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, 2022

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	**47-3779757**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
4 Corporate Drive **Andover, Massachusetts**	**01810**
(Address of principal executive offices)	**(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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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 October 28, 2022, the registrant had 25,973,135 shares of common stock, $0.0001 par value per share, outstanding.

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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 initiation, timing, progress and expected results of our preclinical studies and clinical trials for product candidates from our oncolytic HSV-1 platform, or HSV Platform, including our ongoing Phase 1 clinical trial of ONCR-177 and the reporting of additional clinical data from this trial;
- the initiation, timing, progress and expected results of our preclinical studies and planned clinical trials for product candidates from our selectively self-amplifying viral RNA immunotherapy platform, or vRNA Immunotherapy Platform, including ONCR-021 and ONCR-788;
- the potential therapeutic benefit of our therapies and their ability to improve upon existing immuno-oncology therapies, including other viral immunotherapies and immune checkpoint inhibitors;
- the ability of our HSV Platform to overcome the safety versus potency trade-off and its ability to stimulate multiple arms of the innate and adaptive immune system;
- the ability of our selectively self-amplifying vRNA Immunotherapy Platform to avoid the challenges associated with neutralizing antibodies;
- our manufacturing capabilities, our good manufacturing practices, or GMP, compliant manufacturing facility and related operational timelines;
- the timing of certain regulatory milestones, including the submission of investigational new drug applications, or INDs, and 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;
- impact of the COVID-19 pandemic on our business, operations, strategy, goals and anticipated timelines;
- our ability to fund our working capital requirements;
- our financial performance and our ability to effectively manage our anticipated growth; and
- the sufficiency of our existing funding and our ability to obtain additional funding for our operations.

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 the section titled “Risk Factors” under Part II, Item 1A, below and under "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2021, under Part II, Item 1A in our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2022 and June 30, 2022 and in this Quarterly Report on Form 10-Q, and under similar captions in our periodic reports filed with the SEC from time to time. 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 Quarterly Report on Form 10-Q 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.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

ONCORUS, INC.
Condensed Consolidated Balance Sheets
(in thousands, except for par value data)
(unaudited)

	SEPTEMBER 30, 2022	DECEMBER 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 41,568	$ 100,752
Investments	39,955	23,173
Prepaid expenses and other current assets	1,956	5,185
Total current assets	83,479	129,110
Property and equipment, net	42,883	23,233
Right-of-use asset	33,997	45,218
Restricted cash	3,437	3,437
Other assets	569	589
Total assets	$ 164,365	$ 201,587
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,980	$ 13,009
Accrued expenses and other current liabilities	13,695	6,281
Lease liability - current portion	1,138	1,684
Total current liabilities	16,813	20,974
Term loan, non-current	19,257	—
Lease liability - net of current portion	48,147	50,388
Other long-term liabilities	152	203
Total liabilities	84,369	71,565
Stockholders' equity:		
Preferred stock, $0.0001 par value; authorized — 10,000 shares at September 30, 2022 and December 31, 2021; issued and outstanding — no shares at September 30, 2022 and December 31, 2021	—	—
Common stock, $0.0001 par value; authorized — 100,000 shares at September 30, 2022 and December 31, 2021; issued and outstanding — 25,973 and 25,848 shares at September 30, 2022 and December 31, 2021, respectively	3	3
Additional paid-in capital	331,144	324,620
Accumulated other comprehensive loss	(73)	(14)
Accumulated deficit	(251,078)	(194,587)
Total stockholders' equity	79,996	130,022
Total liabilities and stockholders' equity	$ 164,365	$ 201,587

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 SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 14,087	$ 11,299	$ 39,036	$ 30,406
General and administrative	5,211	5,440	16,721	14,550
Total operating expenses	19,298	16,739	55,757	44,956
Loss from operations	(19,298)	(16,739)	(55,757)	(44,956)
Other income (expense):				
Other income (expense)	8	—	(63)	(1)
Interest income (expense)	(330)	11	(671)	38
Total other income (expense), net	(322)	11	(734)	37
Net loss	$ (19,620)	$ (16,728)	$ (56,491)	$ (44,919)
Comprehensive loss:				
Net unrealized loss on investments	(32)	—	$ (73)	$ —
Comprehensive loss	$ (19,652)	$ (16,728)	$ (56,564)	$ (44,919)
Net loss per share—basic and diluted	$ (0.76)	$ (0.65)	$ (2.18)	$ (1.79)
Weighted-average number of common shares outstanding—basic and diluted	25,972	25,748	25,907	25,153

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

ONCORUS, INC.

Condensed Consolidated Statements of Stockholders' Equity
(in thousands, except share amounts)
(unaudited)

	COMMON STOCK		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED OTHER COMPREHENSIVE LOSS	ACCUMULATED DEFICIT	TOTAL STOCKHOLDERS' EQUITY
	SHARES	AMOUNT				
Balance at December 31, 2020	**22,599,048**	**$ 2**	**$ 264,487**	**$ —**	**$ (129,825)**	**$ 134,664**
Proceeds from issuance of common stock, net of issuance costs of $4,017	3,000,000	—	52,983	—	—	52,983
Stock-based compensation expense	—	—	2,828	—	—	2,828
Vesting of restricted common stock	10,341	—	—	—	—	—
Exercise of options to purchase common stock	131,683	—	347	—	—	347
Net loss	—	—	—	—	(28,191)	(28,191)
Balance at June 30, 2021	**25,741,072**	**$ 3**	**$ 320,645**	**$ —**	**$ (158,016)**	**$ 162,632**
Stock-based compensation expense	—	—	1,889	—	—	1,889
Vesting of restricted common stock	5,171	—	—	—	—	—
Exercise of options to purchase common stock	11,816	—	49	—	—	49
Net loss	—	—	—	—	(16,728)	(16,728)
Balance at September 30, 2021	**25,758,059**	**$ 3**	**$ 322,583**	**$ -**	**$ (174,744)**	**$ 147,842**
Balance at December 31, 2021	**25,848,229**	**$ 3**	**$ 324,620**	**$ (14)**	**$ (194,587)**	**$ 130,022**
Stock-based compensation expense	—	—	4,160	—	—	4,160
Exercise of options to purchase common stock	35,070	—	62	—	—	62
Issuance of common stock under employee stock purchase plan	89,112	—	95	—	—	95
Issuance of warrants in connection with term loan	—	—	567	—	—	567
Other comprehensive loss	—	—	—	(27)	—	(27)
Net loss	—	—	—	—	(36,871)	(36,871)
Balance at June 30, 2022	**25,972,411**	**$ 3**	**$ 329,504**	**$ (41)**	**$ (231,458)**	**$ 98,008**
Stock-based compensation expense	—	—	1,640	—	—	1,640
Exercise of options to purchase common stock	104	—	—	—	—	—
Other comprehensive loss	—	—	—	(32)	—	(32)
Net loss	—	—	—	—	(19,620)	(19,620)
Balance at September 30, 2022	**25,972,515**	**$ 3**	**$ 331,144**	**$ (73)**	**$ (251,078)**	**$ 79,996**

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,	
	2022	2021
Operating activities:		
Net loss	$ (56,491)	$ (44,919)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,993	1,332
Loss on disposal of assets	94	—
Stock-based compensation	5,800	4,717
Non-cash interest expense related to term loan	357	—
Amortization of premium/discount on investments	(12)	—
Non-cash interest income	(52)	—
Gain on lease termination	(520)	—
Changes in:		
Prepaid expenses and other assets	3,226	803
Operating lease right-of-use asset	1,473	2,208
Tenant improvement allowance reimbursements	8,557	1,737
Accounts payable	(11,476)	109
Accrued expenses and other current liabilities	580	1,773
Operating lease liability	(1,077)	854
Net cash used in operating activities	(47,548)	(31,386)
Investing activities		
Purchase of property and equipment	(14,483)	(6,695)
Purchase of investments	(30,353)	—
Proceeds from sales and maturities of investments	13,576	—
Net cash used in investing activities	(31,260)	(6,695)
Financing activities		
Proceeds from exercise of options to purchase common stock	62	396
Proceeds from purchases of common stock under employee stock purchase plan	95	—
Proceeds from borrowings under term loan, net of issuance costs	19,467	—
Proceeds from issuance of common stock, net of issuance costs	—	52,983
Net cash provided by financing activities	19,624	53,379
Increase (decrease) in cash and cash equivalents	(59,184)	15,298
Cash, cash equivalents and restricted cash at beginning of period	104,189	133,182
Cash, cash equivalents and restricted cash at end of period	$ 45,005	$ 148,480
Supplemental disclosure of non-cash investing and financing activities		
Issuance of warrants in connection with term loan	$ 567	$ —
Purchase of property and equipment in accrued expenses and accounts payable	$ 7,231	$ 4,551

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

1. Nature of the Business and Liquidity

Oncorus, Inc. (the "Company") is a clinical-stage 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, commencing a clinical trial and manufacturing scale-up activities. 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 $88.3 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 14,951,554 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 February 2021, the Company completed a follow-on public offering of its common stock in which it sold 3,000,000 shares at an offering price of $19.00 per share, resulting in gross proceeds of $57.0 million and net proceeds of $53.0 million, after deducting underwriting discounts and commissions and offering expenses payable by the Company.

In November 2021, the Company entered into an open market sale agreement pursuant to which the Company may issue and sell shares of its common stock from time to time for aggregate gross proceeds of up to $50.0 million. There have been no sales under this agreement as of September 30, 2022.

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. The Company expects to continue to incur losses from operations for the foreseeable future and additional capital will be required to fund future operations. The Company expects that its cash and cash equivalents as of September 30, 2022, will be sufficient to fund its operating expenses and capital expenditure requirements through at least the next 12 months from the date these financial statements were issued.

2. Summary of Significant Accounting Policies

Basis of Presentation

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, 2022, its results of operations for the three

and nine months ended September 30, 2022 and 2021, its changes in stockholders' equity for the three and nine months ended September 30, 2022 and 2021 and its cash flows for the nine months ended September 30, 2022 and 2021.

The results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for the full year. These unaudited interim condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements as of and for the year ended December 31, 2021, and the notes thereto, which are included in the Company's Annual Report on Form 10-K (the "Annual Report") filed with the Securities and Exchange Commission (the "SEC") on March 9, 2022. The condensed consolidated balance sheet data as of December 31, 2021 presented for comparative purposes was derived from the Company's audited consolidated financial statements but does not include all disclosures required by GAAP. The results for the three and nine months ended September 30, 2022, 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, 2021, included in its Annual Report. Any changes to the Company's significant accounting policies are further discussed below.

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, its ongoing clinical trial, and its regulatory filings. 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.

Going Concern

At each reporting period, the Company evaluates whether there are conditions or events that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. The Company is required to make certain additional disclosures if it concludes substantial doubt exists and it is not alleviated by the Company's plans or when its plans alleviate substantial doubt about the Company's ability to continue as a going concern.

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, 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.

Deferred Offering Costs

The Company capitalizes certain legal, professional, accounting and other third-party fees that are directly associated with in-process equity issuances or debt financings as deferred offering costs until such equity issuances or debt financings are consummated. After consummation, these costs are recorded as a reduction in the capitalized amount associated with the equity issuance or debt financing.

Debt Related Costs

The carrying value of the Company's Term Loan (see Note 7) is recorded net of issuance costs and discount relating to the issuance of warrants and fees paid to the lender. Debt-related costs are amortized over the term of the debt using the effective interest method and recognized as interest expense.

Warrants

In accordance with ASC Topic 470-20-25, when the Company issues debt with warrants, the Company treats the warrants as a debt discount, recorded as a contra-liability against the debt, and amortizes the balance over the life of the underlying debt as amortization

of debt discount expense in the statements of operations. The offset to the contra-liability is recorded as additional paid-in capital in the Company's consolidated balance sheet if the warrants are not treated as a derivative or as liability warrants. The Company determines the fair value of the warrants at issuance using the Black-Scholes option pricing model.

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 and short-term investments. 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. The Company invests its excess cash, in line with its investment policy, primarily in money market funds and high credit quality debt instruments.

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.

Restricted Cash

The Company maintains a balance in a segregated bank account in connection with a letter of credit for the benefit of the landlord in connection with its operating lease for its Andover, Massachusetts facility. As of September 30, 2022, restricted cash consisted of $3.4 million held for the benefit of the landlord. This amount has been classified as part of non-current assets on the Company's unaudited interim condensed consolidated balance sheets.

The Company includes its restricted cash balance in the cash, cash equivalents and restricted cash reconciliation of operating, investing, and financing activities in the unaudited interim condensed consolidated statements of cash flows. The following table provides a reconciliation of cash, cash equivalents and restricted cash in the unaudited interim condensed consolidated balance sheets that sum to the total of the same such amounts shown in the unaudited interim condensed consolidated statements of cash flows:

	SEPTEMBER 30,	
	2022	2021
	(in thousands)	
Cash and cash equivalents	$ 41,568	$ 145,603
Restricted cash	3,437	2,877
Total cash, cash equivalents and restricted cash shown in the unaudited interim consolidated statements of cash flows	$ 45,005	$ 148,480

Investments

Short-term investments consist of commercial paper, corporate bonds, asset-backed securities, and U.S. treasury securities with original maturities greater than three months. The Company may sell investments at any time for use in current operations even if the investments have not yet reached maturity. As a result, the Company classifies its investments, including securities with maturities beyond twelve months, as current assets. As of September 30, 2022, all investments are classified as available-for-sale securities, which are recorded at fair value. Unrealized holding gains and losses on available-for-sale securities are reported as a net amount in accumulated other comprehensive income or loss in stockholders' equity until realized. Purchase premiums and discounts are amortized to other income over the terms of the related securities. Realized gains and losses and declines in fair value that are deemed to be other than temporary are reflected in the statements of operations and comprehensive loss using the specific-identification method. The Company periodically reviews all available-for-sale securities for other than temporary declines in fair value below the cost basis whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The Company also evaluates whether it has plans or is required to sell short-term investments before recovery of their amortized cost bases. For the nine months ended September 30, 2022, the Company has not identified any other than temporary declines in fair value of its short-term investments.

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 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.

Operating Leases

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on specific facts and circumstances, the existence of an identified asset(s), if any, and the Company's control over the use of the identified asset(s), if applicable. The lease liability is measured at the present value of future lease payments, discounted using the discount rate as of the lease commencement date. Future lease payments may include payments that depend on an index or a rate (such as the consumer price index or other market index). The Company initially measures payments based on an index or rate by using the applicable rate at lease commencement and subsequent changes in such rates are recognized as variable lease costs. Variable payments that do not depend on a rate or index are not included in the lease liability and are recognized as they are incurred. The Company's contracts typically do not have variable payments based on index or rate. The Company's contracts that include a lease component generally include additional services that are transferred to the lessee (e.g., common-area maintenance services), which are non-lease components. Contracts typically also include other costs and fees that do not provide a separate service to the lessee, such as costs paid by the lessee to reimburse the lessor for administrative costs or payment for the lessor's costs for property taxes, insurance related to the leased asset, and other lessor costs. The Company elected the practical expedient to account for the lease and its associated non-lease components as a single lease component for its real estate leases, including the office, lab, and its manufacturing space.

When readily determinable, the discount rate used to calculate the lease liability is the rate implicit in the lease. As the Company's leases typically do not provide an implicit rate, the Company uses its incremental borrowing rate based on the lease term and economic environment at the lease commencement date. The lease term used to calculate the lease liability includes options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. With limited exceptions, the nature of the Company's facility leases is such that there are no economic or other conditions that would indicate that it is reasonably certain at lease commencement that the Company will exercise options to extend the term.

The Company recognizes a corresponding right-of-use ("ROU") asset, initially measured as the amount of lease liability, adjusted for any initial lease costs or lease payments made before or at the commencement of the lease, and reduced by any lease incentives. In certain instances when there is unpredictability of payout of leasehold improvement reimbursements, the ROU asset and lease liability will be adjusted on a prospective basis as construction related to leasehold improvements is performed over the life of the lease.

The Company's leases consist of only operating leases. Operating leases are recognized on the balance sheet as ROU assets, lease liabilities current and lease liabilities non-current. Fixed rents are included in the calculation of the lease balances while certain variable costs paid for certain operating and pass-through costs are excluded. Lease expense is recognized over the expected lease term on a straight-line basis. For leases with a term of one year or less, or short-term leases, the Company has elected to not recognize the lease liability for these arrangements and the lease payments are recognized in the consolidated statements of operations and comprehensive loss.

Recently Issued Accounting Pronouncements

In September 2022, the FASB issued ASU 2022-04, Liabilities—Supplier Finance Programs (Subtopic 405-50): *Disclosure of Supplier Finance Program Obligations.* This amendment requires a buyer that uses supplier finance programs to make annual disclosures about the program's key terms, the balance sheet presentation of related amounts, the confirmed amount outstanding at the end of the period, and associated rollforward information. Only the amount outstanding at the end of the period must be disclosed in interim periods. The amendments are effective for all entities for fiscal years beginning after December 15, 2022 on a retrospective basis, including interim periods within those fiscal years, except for the requirement to disclose rollforward information, which is effective prospectively for fiscal years beginning after December 15, 2023. Early adoption is permitted. The Company is currently reviewing the provisions of this new pronouncement, but does not expect this guidance will have a material impact on its consolidated financial statements.

In August 2020, the FASB issued ASU No. 2020-06, Debt - Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40): *Accounting for Convertible Instruments and Contracts in an Entity's Own Equity.* This amendment simplifies accounting for convertible instruments by removing major separation models required under current U.S. GAAP. It also removes certain settlement conditions that are required for equity contracts to qualify for the derivative scope exception, and simplifies the diluted earnings per share calculation in certain areas. ASU No. 2020-06 is effective for public companies for annual periods beginning after December 15, 2021, including interim periods within those fiscal

years. The Company early adopted the provisions of ASU 2020-06 effective January 1, 2022, using the modified retrospective method for transition with no significant impact on its consolidated financial statements at the time of adoption.

There have been no other issued accounting pronouncements other than those described in the Company's audited financial statements as of and for the year ended December 31, 2021, and the notes thereto, which are included in the Annual Report, that will have a material effect on the Company's consolidated financial statements.

3. Cash Equivalents and Investments

The following tables summarize the amortized cost and fair value of the Company's cash equivalents and investments (in thousands):

	SEPTEMBER 30, 2022			
	AMORTIZED COST BASIS	GROSS UNREALIZED GAINS	GROSS UNREALIZED LOSSES	ESTIMATED FAIR VALUE
Cash Equivalents				
Money market funds	$ 31,866	$ —	$ —	$ 31,866
U.S. treasury securities	$ 5,557	$ 1	$ —	$ 5,558
Total Cash Equivalents	$ 37,423	$ 1	$ —	$ 37,424
Investments				
Commercial paper	$ 23,886	$ —	$ —	$ 23,886
Corporate bonds	3,001	—	(15)	2,986
U.S. treasury securities	13,142	—	(59)	13,083
Total Investments	$ 40,029	$ —	$ (74)	$ 39,955

	DECEMBER 31, 2021			
	AMORTIZED COST BASIS	GROSS UNREALIZED GAINS	GROSS UNREALIZED LOSSES	ESTIMATED FAIR VALUE
Cash Equivalents				
Money market funds	$ 98,900	$ —	$ —	$ 98,900
Total Cash Equivalents	$ 98,900	$ —	$ —	$ 98,900
Investments				
Commercial paper	$ 11,084	$ —	$ —	$ 11,084
Asset-backed securities	2,020	—	(2)	2,018
U.S. treasury securities	4,812	—	(8)	4,804
Corporate bonds	5,271	—	(4)	5,267
Total Investments	$ 23,187	$ —	$ (14)	$ 23,173

As of September 30, 2022, the Company held eight investments with unrealized losses. All investments in an unrealized loss position were in this position for less than 12 months. The Company evaluated its securities for potential other-than-temporary impairment and considered the decline in market value to be primarily attributable to current economic and market conditions. Additionally, the Company does not intend to sell the securities in an unrealized loss position and does not expect it will be required to sell the securities before recovery of the unamortized cost basis. Given the Company's intent and ability to hold such securities until recovery, and the lack of a significant change in credit risk for these investments, the Company did not consider these investments to be impaired as of September 30, 2022.

There were no realized gains or losses recognized on investments in the nine months ended September 30, 2022. Interest on investments is recognized as interest income in the consolidated statements of operations and comprehensive loss.

All investments held as of September 30, 2022, were classified as available-for-sale securities and had contractual maturities of less than one year.

4. 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, 2022			
	LEVEL 1	LEVEL 2	LEVEL 3	TOTAL
Assets:				
Money market funds	$ 31,866	$ —	$ —	$ 31,866
U.S. treasury securities	18,641	—	—	18,641
Commercial paper	—	23,886	—	23,886
Corporate bonds	—	2,986	—	2,986
Total Assets	$ 50,507	$ 26,872	$ —	$ 77,379

	FAIR VALUE MEASUREMENTS AS OF DECEMBER 31, 2021			
	LEVEL 1	LEVEL 2	LEVEL 3	TOTAL
Assets:				
Money market funds	$ 98,900	$ —	$ —	$ 98,900
U.S. treasury securities	4,804	—	—	4,804
Commercial paper	—	11,084	—	11,084
Asset-backed securities	—	2,018	—	2,018
Corporate bonds	—	5,267	—	5,267
Total Assets	$ 103,704	$ 18,369	$ —	$ 122,073

The Company classifies its money market funds and U.S. treasury securities as Level 1 assets since it measures fair value using quoted prices in active markets for identical assets. The Level 2 assets include commercial paper, asset-backed securities, and corporate bonds and are valued based on quoted prices for similar assets in active markets and inputs other than quoted prices that are derived from observable market data. The Company did not hold any Level 3 assets during the periods presented.

The Company evaluates transfers between levels at the end of each reporting period. There were no transfers between Level 1 and Level 2 assets during the periods presented.

5. Leases

The Company has an operating lease for approximately 33,518 square feet (the "Pod 4 Portion"), approximately 54,666 square feet (the "Pod 5 Portion"), and approximately 17,150 square feet ("Pod 3 Portion") of a manufacturing facility located in Andover, Massachusetts, that also serves as its corporate headquarters. This lease expires in December 2036 and the Company has two options to extend the term of the lease for a period of ten years each. As of September 30, 2022, the Company had not exercised its options to extend the lease term for either lease and did not consider it reasonably certain that these options would be exercised. The Company agreed to provide the landlord with a $3.4 million letter of credit as support for its obligations under the Andover facility lease. The lease provides a lease incentive in the form of reimbursable leasehold improvements of $14.9 million. Due to the unpredictability of the payout of leasehold improvement reimbursements, the right-of-use asset will be adjusted on a prospective basis to reflect any payments relating to the lease incentive as construction related to these improvements is performed over the life of the lease. As of September 30, 2022, the Company had capitalized $35.6 million of leasehold improvement costs, of which $10.3 million was reimbursed through the lease incentive. The lease payments include fixed base rent payments and variable rents for certain shared facility operating and other costs.

The Company is also party to an operating lease in Cambridge, Massachusetts, which served as its corporate headquarters until September 2022. On September 13, 2022, the Company executed an amendment to its Cambridge lease which accelerated the lease termination date to November 15, 2022, from the previous date of January, 2024. In connection with this amendment, the Company remeasured the remaining lease liability and right-of-use-asset and recognized a gain of $0.5 million, which was included as a reduction of operating expenses in the consolidated statements of operations and comprehensive loss.

During the three and nine months ended September 30, 2022, the Company recognized total rent expense related to the leases described above of $0.9 million and $4.0 million, respectively, compared to $1.4 million and $4.2 million in the same periods of 2021. The amount of variable rent expense and rent for short-term leases for the three and nine months ended September 30, 2022 and 2021, was $0.7 million, $2.3 million, $0.5 million, and $1.3 million, respectively.

Other supplemental information related to leases is as follows:

	AS OF AND FOR NINE MONTHS ENDED SEPTEMBER 30,	
	2022	2021
Weighted average remaining lease term	14.2 years	13.8 years
Weighted average discount rate	7.7%	8.5%
Cash paid for amounts included in the measurement of lease liabilities (in thousands)	$4,129	$1,143

Maturities of operating lease liabilities are as follows as of September 30, 2022 (in thousands):

Year	Amount
2022	$ 1,245
2023	4,850
2024	4,995
2025	5,145
2026	5,299
Thereafter	62,572
Total lease payments	84,106
Less imputed interest	(34,821)
Total lease liabilities	$ 49,285
Current portion	1,138
Long-term portion	48,147

6. Accrued Expenses and Other Liabilities

Accrued expenses and other liabilities consisted of the following (in thousands):

	SEPTEMBER 30, 2022	DECEMBER 31, 2021
Accrued research and development costs	$ 3,535	$ 1,474
Accrued leasehold improvement costs	6,457	999
Accrued compensation	2,704	2,697
Accrued professional fees	599	846
Accrued interest expense	166	—
Miscellaneous accrued expenses	386	468
Total accrued expenses and other liabilities	$ 13,847	$ 6,484

As of September 30, 2022, other long-term liabilities of $0.2 million was the value of unmet conditions associated with a governmental grant received in 2021. The Company anticipates meeting these conditions between 2024 and 2026 and, upon satisfaction, will reduce these liabilities with a corresponding reduction to research and development expenses.

7. Convertible Debt

On April 1, 2022, the Company entered into a loan and security agreement (the "Loan Agreement") with K2 HealthVentures LLC ("K2HV"), and together with any other lender from time to time party thereto, the “Lenders”), K2HV as administrative agent for the Lenders, and Ankura Trust Company, LLC, as collateral agent for the Lenders. The Loan Agreement provides term loan commitments of up to $45.0 million in four potential tranches: (i) a $20.0 million term loan funded on April 1, 2022, (the “First Tranche Term Loan”), (ii) a $5.0 million term loan commitment (the “Second Tranche Term Loan Commitment”), (iii) a $15.0 million term loan commitment (reduced to $10.0 million if a second tranche term loan is made) (the “Third Tranche Term Loan Commitment”), and (iv) a $10.0 million term loan commitment (the “Fourth Tranche Term Commitment”). The timing and availability of the tranche term loan commitments are subject to various conditions, including that no events of default have occurred. The availability period of the Second Tranche Term Loan Commitment ends December 31, 2022. The availability of the Third Tranche Term Loan Commitment begins January 1, 2023 and ends no later than July 31, 2023 and is subject to the achievement of a clinical milestone event. The Fourth Term Loan Commitment availability ends May 1, 2024, unless the third tranche milestone is met, which would adjust such date to May 1, 2025. The Second Tranche Term Loan Commitment and Fourth Tranche Term Loan Commitment are subject to a satisfactory loan review by the Lenders who may provide the advances in their sole discretion. The Fourth Tranche Term Loan Commitment is also subject to an additional 1% facility fee.

The facility carries a 48-month term with interest only payments for 24 months, subject to increase to up to 36 months upon the Company drawing on the Third Tranche Loan Commitment and no event of default having occurred. Subsequent to the interest-only period, the Company is required to make equal monthly payments of principal plus interest until the loans mature on April 1, 2026. The term loans bear a variable interest rate equal to the greater of 7.75% and (ii) the sum of (A) the prime rate last quoted in The Wall Street Journal (or a comparable replacement rate if The Wall Street Journal ceases to quote such rate) and (B) 4.25%. The variable interest rate at September 30, 2022, was 10.5%. Upon final payment or prepayment of the loans, the Company must pay a final payment equal to 5.45% of the loans borrowed (the "Final Fee"), which is being accrued to interest expense over the term of the loan. The Company has an option to prepay the loans in whole, subject to a prepayment fee of 3% prior to the first anniversary of the April 1, 2022, funding date, 2% after the first anniversary but prior the second anniversary of the funding date, and 1% thereafter if prior to the maturity date.

The Lenders may elect at any time prior to the full repayment of the term loans to convert any portion of the principal amount of the term loans then outstanding, up to an aggregate of $5.0 million in principal amount, into shares of the Company's common stock at a conversion price of $2.2689, subject to customary beneficial ownership limitations.

The Loan Agreement contains customary representations and warranties, events of default and affirmative and negative covenants, including covenants that limit or restrict the Company’s ability to, among other things, dispose of assets, make changes to the Company’s business, management, ownership or business locations, merge or consolidate, incur additional indebtedness, pay dividends or other distributions or repurchase equity, make investments, and enter into certain transactions with affiliates, in each case subject to certain exceptions. As security for its obligations under the Loan Agreement, the Company granted the Lenders a first priority security interest on substantially all of the Company’s assets (other than intellectual property), subject to certain exceptions. Upon occurrence of an event of default, which includes the failure to maintain solvency, the Company may have to prepay the term loans in an amount equal to the sum of the (a) outstanding principal together with accrued interest, (b) prepayment fee, and (c) Final Fee.

In connection with entering into the Loan Agreement, the Company also issued to K2HV a warrant to purchase a number of shares of Common Stock equal to the quotient of 2.95% of the aggregate funded term loan amount divided by $1.5126, the exercise price, up to a maximum of 877,627 shares (the "Warrant"). The Warrant expires on April 1, 2032. The Warrant has been classified within equity since it (i) is indexed to the Company’s own equity and (ii) meets the equity classification conditions. As of September 30, 2022, the Warrant is exercisable for 390,056 shares of common stock. The Company allocated the proceeds between the term loan and the Warrant on a relative fair value basis, resulting in a discount on the term loan. The Loan Agreement and the Warrant each provide the Lenders with certain piggyback registration rights with respect to the shares of common stock issuable upon conversion under the Loan Agreement or upon exercise of the Warrant.

The Company incurred fees and issuance costs associated with the Loan Agreement of $0.5 million. The Company recorded contractual interest expense related to the Loan Agreement of $0.9 million and additional interest expense related to the amortization of the debt discount and issuance costs and accretion of the Final Fee of $0.4 million in the nine months ended September 30, 2022. The effective interest rate at September 30, 2022, which includes the non-cash interest components noted above, was 14.00%.

Future principal debt payments on the Loan Agreement are as follows (in thousands):

	SEPTEMBER 30, 2022
2022	$ —
2023	—
2024	6,187
2025	10,146
2026	3,667
Total principal payments	20,000
Final Fee	1,090
Total principal payments and Final Fee	21,090
Less: Unamortized debt discount	(849)
Less: Unamortized debt issuance costs	(71)
Less: Unaccreted Final Fee	(913)
Term loan, non-current	$ 19,257

8. Common Stock

Each share of the Company's 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 preferred stock.

Upon the closing of the IPO, the Company amended and restated its certificate of incorporation to provide for 100,000,000 shares designated as common stock with a par value of $0.0001 per share as part of its authorized capital.

Restricted Stock

The Company issued restricted stock to its founders and certain officers of the Company. In general, the shares of restricted stock vested over a four-year period, with 25% of the shares vesting after one year, followed by monthly vesting over the remaining three years. As of September 30, 2022, all restricted stock awards were fully vested.

Common Stock Warrants

The Company issued warrants to purchase common stock in connection with a preferred stock financing in March 2016. These common stock warrants allow for the holders to purchase 71,544 shares of common stock at $1.21 per share. As of September 30, 2022, all of the common stock warrants were fully exercisable. The common stock warrants expire in 2031.

As described in Note 7, on April 1, 2022, the Company issued a warrant to K2HV to purchase 390,056 shares of common stock. This warrant expires in 2032.

Reserved Shares

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

	SEPTEMBER 30, 2022	DECEMBER 31, 2021
Exercise of common stock warrants	461,600	71,544
Exercise of options to purchase common stock	4,680,473	3,681,793
Shares available for issuance under employee stock purchase plan	190,888	—
Shares available for issuance under equity incentive plans	2,390,982	2,132,067
Total	7,723,943	5,885,404

9. Equity Incentive Plans

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. 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. The provisions of the 2016 Plan allow for early exercises for options that have not yet vested. Early exercises have historically been for a de minimis number of shares.

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 serves as the successor to the 2016 Plan. The 2020 Plan authorizes the award of stock options, restricted stock awards, stock appreciation rights, restricted stock units, cash awards, performance awards and stock bonus awards. The number of shares reserved for issuance under the 2020 Plan increases automatically on January 1 of each fiscal year, through 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). On January 1, 2022, the board of directors authorized an increase in the number of shares reserved for issuance under the 2020 Plan by 1,292,458 shares of common stock.

At September 30, 2022, there were 2,390,982 shares of common stock available for issuance under the 2020 Plan.

On September 23, 2020, the Company adopted the 2020 Employee Stock Purchase Plan (the "ESPP"), which became effective upon the execution of the underwriting agreement related to the IPO. The Company initially reserved 280,000 shares of common stock for sale under the ESPP. The aggregate number of shares reserved for sale under the ESPP increases automatically on January 1st of each fiscal year through 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 lesser number of shares for such increase. In December 2021, the board of directors determined that there would be no automatic increase in the number of shares of common stock reserved under the ESPP on January 1, 2022. The ESPP provides for six-month offering periods commencing on January 1 and ending on June 30 and commencing on July 1 and ending on December 31 of each calendar year. The Company began its first offering period on January 1, 2022, and issued 89,112 shares of common stock on June 30, 2022 at the end of the offering period.

Total stock-based compensation was classified as follows on the unaudited interim condensed consolidated statements of operations (in thousands):

	THREE MONTHS ENDED SEPTEMBER 30,		NINE MONTHS ENDED SEPTEMBER 30,	
	2022	2021	2022	2021
General and administrative	$ 1,083	$ 1,222	$ 3,821	$ 2,990
Research and development	557	667	1,979	1,727
Total stock-based compensation	$ 1,640	$ 1,889	$ 5,800	$ 4,717

In December 2020, the Company granted an employee an option to purchase 113,000 shares of the Company's common stock with an exercise price per share equal to the fair value of the Company's common stock on the date of grant. This grant is included in the outstanding options in the summary table below. The option grant includes three separate tranches (each tranche representing one-third of the total grant) that will each vest four years from the date of grant. This option grant and its tranches are subject to accelerated vesting in the event that the Company achieves certain defined milestones related to the Company's manufacturing efforts. As of September 30, 2022, the Company determined that the requisite service period for two of the three tranches of this award is four years and recognized $0.3 million of stock-based compensation expense for the nine months ended September 30, 2022. Accelerated vesting was considered to be probable for one of the tranches as of September 30, 2022. Accordingly, the Company recognized stock-based compensation expense of $0.3 million for this tranche in the nine months ended September 30, 2022, which included a cumulative adjustment reflecting the retroactive application of the accelerated vesting.

A summary of option activity for the nine months ended September 30, 2022 is presented below:

	SHARES	WEIGHTED AVERAGE EXERCISE PRICE	WEIGHTED-AVERAGE REMAINING CONTRACTUAL TERM (YEARS)	AGGREGATE INTRINSIC VALUE (IN THOUSANDS)
Outstanding at December 31, 2021	3,681,793	$ 10.84		
Granted	1,781,525	$ 1.74		
Exercised	(34,863)	$ 1.77		
Canceled, expired or forfeited	(747,982)	$ 7.82		
Outstanding at September 30, 2022	4,680,473	$ 7.93	7.40	$ —
Vested and expected to vest at September 30, 2022	4,680,473	$ 7.93	7.40	$ —
Exercisable at September 30, 2022	2,076,887	$ 8.03	5.51	$ 25

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, 2022 and 2021 was $1.27 and $11.25, respectively. The total intrinsic value of options exercised was $0.02 million and $1.8 million for the nine months ended September 30, 2022 and 2021, respectively. Total unrecognized stock-based compensation expense related to options was $12.9 million at September 30, 2022, and is expected to be recognized over a weighted-average period of 2.6 years.

10. Commitments and Contingencies

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 costs related to such legal proceedings as incurred.

11. 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:

	NINE MONTHS ENDED SEPTEMBER 30,	
	2022	2021
Outstanding stock options	4,680,473	3,636,492
Restricted stock	—	6,893
Shares available for purchase under employee stock purchase plan	190,888	—
Common stock warrants	461,600	71,544
Potential conversion of note payable	2,203,711	—
Total	7,536,672	3,714,929

12. Subsequent Events

The Company has evaluated subsequent events from the balance sheet date through the date on which these financial statements were issued and identified the following:

NOF License Agreement

On October 31, 2022, the Company entered into a license agreement with NOF Corporation ("NOF"). Under this license agreement, the Company obtained a non-exclusive, worldwide (except with respect to China and other specified territories in Asia), sublicensable (subject to certain limitations) license from NOF under certain patent claims of NOF relating to NOF's cationic lipid, or NOF Lipid. The NOF Lipid is one of multiple lipids that comprise the proprietary LNP associated with ONCR-021. NOF will supply NOF Lipid to be used for the development, manufacture, and commercialization of Oncorus Products pursuant to a supply agreement to be negotiated and entered into by the parties.

The NOF Agreement provides for an initial license payment of $0.5 million to NOF upon signing, which will be recorded to research and development expense in October 2022. Additionally, the Company may be obligated to make milestone payments to NOF of up to approximately $25 million in the aggregate upon the achievement of specified development and regulatory milestones. In the event that more than one Oncorus Product achieves such milestones, or if an Oncorus Product achieves the specified milestones for additional indications, the Company will be obligated to make additional milestone payments. Such payments would be between approximately $5 million and approximately $10 million for each such additional product and/or indication. The Company is also obligated to pay NOF royalties on net sales of Oncorus Products at a percentage in the low single digits, subject to standard reductions. The obligation to pay royalties under the NOF Agreement commences on the first commercial sale of the first Oncorus Product anywhere in the licensed territory, and expires on a jurisdiction-by-jurisdiction basis after a specified number of years following the first commercial sale of the first Oncorus Product anywhere in the licensed territory, or if later, the date upon which no licensed patent claim validly exists in such jurisdiction.

Nasdaq Compliance Notice

On November 1, 2022, the Company received written notice from the Listing Qualifications Department of The Nasdaq Stock Market ("Nasdaq") notifying the Company that, based on the closing bid price of the Company's common stock for the last 30 consecutive business days, the Company no longer complies with the minimum bid price requirement for continued listing on The Nasdaq Global Market. Nasdaq Listing Rule 5450(a) requires listed securities to maintain a minimum bid price of $1.00 per share (the "Minimum Bid Price Requirement"), and Nasdaq Listing Rule 5810(c)(3)(A) provides that a failure to meet the Minimum Bid Price Requirement exists if the deficiency continues for a period of 30 consecutive business days.

The Notice has no immediate effect on the listing of the Company's Common Stock on The Nasdaq Global Market. Pursuant to Nasdaq Listing Rule 5810(c)(3)(A), the Company has been provided an initial compliance period of 180 calendar days from receipt of the Notice, or until June 1, 2023, to regain compliance with the Minimum Bid Price Requirement. To regain compliance, the closing bid price of the Company's Common Stock must be at least $1.00 per share for a minimum of 10 consecutive business days prior to June 1, 2023, unless Nasdaq exercises its discretion to extend this period pursuant to Nasdaq Listing Rule 5810(c)(3)(H).

The Company intends to monitor the closing bid price of the Company's Common Stock and consider its available options to resolve the noncompliance with the Minimum Bid Price Requirement.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion of our financial condition and results of operations in conjunction with our unaudited interim condensed consolidated financial statements and the related notes and other financial information included elsewhere in this Quarterly Report on Form 10-Q. In addition to historical financial information, this discussion contains forward-looking statements based upon current expectations that involve risks and uncertainties, such as statements of our plans, objectives, expectations, intentions and belief. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth in the section titled "Risk Factors" under Part II, Item 1A, below and under "Part I, Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the Securities and Exchange Commission, or the SEC, on March 9, 2022; under Part II, Item 1A in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, filed with the SEC on May 4, 2022; and under Part II, Item 1A in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, filed with the SEC on August 4, 2022.

These statements are based upon information available to us as of the date of this Quarterly Report on Form 10-Q, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely upon these 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. Our 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, 2022, to the three and nine months ended September 30, 2021.

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 clinical-stage biopharmaceutical company focused on developing next-generation, systemically active 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. We believe that the therapies we are developing could bring significant benefit to many patients who are currently underserved by approved immuno-oncology therapies, including other viral immunotherapies and immune checkpoint inhibitors.

Our HSV Platform

Our lead product candidate, ONCR-177, is an intratumorally administered viral immunotherapy based on our oncolytic HSV-1 platform, referred to as our HSV Platform, which leverages the Herpes Simplex Virus type 1, or HSV-1, a virus which has been clinically proven to effectively treat certain cancers. Using our HSV Platform, we engineered ONCR-177 to overcome the limitations of existing viral immunotherapies by enhancing potency and driving strong systemic anti-tumor immune responses at injected as well as distant non-injected tumor sites. ONCR-177 is armed with five immunostimulatory transgenes—a greater number of transgenes than viral immunotherapies that are either currently approved or in clinical development. Product candidates from our HSV Platform are designed to maintain full viral replication competency in tumors and to be selectively attenuated in healthy tissues, meaning they replicate and express transgenes only in tumor cells while disabling potentially harmful effects on healthy tissues. In multiple preclinical cancer models, we observed that these attributes of ONCR-177 were achieved without either the systemic release of cytokines that can be associated with toxicity or significant presence of the virus in non-injected tumors or in circulation, in addition to favorable tolerability when administered via intravenous and intratumoral injection in a validated murine model of HSV-1 infection. We believe this combination of features allows our HSV Platform to overcome the safety versus potency trade-off that has generally limited the viral immunotherapy field to date. Based on safety and tolerability profile observed to date and its ability to stimulate multiple arms of the immune system to attack cancer systemically, we also believe that ONCR-177 has potential in pre-surgical, or neoadjuvant, settings.

In June 2020, we initiated our Phase 1 clinical trial of ONCR-177 in patients with several different types of solid tumors, including breast cancers and cutaneous tumors. We presented our preliminary findings from the Phase 1 clinical trial in November 2021, which

included data from 14 patients in the fully enrolled and completed dose escalation cohorts of the trial and five patients enrolled in the dose expansion monotherapy portion of the trial. In the fully enrolled and completed surface lesion dose escalation portion of the trial, ONCR-177 administered to heavily pretreated patients with advanced, injectable solid tumors was well tolerated with no dose-limiting toxicities. No treatment-related adverse events exceeded Grade 2, and no infectious virions were detected in skin swabs. After four weeks of monotherapy treatment with ONCR-177 at the recommended Phase 2 dose, or RP2D, three of eight evaluable patients (one with cutaneous melanoma, one with squamous cell carcinoma of the head and neck, or SCCHN, and one with mucosal melanoma) had demonstrated clinical benefit. Enrollment continues in the surface lesion dose combination expansion portion of the clinical trial. Patients in the trial are receiving ONCR-177 in combination with Merck's KEYTRUDA® (pembrolizumab), an immune checkpoint inhibitor. In addition, we are enrolling and currently dosing separate cohorts of patients with visceral tumors in the liver with the goal of showing additional safety data. We plan to report additional surface lesion monotherapy expansion data as well as initial surface lesion combination expansion data by the end of 2022.

In addition to ONCR-177, we also have additional preclinical stage programs leveraging our HSV Platform that are intended to yield both intratumoral and intravenous solutions to other unmet medical needs. These preclinical programs include ONCR-GBM, which is designed to target brain cancer through intratumoral injection.

Our Selectively Self-Amplifying vRNA Immunotherapy Platform

We are also developing a broad pipeline of product candidates that leverages our second platform, our selectively self-amplifying viral RNA, or vRNA, immunotherapy platform, referred to as our vRNA Immunotherapy Platform, which aims to enable repeat intravenous, or IV, administration of viral immunotherapies to treat cancers that are less amenable to intratumoral injection due to safety and feasibility reasons, such as cancers of the lung. Our IV-administered approach involves encapsulating in a lipid nanoparticle, or LNP, the genomes of RNA viruses known to kill cancer cells, creating a selectively self-amplifying vRNA immunotherapy. We believe this approach can avoid the rapid immune clearance from circulation caused by neutralizing antibodies otherwise observed to date with IV-administered oncolytic viruses and is thought to limit their effectiveness in the clinic. Once inside the tumor, the synthetic viral genome from our synthetic viruses is first amplified and then instructs tumor cells to synthesize actual infectious virions, which can cause tumor lysis before infecting nearby tumor cells while stimulating immune cell recruitment and activity.

Our two product candidates from our vRNA Immunotherapy Platform are ONCR-021 and ONCR-788. ONCR-021 encodes an optimized strain of Coxsackievirus A21, or CVA21, and ONCR-788 encodes for a modified version of the Seneca Valley Virus, or SVV. Both CVA21 and SVV have extensive clinical experience and favorable safety profiles when administered IV. We believe our selectively self-amplifying vRNA Immunotherapy Platform holds the potential for IV administration and avoids the challenge of neutralizing antibodies seen in previous approaches with IV-administered RNA-based oncology therapeutics. We plan to investigate our novel vRNA immunotherapies in multiple histologies, including cancers of the lung, both as monotherapy and in combination with immune checkpoint inhibitors and other cancer treatments. We plan to submit an investigational new drug application, or IND, to the U.S. Food and Drug Administration, or FDA, for ONCR-021 in mid-2023 to enable clinical development for non-small cell lung cancer and other cancers such as clear cell renal cell carcinoma and melanoma, both as a single agent and in combination with immune checkpoint inhibitors. Following the IND submission for ONCR-021 and pending additional financing, we plan to submit an IND for ONCR-788 to enable its development in small cell lung cancer, neuroendocrine prostate and other neuroendocrine cancers, both as a single agent and in combination with immune checkpoint inhibitors and other cancer treatments. In the process of developing our vRNA Immunotherapy Platform, we also developed a proprietary LNP platform intended to efficiently deliver large nucleic acids with minimal endosomal escape.

Manufacturing

We plan to manufacture our product candidates at our approximately 105,000 square foot manufacturing facility in Andover, Massachusetts, 41,000 square feet of which is specifically dedicated to processes that are compliant with good manufacturing practices, or GMP. We began process development activities at the facility in 2021 and, as of the date of this report, construction at the facility is complete. We are on track to initiate engineering batches at the facility by the end of 2022.

Financial

Since inception in 2015, 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, commencing a clinical trial, and manufacturing scale-up activities. 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.

We have funded our operations primarily through the sale of redeemable convertible preferred stock and from our initial public offering, or IPO, of our common stock in 2020 and a follow-on public offering of common stock in 2021. From inception through September 30, 2022, we raised an aggregate of $306.3 million in gross proceeds from these equity transactions. In November 2021, we also entered into an open market sale agreement pursuant to which we may sell shares of common stock from time to time for aggregate gross proceeds of up to $50.0 million, although, to date, we have not made any sales under this agreement.

On April 1, 2022, we entered into a loan and security agreement, or the Loan Agreement, with K2 HealthVentures, LLC, or K2HV, which provides for term loan commitments of up to $45.0 million in four potential tranches. As of September 30, 2022, we have borrowed $20.0 million under this Loan Agreement.

Since inception, we have incurred significant operating losses. Our net losses were $56.5 million and $44.9 million for the nine months ended September 30, 2022 and 2021, respectively. As of September 30, 2022, we had an accumulated deficit of $251.1 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.

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.

As of September 30, 2022, we had aggregate cash and cash equivalents and investments of $81.5 million. We believe that our existing cash and cash equivalents and investments will enable us to fund our operating expenses and capital expenditure requirements into the first quarter of 2024.

Recent Developments

In April 2022, we announced plans to relocate all of our company operations to the Andover facility. As of the date of this report, we have completed the relocation of our corporate headquarters to the Andover facility.

In October 2022, we entered into a license agreement with NOF Corporation related to a lipid component of the LNP associated with ONCR-021. See "Item 5. Other Information—License Agreement with NOF Corporation".

Impact of the COVID-19 Pandemic on Our Business

In response to the COVID-19 pandemic, we implemented a work-from-home policy allowing employees who can work from home to do so. We have transitioned back to in-office work for the majority of our employees. 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. Business travel was previously suspended but is now becoming more frequent, and online and teleconference technology continues to be used regularly. We continue to monitor guidance from the CDC and other relevant health regulatory authorities and may adjust our plans to the extent there are changes in such guidance.

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, bonuses, benefits and stock-based compensation expense for our research and development personnel;
- 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 stock-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 they are 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. For example, ONCR-021 and ONCR-788 were both nominated as candidates in May 2021, at which time we began tracking their external research and development costs. 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.

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, bonuses 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, audit and tax fees, recruiting costs, costs for consultants who we utilize to supplement our personnel and insurance costs. General and administrative expenses also include travel costs, facility and office-related costs that are not included in research and development expenses, as well as 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 SEC and Nasdaq listing standards, 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) consists primarily of interest expense associated with our Loan Agreement with K2HV and interest income earned on our investments and cash equivalents.

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	
	2022	2021	$	%	2022	2021	$	%
	(in thousands, except percentages)							
Operating expenses:								
Research and development	$ 14,087	$ 11,299	$ 2,788	25%	$ 39,036	$ 30,406	$ 8,630	28%
General and administrative	5,211	5,440	(229)	-4%	16,721	14,550	2,171	15%
Total operating expenses	19,298	16,739	2,559	15%	55,757	44,956	10,801	24%
Loss from operations	(19,298)	(16,739)	(2,559)	-15%	(55,757)	(44,956)	(10,801)	-24%
Total other income (expense), net	(322)	11	(333)	-3027%	(734)	37	(771)	-2084%
Net loss	$ (19,620)	$ (16,728)	$ (2,892)	-17%	$ (56,491)	$ (44,919)	$ (11,572)	-26%

Three Months Ended September 30, 2022, Compared to the Three Months Ended September 30, 2021

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
	2022	2021	
	(in thousands)		
Direct external expenses by program			
ONCR-177	$ 2,528	$ 2,362	$ 166
ONCR-021	3,546	825	2,721
ONCR-788	17	304	(287)
Platform development, early stage research and unallocated expenses:			
Employee compensation and related	3,937	4,153	(216)
External research, development and consulting	697	234	463
Laboratory supplies	713	988	(275)
Facility-related	1,476	1,689	(213)
Other expenses	1,173	744	429
Total research and development	$ 14,087	$ 11,299	$ 2,788

Research and development expenses increased from $11.3 million for the three months ended September 30, 2021 to $14.1 million for the three months ended September 30, 2022. The increase of $2.8 million, or 25%, was primarily the result of:

- a $0.2 million increase in direct external expenses for ONCR-177 due to increased clinical trial costs associated with our Phase 1 trial of ONCR-177;
- a $2.7 million increase in direct external expenses for ONCR-021, which was attributable to pre-clinical development costs that were incurred subsequent to candidate nomination in May 2021;

- a $0.3 million decrease in direct external expenses for ONCR-788, due to resources being directed to our other drug candidates;
- a $0.2 million decrease in employee compensation costs, primarily bonus and stock compensation expense, due to employee turnover and decreased headcount in 2022 as compared to 2021;
- a $0.5 million increase in external research, development and consulting costs as we engaged third parties to perform some functions due to employee turnover;
- a $0.3 million decrease in laboratory supply costs due to lower consumption of supplies as a result of employee turnover and costs related to ONCR-021 being captured as program costs following candidate nomination in May 2021;
- a $0.2 million decrease in facility-related costs due to a reduction of rent expense from accelerating the termination of our Cambridge lease; and
- a $0.4 million increase in other expenses primarily related to increased support costs attributable to our growth and the continuing work to operationalize our Andover facility.

General and Administrative Expenses

	THREE MONTHS ENDED SEPTEMBER 30,		
	2022	2021	CHANGE
		(in thousands)	
Employee compensation and related	$ 2,466	$ 2,530	$ (64)
Professional service and consultant fees	1,840	2,345	(505)
Facility-related	343	76	267
Other expenses	562	489	73
Total general and administrative expenses	$ 5,211	$ 5,440	$ (229)

General and administrative expenses decreased from $5.4 million for the three months ended September 30, 2021, to $5.2 million for the three months ended September 30, 2022. The decrease of $0.2 million, or -4%, was primarily the result of:

- a $0.5 million decrease in professional service and consultant fees primarily related to the expansion of internal headcount replacing more expensive outsourced functions; and
- a $0.3 million increase in facility-related costs primarily due to expansion of our Andover lease in December 2021 and changes in rent expense allocation driven by changes in our employee headcount.

Other Income (Expense)

Other income (expense) for the three months ended September 30, 2022, decreased by $0.3 million compared to the three months ended September 30, 2021. This decrease was driven by interest expense incurred as a result of our debt arrangement with K2HV, which we entered into on April 1, 2022.

Nine Months Ended September 30, 2022, Compared to the Nine Months Ended September 30, 2021

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,		
	2022	2021	CHANGE
	(in thousands)		
Direct external expenses by program			
ONCR-177	$ 7,336	$ 6,770	$ 566
ONCR-021	6,997	1,293	5,704
ONCR-788	104	388	(284)
Platform development, early stage research and unallocated expenses:			
Employee compensation and related	12,807	10,687	2,120
External research, development and consulting	1,402	1,800	(398)
Laboratory supplies	2,288	2,848	(560)
Facility-related	5,479	4,743	736
Other expenses	2,623	1,877	746
Total research and development	$ 39,036	$ 30,406	$ 8,630

Research and development expenses increased from $30.4 million for the nine months ended September 30, 2021, to $39.0 million for the nine months ended September 30, 2022. The increase of $8.6 million, or 28%, was primarily the result of:

- a $0.6 million increase in direct external expenses for our product candidate ONCR-177, due to increased clinical trial costs associated with our Phase 1 trial of ONCR-177;
- a $5.7 million increase in direct external expenses for our product candidate ONCR-021, resulting from pre-clinical development costs that were incurred subsequent to candidate nomination in May 2021;
- a $0.3 million decrease in direct external expenses for our product candidate ONCR-788, as our resources have been directed to our other drug candidates;
- a $2.1 million increase in employee compensation costs, substantially all related to salaries and employee benefits, due to increased headcount and annual salary increases in 2022, as well as higher stock compensation expense for stock option grants to existing and new employees in 2021 and 2022;
- a $1.0 million decrease in external research, development, and consulting as well as laboratory supplies, as costs in these categories previously related to ONCR-021 are now being captured as program costs following candidate nomination in May 2021;
- a $0.7 million increase in facility-related costs primarily due to expansion at our Andover facility in December 2021, changes in rent expense allocation driven by changes in our employee headcount, and common area maintenance expenses for the Andover manufacturing facility for which we commenced payments in July 2021; and
- a $0.7 million increase in other expenses primarily related to increased support costs attributable to our growth and the continuing work to operationalize the Andover facility.

General and Administrative Expenses

	NINE MONTHS ENDED SEPTEMBER 30,		
	2022	2021	CHANGE
	(in thousands)		
Employee compensation and related	$ 7,920	$ 6,270	$ 1,650
Professional service and consultant fees	5,997	6,707	(710)
Facility-related	1,286	282	1,004
Other expenses	1,518	1,291	227
Total general and administrative expenses	$ 16,721	$ 14,550	$ 2,171

General and administrative expenses increased from $14.6 million for the nine months ended September 30, 2021, to $16.7 million for the nine months ended September 30, 2022. The increase of $2.2 million, or 15%, was primarily the result of:

- a $1.7 million increase in employee compensation costs related to higher stock compensation expense from increased stock option grants to existing and new employees in 2021 and 2022 as well as higher salaries, bonus, and employee benefits costs due to increased headcount and annual salary increases in 2022;

- a $0.7 million decrease in professional service and consultant fees primarily related to internal personnel replacing outsourced solutions; and
- a $1.2 million increase in facility-related and other expenses primarily as a result of commencing payments on rent-associated expenses in July 2021 and changes in rent expense allocation driven by changes in our employee headcount.

Other Income (Expense)

Other income (expense) for the nine months ended September 30, 2022 decreased by $0.7 million compared to the nine months ended September 30, 2021. This decrease was primarily driven by interest expense incurred as a result of our debt arrangement with K2HV, which we entered into on April 1, 2022.

Liquidity and Capital Resources

Sources of Liquidity

As of September 30, 2022, our cash and cash equivalents and investments totaled $81.5 million.

From inception through September 30, 2022, we funded our operations with aggregate gross proceeds of $306.3 million from equity financings and $20.0 million from our Loan Agreement with K2HV, which we entered into in April 2022.

The Loan Agreement provides for loans of up to an aggregate of $45.0 million to be funded upon the achievement of certain time-based, clinical and regulatory milestones. Amounts borrowed under the Loan Agreement are collectively referred to as the Term Loan. The Term Loan will mature on April 1, 2026 and bears a variable interest rate equal to the greater of (i) 7.75% and (ii) the sum of (A) the prime rate last quoted in The Wall Street Journal (or a comparable replacement rate if The Wall Street Journal ceases to quote such rate) and (B) 4.25%. The variable interest rate was 10.5% as of September 30, 2022. The Loan Agreement contains customary representations and warranties, events of default and affirmative and negative covenants, including covenants that limit or restrict our ability to, among other things, dispose of assets, make changes to our business, management, ownership or business locations, merge or consolidate, incur additional indebtedness, pay dividends or other distributions or repurchase equity, make investments, and enter into certain transactions with affiliates, in each case subject to certain exceptions. As security for our obligations under the Loan Agreement, we granted the Lenders a first priority security interest on substantially all of our assets (other than intellectual property), subject to certain exceptions.

In November 2021, we entered into an open market sale agreement pursuant to which we may sell shares of common stock from time to time for aggregate gross proceeds of $50.0 million. There have been no sales under this agreement as of September 30, 2022.

Cash Flows

	NINE MONTHS ENDED SEPTEMBER 30,	
	2022	2021
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (47,548)	$ (31,386)
Investing activities	(31,260)	(6,695)
Financing activities	19,624	53,379
Net (decrease) increase in cash and cash equivalents	$ (59,184)	$ 15,298

Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2022, was $47.5 million and primarily related to our net loss for the period of $56.5 million, partially offset by non-cash charges consisting primarily of depreciation and amortization of $2.0 million, stock-based compensation expense of $5.8 million, non-cash interest expense related to our Term Loan of $0.4 million, and a $0.5 million non-cash reduction in rent expense following our Cambridge lease modification. Our net cash used in operating activities also included a net source of cash of $1.3 million related to changes in operating assets and liabilities as follows:

- a source of cash of $8.6 million from the reimbursement of certain Andover construction costs through our tenant improvement allowance;
- a net source of cash of $3.2 million due to a decrease in prepaid expenses and other current assets primarily due to services being performed on amounts already paid to vendors;
- a net source of cash of $0.4 million from changes in operating lease liability and associated right-of-use asset due to the difference in the timing of rent expense compared to rent payments; and

- a net use of cash of $10.9 million from decreases in accounts payable and accrued expenses primarily due to the timing of Andover construction invoices.

Net cash used in operating activities for the nine months ended September 30, 2021, was $31.4 million and primarily related to our net loss for the period of $44.9 million, partially offset by non-cash charges consisting of depreciation and amortization of $1.3 million and stock-based compensation expense of $4.7 million. Our net cash used in operating activities also included a net source of cash of $7.5 million related to changes in operating assets and liabilities as follows:

- a net source of cash of $3.1 million from changes in the operating lease liability and associated right-of-use asset due to the difference in the timing of rent expense compared to rent payments;
- a source of cash of $1.7 million from the reimbursement of certain Andover construction costs through our tenant improvement allowances;
- a net source of cash of $1.8 million from an increase in accrued expenses and other current liabilities primarily due to the timing of invoices; and
- a net source of cash of $0.8 million from a decrease in prepaid expenses and other current assets primarily due to a decrease in payments to vendors in advance of services being performed.

Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2022, was $31.3 million, which consisted of purchases of property and equipment of $14.5 million, and net purchases of short-term investments of $16.8 million. Net cash used by investing activities of $6.7 million for the nine months ended September 30, 2021, was for purchases of property and equipment.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2022, was $19.6 million, which consisted primarily of borrowings under our term loan from K2HV. Net cash provided by financing activities for the nine months ended September 30, 2021, was $53.4 million and consisted primarily of net proceeds from the issuance of common stock in connection with our follow-on offering of common stock.

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, expand operations at our Andover manufacturing facility 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.

We believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements into the first quarter of 2024. 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 associated with the expansion of operations at our Andover facility;
- 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, research and development activities and manufacturing capabilities; and
- the costs of operating as a public company.

Our cash and cash equivalents and investments as of September 30, 2022, 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. We may also raise additional capital from sales of common stock under our Sales Agreement. To the extent that we raise additional capital through the sale of equity or convertible debt securities, ownership interests of stockholders may be diluted, and the terms of these securities may include liquidation or other preferences that could adversely affect the rights of our common stockholders. In addition to the Term Loan, 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 or other significant judgments and estimates from those described in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on March 9, 2022.

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

On April 1, 2022, we entered into the Loan Agreement with K2HV, which increased our contractual obligations and commitments related to future principal and interest payments. See "—Sources of Liquidity" above for further discussion about the Loan Agreement.

As of September 30, 2022, there have been no other material changes to our contractual obligations and commitments, consisting of operating lease obligations, from those described in our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on March 9, 2022.

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 $1.235 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 of our variable rate debt and our cash equivalents, in the form of a money market fund, are primarily invested in U.S. treasury obligations.

Based on the $20.0 million outstanding principal balance under the Term Loan at September 30, 2022, a 100-basis point increase in interest rates would increase our interest expense by $0.2 million annually.

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.

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 and certain supply chain costs. 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, 2021 and the three and nine months ended September 30, 2022.

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 principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2022, 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, 2022, our principal executive officer and principal 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 risks and events that, if they occur, could adversely affect our financial condition and results of operations and the trading price of our securities. Except as provided below, our risk factors as of the date of this Quarterly Report on Form 10-Q have not changed materially from those described in "Part I, Item 1A. Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2021, filed with the SEC on March 9, 2022, and our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2022 and June 30, 2022, filed with the SEC on May 4, 2022 and August 4, 2022, respectively.

If we cannot comply with Nasdaq's continued listing standards, our common stock could be delisted, which would harm our business and could have an adverse impact on the liquidity and trading price of our common stock and our ability to raise additional capital.

Our common stock is currently listed on The Nasdaq Global Market. To maintain the listing of our common stock on The Nasdaq Global Market, we must satisfy minimum financial and other continued listing requirements and standards, including those related to the price of our common stock. On November 1, 2022, we received a written notice from the Listing Qualifications Department of The Nasdaq Stock Market, or Nasdaq, notifying us that, based on the closing bid price of our common stock being below $1.00 per share for 30 consecutive business days, we no longer complied with Nasdaq's minimum bid price requirement in Listing Rule 5450(a)(1) for continued listing on The Nasdaq Global Market.

Pursuant to Nasdaq Listing Rule 5810(c)(3)(A), we have been provided an initial compliance period of 180 calendar days from receipt of the Notice, or until May 1, 2023, to regain compliance with the minimum bid price requirement. To regain compliance, the bid price for our common stock would need to close at $1.00 per share or more for a minimum of 10 consecutive business days during this 180-day grace period, among other requirements. While we may be able to qualify for additional time to attempt to regain compliance, there can be no assurance that we will qualify for additional time to regain compliance, or that we will regain compliance with or without such additional time. If we are unable to meet Nasdaq's listing maintenance standards for any reason within the allotted compliance period(s), including any extensions that may be granted by Nasdaq, our common stock could be delisted from The Nasdaq Global Market.

If necessary to regain compliance with Nasdaq listing standards, we may, subject to approval of our Board of Directors and stockholders, implement a reverse stock split. However, there can be no assurance that a reverse stock split, or any other alternatives we may consider to regain compliance with the minimum bid price requirement, would be approved or would result in a sustained higher stock price that would allow us to meet the Nasdaq stock price listing requirements. If our common stock were to be delisted from Nasdaq and is not eligible for quotation or listing on another market or exchange, trading of our common stock could be conducted only in the over-the-counter market or on an electronic bulletin board established for unlisted securities such as the Pink Sheets or the OTC Bulletin Board. In such event, it could become more difficult to dispose of, or obtain accurate price quotations for, our common stock, and there would likely also be a reduction in our coverage by securities analysts and the news media, which could cause the price of our common stock to decline further. Also, it may be difficult for us to raise additional capital if we are not listed on a major exchange.

The delisting of our common stock could also result in an event of default under our loan and security agreement with K2 HealthVentures, LLC, in certain circumstances.

We are highly dependent on our key personnel. 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, and John Goldberg, M.D., our Chief Medical Officer. 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. Christophe Quéva, Ph.D., our former Chief Scientific Officer and Senior Vice President, Research, resigned from those roles in September 2022 to pursue other professional opportunities. Dr. Ashburn has assumed responsibilities for the company's research and development function and oversight of its research and development personnel. We currently do not have "key person" insurance on any of our employees. The loss of the services 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.

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.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

License Agreement with NOF Corporation

On October 31, 2022, we entered into a license agreement with NOF Corporation, or NOF. Under the license agreement with NOF, or the NOF Agreement, we obtained a non-exclusive, worldwide (except with respect to China and other specified territories in Asia), sublicensable (subject to certain limitations) license from NOF under certain patent claims of NOF relating to NOF's cationic lipid, or NOF Lipid, to develop, manufacture, and commercialize products made of or from NOF Lipid and a nucleic acid, or Oncorus Products, including ONCR-021. The NOF Lipid is one of multiple lipids that comprise the proprietary LNP associated with ONCR-021. NOF will supply NOF Lipid to be used for the development, manufacture and commercialization of Oncorus Products pursuant to a supply agreement to be negotiated and entered into by the parties.

The NOF Agreement provides for an initial license payment of $0.5 million to NOF upon signing, and we may be obligated to make milestone payments to NOF of up to approximately $25 million in the aggregate upon the achievement of specified development and regulatory milestones. In the event that more than one Oncorus Product achieves such milestones, or if an Oncorus Product achieves the specified milestones for additional indications, we will be obligated to make additional milestone payments between approximately $5 million and approximately $10 million for each such additional product and/or indication. We are also obligated to pay NOF royalties on net sales of Oncorus Products at a percentage in the low single digits, subject to standard reductions. The obligation to pay royalties under the NOF Agreement commences on the first commercial sale of the first Oncorus Product anywhere in the licensed territory, and expires on a jurisdiction-by-jurisdiction basis after a specified number of years following the first commercial sale of the first Oncorus Product anywhere in the licensed territory, or if later, the date upon which no licensed patent claim validly exists in such jurisdiction.

The NOF Agreement expires upon expiration of all royalty obligations. We may terminate the NOF Agreement for convenience upon prior written notice to NOF. NOF may terminate the NOF Agreement if we fail to pay any undisputed amount due under the NOF Agreement, or if NOF reasonably determines that we have not been engaged in any material activities for the development, manufacture or commercialization of any Oncorus Product for a specified period of time. Additionally, either party may terminate the NOF Agreement upon an uncured material breach by the other party, in the event of the other party's insolvency, or if all clinical trials for the Oncorus Products in all jurisdictions in the licensed territory fail and/or all applications for regulatory approvals in all jurisdictions in the licensed territory are rejected, and it is reasonably determined that there is no possibility of further clinical trials or applications for regulatory approvals in any jurisdiction in the licensed territory being successful.

Nasdaq Compliance Notice

On November 1, 2022, we received written notice, or the Notice, from the Listing Qualifications Department of Nasdaq notifying us that, based on the closing bid price of our common stock for the last 30 consecutive business days, we no longer comply with the minimum bid price requirement for continued listing on The Nasdaq Global Market. Nasdaq Listing Rule 5450(a)(1) requires listed securities to maintain a minimum bid price of $1.00 per share, or the Minimum Bid Price Requirement, and Nasdaq Listing Rule 5810(c)(3)(A) provides that a failure to meet the Minimum Bid Price Requirement exists if the deficiency continues for a period of 30 consecutive business days.

The Notice has no immediate effect on the listing of our common stock on The Nasdaq Global Market. Pursuant to Nasdaq Listing Rule 5810(c)(3)(A), we have been provided an initial compliance period of 180 calendar days from receipt of the Notice, or until May

1, 2023, to regain compliance with the Minimum Bid Price Requirement. To regain compliance, the closing bid price of our common stock must meet or exceed $1.00 per share for a minimum of 10 consecutive business days prior to May 1, 2023, unless Nasdaq exercises its discretion to extend this period pursuant to Nasdaq Listing Rule 5810(c)(3)(H). There can be no assurance we will be able to regain compliance.

If we do not regain compliance with the Minimum Bid Price Requirement by May 1, 2023, we may be eligible for an additional 180 calendar day compliance period. To qualify, we must submit an application to transfer to The Nasdaq Capital Market and will be required to meet Nasdaq's continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, with the exception of the requirement that listed securities maintain a minimum bid price. We would also need to provide written notice of our intention to cure the bid price deficiency during the second 180 calendar day compliance period.

If we do not regain compliance within the compliance period(s), including any extensions that may be granted by Nasdaq, Nasdaq will provide notice that our common stock will be subject to delisting. We could seek review of such delisting determination by a hearing panel and also appeal a decision of such hearing panel to the Nasdaq Listing and Hearing Review Council. There can be no assurance that, if we were to appeal such a delisting determination, such appeal would be successful.

We intend to monitor the bid price of our common stock and will consider all available options to resolve the noncompliance with the Minimum Bid Price Requirement, including, subject to approval of our board of directors and stockholders, implementing a reverse stock split. There can be no assurance that a reverse stock split would be approved or would result in a sustained higher stock price that would allow us to meet the Minimum Bid Price Requirement or to otherwise remain in compliance with Nasdaq's listing criteria.

Stock Option Grant

On November 1, 2022, we granted an option to purchase 150,000 shares of our common stock, or the Option, to Stephen W. Harbin, our Chief Operating Officer and Chief of Staff, under our 2020 Equity Incentive Plan. The Option is exercisable at a price per share equal to the closing price of our Common Stock on November 1, 2022, as reported by Nasdaq, which was $0.67, and vests as to 50% of the underlying shares on March 31, 2023, and the remaining 50% of the underlying shares on December 31, 2023, subject to Mr. Harbin's continuous service through each applicable vesting date.

Item 6. Exhibits.

Exhibit Number	Description
3.1	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).
3.2	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).
10.1	Second Amendment to Hampshire Street Lease by and between the Registrant and BMR Hampshire LLC, dated September 13, 2022 (incorporated by reference to Exhibit 10.1 of the Registrant's Current Report of Form 8-K (File No. 001-39575), filed with the SEC on September 14, 2022.
10.2*	Third Amendment to Lease Agreement by and between the Registrant and IQHQ-4 Corporate, LLC, dated September 26, 2022.
31.1*	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.
31.2*	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.
32.1^	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.
32.2^	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.
101.INS*	Inline 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*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* 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.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ONCORUS, INC.

Date: November 2, 2022 By: /s/ Theodore (Ted) Ashburn

Theodore (Ted) Ashburn, M.D., Ph.D.
President, Chief Executive Officer and Director
(Principal Executive Officer)

ONCORUS, INC.

Date: November 2, 2022 By: /s/ Richard Wanstall

Richard Wanstall
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 10.2

THIRD AMENDMENT TO LEASE
(Innovation Park)

THIS THIRD AMENDMENT TO LEASE ("**Third Amendment**") is made and entered into as of the 26th day of September, 2022 ("**Effective Date**"), by and between IQHQ-4 CORPORATE, LLC, a Delaware limited liability company ("**Landlord**") and ONCORUS, INC., a Delaware corporation ("**Tenant**").

R E C I T A L S:

A. Landlord and Tenant entered into that certain Lease Agreement entered into as of December 29, 2020 (the "**Original Lease**"), as amended by that certain First Amendment to Lease dated as of July 7, 2021, as amended by that certain Amended and Restated First Amendment to Lease dated October 25, 2021 and as amended by that certain Second Amendment to Lease dated as of November 17, 2021 (as so amended, the "**Lease**"), whereby Tenant leases certain premises (the "**Premises**") containing 105,334 rentable square feet containing the entirety of Pod 3, Pod 4 and Pod 5 in the South Building (such building includes Pods 2, 3, 4 and 5) ("**Building**") of the project ("**Project**") now known as Innovation Park @ 4 Corporate Drive whose address is 4 Corporate Drive, Andover, Massachusetts, all as more particularly described in the Lease.

B. Pursuant to Section 9(a) and Exhibit A-1 of the Original Lease, Landlord has certain repair and maintenance responsibilities respecting the shared air handling unit referred to as 'Air handler #6 and applicable Exhaust fan' ("**AHU6**"), which AHU6 services the fitness center ("**Gym**"), and the management office ("**Office**") in the Building, and portions of the Premises.

C Tenant desires to assume all of Landlord's responsibilities under the Lease for the repair, maintenance and replacement of AHU6 and Landlord and Tenant wish to amend the Lease to (i) provide for Tenant to assume control of AHU6 and to assume Landlord's obligations as to AHU6; and (ii) amend certain other terms of the Lease as more particularly set forth herein.

A G R E E M E N T:

NOW, THEREFORE, in consideration of the foregoing recitals and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto hereby agree as follows:

1. **Capitalized Terms**. Each capitalized term used but not otherwise defined herein shall have the meaning ascribed thereto in the Lease.

2. **AHU6**. As of the Effective Date, Landlord and Tenant hereby agree as follows:

(a) Tenant shall assume all repair, maintenance and replacement obligations under the Lease with respect to AHU6 including, without limitation, Landlord's obligations as set forth under Section 9(a) and Exhibit A-1 of the Lease and Landlord shall have no repair, maintenance or replacement or other obligations with respect to AHU6. All such repairs and maintenance to, and replacement of, AHU6 shall be performed at Tenant's sole cost and expense and in compliance with the terms, provisions and conditions of the Lease.

(b) Tenant shall provide to Landlord Preventative Maintenance Reports for AHU6 in accordance with Tenant's obligations under Section 9(b)(ii) of the Lease.

(c) Tenant shall ensure that all utilities associated with AHU6 are connected to Tenant's separately metered utilities, and Tenant shall pay all utility costs associated with AHU6 directly to the service provider(s) as required by the Lease.

(d) Within a commercially reasonable time following the Effective Date, Tenant shall (with Landlord's cooperation) ensure that AHU6 is connected to Tenant's building management system, and upon reasonably notice from Landlord, Tenant shall allow Landlord read-only access to the controls, settings, and output readings of AHU6.

(e) Tenant shall ensure that the cfm distribution to the Gym and Office shall comply with the cfm distribution design for AHU6 during all Building Hours throughout the Term, as it may be extended. Within a commercially reasonable time following the Effective Date, Tenant shall provide an engineering report and/or rebalancing report to Landlord which report(s) confirms the then current cfm distribution measurements to the Gym and Office comply with the AHU6 distribution design.

(f) Tenant shall make diligent efforts to promptly provide temporary air conditioning and/or heating unit(s) to the Gym and/or Office in the event AHU6 is shutdown, inoperable, or is not providing sufficient heating or air conditioning to the Office and/or Gym for any reason, for a period exceeding two (2) business days.

(g) Tenant shall provide 24 hours' prior written notice to Landlord (except in the case of emergency) of any planned or unplanned shutdowns of AHU6, or any repairs or maintenance to AHU6.

(h) If Tenant is unable to obtain FDA approval necessary to validate its manufacturing GMP space within the Premises for any reason related to AHU6 and, as a result, Tenant is required to obtain a new air handler and exhaust fan (or similar equipment) solely dedicated to the GMP space within the Premises, Tenant shall procure and install such new air handler and exhaust fan at Tenant's sole cost and expense, provided that Landlord has approved Tenant's design and installation plans for the new air handler and exhaust fan. Landlord agrees to work in good faith with Tenant to reassume its obligations with respect to AHU6 at such time on substantially the same terms as set forth under Section 9(a). Tenant shall be solely responsible for any costs and expenses associated with the reassumption of AHU6 by Landlord.

3. **Brokers**. Each party represents and warrants to the other that no broker, agent or finder negotiated or was instrumental in negotiating or consummating this Third Amendment. Each party further agrees to defend, indemnify and hold harmless the other party from and against any claim for commission or finder's fee by any entity who claims or alleges that they were retained or engaged by the first party or at the request of such party in connection with this Third Amendment.

4. **No Offer**. Submission of this instrument for examination and signature by Tenant does not constitute an offer to amend the Lease or a reservation of or option to amend the Lease,

and this instrument is not effective as a lease amendment or otherwise until executed and delivered by both Landlord and Tenant.

5. **No Further Modification**. Except as set forth in this Third Amendment, all of the terms and provisions of the Lease shall remain unmodified and in full force and effect. Effective as of the date hereof, all references to the "Lease" shall refer to the Lease as amended by this Third Amendment.

6. **Counterparts/Electronic Signature**. This Third Amendment may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same agreement. This Third Amendment may be executed by a party's signature transmitted electronically (including by DocuSign), and copies of this Third Amendment executed and delivered by electronic means shall have the same force and effect as copies hereof executed and delivered with original wet signatures. All parties hereto may rely upon electronic signatures as if such signatures were original wet signatures. Any party executing and delivering this Third Amendment by electronic means shall, if requested by the other party, promptly thereafter deliver a counterpart signature page of this Third Amendment containing said party's original signature; provided, however, any failure to do so shall not affect the enforceability of this Third Amendment. All parties hereto agree that a signature page executed and delivered by electronic means may be introduced into evidence in any proceeding arising out of or related to this Third Amendment as if it were an original wet signature page.

[Signatures on following page]

IN WITNESS WHEREOF, this Third Amendment has been executed as of the Effective Date first above written.

"LANDLORD" IQHQ-4 CORPORATE LLC,
a Delaware limited liability company

By: /s/ Tracy Murphy

Print Name: Tracy Murphy

Title: President

"TENANT" ONCORUS, INC.,
a Delaware corporation

By: /s/ Steve Harbin

Print Name: Steve Harbin

Title: COO & Chief of Staff

Exhibit 31.1

CERTIFICATION 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

I, Theodore (Ted) Ashburn, M.D., Ph.D., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Oncorus, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 2, 2022

By: /s/ Theodore (Ted) Ashburn, M.D., Ph.D.
Theodore (Ted) Ashburn, M.D., Ph.D.
President, Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION 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

I, Richard Wanstall, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Oncorus, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 2, 2022

By: /s/ Richard Wanstall
Richard Wanstall
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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, 2022, 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 2, 2022

By: /s/ Theodore (Ted) Ashburn, M.D., Ph.D.
Theodore (Ted) Ashburn, M.D., Ph.D.
President, Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 32.2

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, 2022, 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 2, 2022

By: /s/ Richard Wanstall
Richard Wanstall
Chief Financial Officer
(Principal Financial Officer)