell shares of Common Stock thereunder unless the Company determines, in its sole discretion, that doing so would cause the Company to incur costs that are unreasonable. If, after commercially reasonable efforts, the Company is unable to obtain the authority that counsel for the Company deems necessary for the grant of Purchase Rights or the lawful issuance and sale of Common Stock under the Plan, and at a commercially reasonable cost, the Company will be relieved from any liability for failure to grant Purchase Rights and/or to issue and sell Common Stock upon exercise of such Purchase Rights.

## **10. DESIGNATION OF BENEFICIARY.**

(a) The Company may, but is not obligated to, permit a Participant to submit a form designating a beneficiary who will receive any shares of Common Stock and/or Contributions from the Participant's account under the Plan if the Participant dies before such shares and/or Contributions are delivered to the Participant. The Company may, but is not obligated to, permit the Participant to change such designation of beneficiary. Any such designation and/or change must be on a form approved by the Company.

(b) If a Participant dies, and in the absence of a valid beneficiary designation, the Company will deliver any shares of Common Stock and/or Contributions to the executor or administrator of the estate of the Participant. If no executor or administrator has been appointed (to the knowledge of the Company), the Company, in its sole discretion, may deliver such shares of Common Stock and/or Contributions, without interest (unless the payment of interest is otherwise required by Applicable Law), to the Participant's spouse, dependents or relatives, or if no spouse, dependent or relative is known to the Company, then to such other person as the Company may designate.

## **11. ADJUSTMENTS UPON CHANGES IN COMMON STOCK; CORPORATE TRANSACTIONS.**

(a) In the event of a Capitalization Adjustment, the Board will appropriately and proportionately adjust: (i) the class(es) and maximum number of securities subject to the Plan pursuant to Section 3(a), (ii) the class(es) and maximum number of securities by which the share reserve is to increase automatically each year pursuant to Section 3(a), (iii) the class(es) and number of securities subject to, and the purchase price applicable to outstanding Offerings and Purchase Rights, and (iv) the class(es) and number of securities that are the subject of the purchase limits under each ongoing Offering. The Board will make these adjustments, and its determination will be final, binding and conclusive.

(b) In the event of a Corporate Transaction, then: (i) any surviving corporation or acquiring corporation (or the surviving or acquiring corporation's parent company) may assume or continue outstanding Purchase Rights or may substitute similar rights (including a right to acquire the same consideration paid to the stockholders in the Corporate Transaction) for outstanding Purchase Rights, or (ii) if any surviving or acquiring corporation (or its parent company) does not assume or continue such Purchase Rights or does not substitute similar rights for such Purchase Rights, then the Participants' accumulated Contributions will be used to purchase shares of Common Stock (rounded down to the nearest whole share) within ten business days prior to the Corporate Transaction under the outstanding Purchase Rights, and the Purchase Rights will terminate immediately after such purchase.

## **12. AMENDMENT, TERMINATION OR SUSPENSION OF THE PLAN.**

(a) The Board may amend the Plan at any time in any respect the Board deems necessary or advisable. However, except as provided in Section 11(a) relating to Capitalization Adjustments, stockholder approval will be required for any amendment of the Plan for which stockholder approval is required by Applicable Law.

**(b)** The Board may suspend or terminate the Plan at any time. No Purchase Rights may be granted under the Plan while the Plan is suspended or after it is terminated.

Any benefits, privileges, entitlements and obligations under any outstanding Purchase Rights granted before an amendment, suspension or termination of the Plan will not be materially impaired by any such amendment, suspension or termination except (i) with the consent of the person to whom such Purchase Rights were granted, (ii) as necessary to comply with any laws, listing requirements, or governmental regulations (including, without limitation, the provisions of Section 423 of the Code and the regulations and other interpretive guidance issued thereunder relating to Employee Stock Purchase Plans) including without limitation any such regulations or other guidance that may be issued or amended after the date the Plan is adopted by the Board, or (iii) as necessary to obtain or maintain favorable tax, listing, or regulatory treatment. To be clear, the Board may amend outstanding Purchase Rights without a Participant's consent if such amendment is necessary to ensure that the Purchase Right and/or the Plan complies with the requirements of Section 423 of the Code with respect to the 423 Component or with respect to other Applicable Laws. Notwithstanding anything in the Plan or any Offering Document to the contrary, the Board will be entitled to: (i) establish the exchange ratio applicable to amounts withheld in a currency other than U.S. dollars; (ii) permit Contributions in excess of the amount designated by a Participant in order to adjust for mistakes in the Company's processing of properly completed Contribution elections; (iii) establish reasonable waiting and adjustment periods and/or accounting and crediting procedures to ensure that amounts applied toward the purchase of Common Stock for each Participant properly correspond with amounts withheld from the Participant's Contributions; (iv) amend any outstanding Purchase Rights or clarify any ambiguities regarding the terms of any Offering to enable the Purchase Rights to qualify under and/or comply with Section 423 of the Code with respect to the 423 Component; and (v) establish other limitations or procedures as the Board determines in its sole discretion advisable that are consistent with the Plan. The actions of the Board pursuant to this paragraph will not be considered to alter or impair any Purchase Rights granted under an Offering as they are part of the initial terms of each Offering and the Purchase Rights granted under each Offering.

### **13. TAX QUALIFICATION; TAX WITHHOLDING.**

**(a)** Although the Company may endeavor to (i) qualify a Purchase Right for special tax treatment under the laws of the United States or jurisdictions outside of the United States or (ii) avoid adverse tax treatment, the Company makes no representation to that effect and expressly disavows any covenant to maintain special or to avoid unfavorable tax treatment, notwithstanding anything to the contrary in this Plan. The Company will be unconstrained in its corporate activities without regard to the potential negative tax impact on Participants.

**(b)** Each Participant will make arrangements, satisfactory to the Company and any applicable Related Corporation, to enable the Company or the Related Corporation to fulfill any withholding obligation for Tax-Related Items. Without limitation to the foregoing, in the Company's sole discretion and subject to Applicable Law, such withholding obligation may be satisfied in whole or in part by (i) withholding from the Participant's salary or any other cash payment due to the Participant from the Company or a Related Corporation; (ii) withholding from the proceeds of the sale of shares of Common Stock acquired under the Plan, either through a voluntary sale or a mandatory sale arranged by the Company; or (iii) any other method deemed acceptable by the Board.

### **14. EFFECTIVE DATE OF PLAN.**

The Plan will become effective immediately prior to and contingent upon the IPO Date. No Purchase Rights will be exercised unless and until the Plan has been approved by the stockholders of the Company, which approval must be within 12 months before or after the date the Plan is adopted (or if required under Section 12(a) above, materially amended) by the Board.

## 15. MISCELLANEOUS PROVISIONS.

(a) Proceeds from the sale of shares of Common Stock pursuant to Purchase Rights will constitute general funds of the Company.

(b) A Participant will not be deemed to be the holder of, or to have any of the rights of a holder with respect to, shares of Common Stock subject to Purchase Rights unless and until the Participant's shares of Common Stock acquired upon exercise of Purchase Rights are recorded in the books of the Company (or its transfer agent).

(c) The Plan and Offering do not constitute an employment contract. Nothing in the Plan or in the Offering will in any way alter the at will nature of a Participant's employment, if applicable, or be deemed to create in any way whatsoever any obligation on the part of any Participant to continue in the employ of the Company or a Related Corporation, or on the part of the Company or a Related Corporation to continue the employment of a Participant.

(d) The provisions of the Plan will be governed by the laws of the State of Delaware without resort to that state's conflicts of laws rules.

(e) If any particular provision of the Plan is found to be invalid or otherwise unenforceable, such provision will not affect the other provisions of the Plan, but the Plan will be construed in all respects as if such invalid provision were omitted.

(f) If any provision of the Plan does not comply with Applicable Law, such provision shall be construed in such a manner as to comply with Applicable Law.

## 16. DEFINITIONS.

As used in the Plan, the following definitions will apply to the capitalized terms indicated below:

(a) "**423 Component**" means the part of the Plan, which excludes the Non-423 Component, pursuant to which Purchase Rights that satisfy the requirements for an Employee Stock Purchase Plan may be granted to Eligible Employees.

(b) "**Applicable Law**" means shall mean any applicable securities, federal, state, foreign, material local or municipal or other law, statute, constitution, principle of common law, resolution, ordinance, code, edict, decree, rule, listing rule, regulation, judicial decision, ruling or requirement issued, enacted, adopted, promulgated, implemented or otherwise put into effect by or under the authority of any Governmental Body (or under the authority of the NASDAQ Stock Market or the Financial Industry Regulatory Authority).

(c) "**Board**" means the Board of Directors of the Company.

(d) "**Capital Stock**" means the Common Stock of the Company.

(e) "**Capitalization Adjustment**" means any change that is made in, or other events that occur with respect to, the Common Stock subject to the Plan or subject to any Purchase Right after the date the Plan is adopted by the Board without the receipt of consideration by the Company through merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large

nonrecurring cash dividend, stock split, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or other similar equity restructuring transaction, as that term is used in Financial Accounting Standards Board Accounting Standards Codification Topic 718 (or any successor thereto). Notwithstanding the foregoing, the conversion of any convertible securities of the Company will not be treated as a Capitalization Adjustment.

(f) “**Code**” means the U.S. Internal Revenue Code of 1986, as amended, including any applicable regulations and guidance thereunder.

(g) “**Committee**” means a committee of one or more members of the Board to whom authority has been delegated by the Board in accordance with Section 2(c).

(h) “**Common Stock**” means the Common Stock of the Company.

(i) “**Company**” means Oncorus, Inc., a Delaware corporation.

(j) “**Contributions**” means the payroll deductions and other additional payments specifically provided for in the Offering that a Participant contributes to fund the exercise of a Purchase Right. A Participant may make additional payments into his or her account if specifically provided for in the Offering, and then only if the Participant has not already had the maximum permitted amount withheld during the Offering through payroll deductions.

(k) “**Corporate Transaction**” means the consummation, in a single transaction or in a series of related transactions, of any one or more of the following events:

(i) a sale or other disposition of all or substantially all, as determined by the Board in its sole discretion, of the consolidated assets of the Company and its subsidiaries;

(ii) a sale or other disposition of more than 50% of the outstanding securities of the Company;

(iii) a merger, consolidation or similar transaction following which the Company is not the surviving corporation; or

(iv) a merger, consolidation or similar transaction following which the Company is the surviving corporation but the shares of Capital Stock outstanding immediately preceding the merger, consolidation or similar transaction are converted or exchanged by virtue of the merger, consolidation or similar transaction into other property, whether in the form of securities, cash or otherwise.

(l) “**Director**” means a member of the Board.

(m) “**Eligible Employee**” means an Employee who meets the requirements set forth in the document(s) governing the Offering for eligibility to participate in the Offering, provided that such Employee also meets the requirements for eligibility to participate set forth in the Plan.

(n) “**Employee**” means any person, including an Officer or Director, who is “employed” for purposes of Section 423(b)(4) of the Code by the Company or a Related Corporation. However, service solely as a Director, or payment of a fee for such services, will not cause a Director to be considered an “Employee” for purposes of the Plan.

(o) “**Employee Stock Purchase Plan**” means a plan that grants Purchase Rights intended to be options issued under an “employee stock purchase plan,” as that term is defined in Section 423(b) of the Code.

(p) “**Exchange Act**” means the U.S. Securities Exchange Act of 1934, as amended and the rules and regulations promulgated thereunder.

(q) “**Fair Market Value**” means, as of any date, the value of the Common Stock determined as follows:

(i) If the Common Stock is listed on any established stock exchange or traded on any established market, the Fair Market Value of a share of Common Stock will be the closing sales price for such stock as quoted on such exchange or market (or the exchange or market with the greatest volume of trading in the Common Stock) on the date of determination, as reported in such source as the Board deems reliable. Unless otherwise provided by the Board, if there is no closing sales price for the Common Stock on the date of determination, then the Fair Market Value will be the closing sales price on the last preceding date for which such quotation exists.

(ii) In the absence of such markets for the Common Stock, the Fair Market Value will be determined by the Board in good faith in compliance with Applicable Laws and regulations and in a manner that complies with Sections 409A of the Code

(iii) Notwithstanding the foregoing, for any Offering that commences on the IPO Date, the Fair Market Value of the shares of Common Stock on the Offering Date will be the price per share at which shares are first sold to the public in the Company’s initial public offering as specified in the final prospectus for that initial public offering.

(r) “**Governmental Body**” means any: (a) nation, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (b) federal, state, local, municipal, foreign or other government; (c) governmental or regulatory body, or quasi-governmental body of any nature (including any governmental division, department, administrative agency or bureau, commission, authority, instrumentality, official, ministry, fund, foundation, center, organization, unit, body or entity and any court or other tribunal, and for the avoidance of doubt, any tax authority) or other body exercising similar powers or authority; or (d) self-regulatory organization (including the NASDAQ Stock Market and the Financial Industry Regulatory Authority).

(s) “**IPO Date**” means the date of the underwriting agreement between the Company and the underwriters managing the initial public offering of the Common Stock, pursuant to which the Common Stock is priced for the initial public offering.

(t) “**Non-423 Component**” means the part of the Plan, which excludes the 423 Component, pursuant to which Purchase Rights that are not intended to satisfy the requirements for an Employee Stock Purchase Plan may be granted to Eligible Employees.

(u) “**Offering**” means the grant to Eligible Employees of Purchase Rights, with the exercise of those Purchase Rights automatically occurring at the end of one or more Purchase Periods. The terms and conditions of an Offering will generally be set forth in the “**Offering Document**” approved by the Board for that Offering.

(v) “**Offering Date**” means a date selected by the Board for an Offering to commence.

(w) “**Officer**” means a person who is an officer of the Company or a Related Corporation within the meaning of Section 16 of the Exchange Act.

---

(x) “**Participant**” means an Eligible Employee who holds an outstanding Purchase Right.

(y) “**Plan**” means this Oncorus, Inc. 2020 Employee Stock Purchase Plan, as amended from time to time, including both the 423 Component and the Non-423 Component.

(z) “**Purchase Date**” means one or more dates during an Offering selected by the Board on which Purchase Rights will be exercised and on which purchases of shares of Common Stock will be carried out in accordance with such Offering.

(aa) “**Purchase Period**” means a period of time specified within an Offering, generally beginning on the Offering Date or on the first Trading Day following a Purchase Date, and ending on a Purchase Date. An Offering may consist of one or more Purchase Periods.

(bb) “**Purchase Right**” means an option to purchase shares of Common Stock granted pursuant to the Plan.

(cc) “**Related Corporation**” means any “parent corporation” or “subsidiary corporation” of the Company whether now or subsequently established, as those terms are defined in Sections 424(e) and (f), respectively, of the Code.

(dd) “**Securities Act**” means the U.S. Securities Act of 1933, as amended.

(ee) “**Tax-Related Items**” means any income tax, social insurance, payroll tax, fringe benefit tax, payment on account or other tax-related items arising out of or in relation to a Participant’s participation in the Plan, including, but not limited to, the exercise of a Purchase Right and the receipt of shares of Common Stock or the sale or other disposition of shares of Common Stock acquired under the Plan.

(ff) “**Trading Day**” means any day on which the exchange(s) or market(s) on which shares of Common Stock are listed, including but not limited to the NYSE, Nasdaq Global Select Market, the Nasdaq Global Market, the Nasdaq Capital Market or any successors thereto, is open for trading.







**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Oncorus, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: November 12, 2020

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