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, 2021

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: 001-38958

Karuna Therapeutics, Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**27-0605902**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
99 High Street, 26th Floor Boston, Massachusetts	**02110**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (857) 449-2244

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	KRTX	Nasdaq Global Market

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 31, 2021, the registrant had 29,623,555 shares of common stock, $0.0001 par value per share, outstanding.

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Item 1. Consolidated Financial Statements.

KARUNA THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)
(Unaudited)

	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 252,221	$ 53,048
Investment securities, available-for-sale	246,682	269,282
Prepaid expenses and other current assets	30,134	21,864
Deferred offering costs	405	405
Total current assets	529,442	344,599
Restricted cash	261	157
Right-of-use lease assets - operating, net	6,906	2,420
Property and equipment, net	2,981	449
Other non-current assets	508	—
Total assets	$ 540,098	$ 347,625
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,989	$ 865
Accrued expenses	11,658	5,144
Current portion of operating lease liability	2,132	844
Total current liabilities	15,779	6,853
Operating lease liability, net of current portion	5,887	1,841
Other non-current liabilities	104	—
Total liabilities	21,770	8,694
Commitments and Contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized and 0 shares outstanding as of September 30, 2021 and December 31, 2020	—	—
Common stock, $0.0001 par value; 150,000,000 shares authorized at September 30, 2021 and December 31, 2020; 29,606,005 and 26,988,458 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	3	3
Additional paid-in capital	778,271	482,955
Accumulated deficit	(259,911)	(144,066)
Accumulated other comprehensive income (loss)	(35)	39
Total stockholders' equity	518,328	338,931
Total liabilities and stockholders' equity	$ 540,098	$ 347,625

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

KARUNA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue	—	—	—	—
Operating expenses:				
Research and development	$ 38,775	$ 12,585	$ 83,108	$ 27,824
General and administrative	12,393	6,944	32,554	19,585
Total operating expenses	51,168	19,529	115,662	47,409
Loss from operations	(51,168)	(19,529)	(115,662)	(47,409)
Other income (loss), net:				
Impairment loss on right-of-use assets	—	—	(677)	—
Interest income	114	688	363	2,864
Sublease income	122	—	131	—
Total other income (loss), net	236	688	(183)	2,864
Net loss before income taxes	(50,932)	(18,841)	(115,845)	(44,545)
Income tax provision	—	—	—	—
Net loss attributable to common stockholders	$ (50,932)	$ (18,841)	$ (115,845)	$ (44,545)
Net loss per share, basic and diluted (Note 5)	$ (1.72)	$ (0.71)	$ (4.00)	$ (1.69)
Weighted average common shares outstanding used in computing net loss per share, basic and diluted	29,572,289	26,663,968	28,953,654	26,298,969

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

KARUNA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net loss	$ (50,932)	$ (18,841)	$ (115,845)	$ (44,545)
Other comprehensive income (loss):				
Unrealized gains (losses) on available-for-sale investments	(30)	(527)	(74)	365
Comprehensive loss	$ (50,962)	$ (19,368)	$ (115,919)	$ (44,180)

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

KARUNA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands, except share data)
(Unaudited)

	Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Value	Capital	Deficit	Income (loss)	Equity
Balance, December 31, 2020	26,988,458	$ 3	$ 482,955	$ (144,066)	$ 39	$ 338,931
Issuance of common stock upon public offering, net of $17,250 in under-writing discounts and commissions and $233 in offering costs	2,395,834	—	270,017	—	—	270,017
Stock-based compensation expense	—	—	13,288	—	—	13,288
Exercise of common options	159,518	—	3,059	—	—	3,059
Other comprehensive loss	—	—	—	—	(44)	(44)
Net loss	—	—	—	(64,913)	—	(64,913)
Balance, June 30, 2021	29,543,810	$ 3	$ 769,319	$ (208,979)	$ (5)	$ 560,338
Stock-based compensation expense	—	—	8,203	—	—	8,203
Exercise of common options	62,195	—	749	—	—	749
Other comprehensive loss	—	—	—	—	(30)	(30)
Net loss	—	—	—	(50,932)	—	(50,932)
Balance, September 30, 2021	29,606,005	$ 3	$ 778,271	$ (259,911)	$ (35)	$ 518,328

	Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Value	Capital	Deficit	Income	Equity
Balance, December 31, 2019	26,012,754	$ 3	$ 465,420	$ (75,512)	$ 5	$ 389,916
Follow-on offering costs	—	—	(34)	—	—	(34)
Stock-based compensation expense	—	—	4,860	—	—	4,860
Exercise of common options	567,779	—	1,873	—	—	1,873
Other comprehensive income	—	—	—	—	892	892
Net loss	—	—	—	(25,704)	—	(25,704)
Balance, June 30, 2020	26,580,533	$ 3	$ 472,119	$ (101,216)	$ 897	$ 371,803
Stock-based compensation expense	—	—	4,144	—	—	4,144
Exercise of common options	207,283	—	680	—	—	680
Other comprehensive loss	—	—	—	—	(527)	(527)
Net loss	—	—	—	(18,841)	—	(18,841)
Balance, September 30, 2020	26,787,816	$ 3	$ 476,943	$ (120,057)	$ 370	$ 357,259

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

KARUNA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2021	**2020**
Cash flows from operating activities		
Net loss	$ (115,845)	$ (44,545)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	21,491	9,004
Impairment loss on right-of-use assets	677	—
Amortization of premiums and accretion of discounts on investment securities	735	266
Depreciation and amortization expense	270	97
Changes in operating assets and liabilities:		
Accrued interest on investment securities	156	(569)
Prepaid expenses and other current assets	(8,397)	(12,609)
Right-of-use assets	1,004	447
Other non-current assets	(508)	—
Accounts payable	1,005	578
Accrued expenses	6,134	794
Operating lease liability	(706)	(374)
Other non-current liabilities	104	—
Net cash used in operating activities	(93,880)	(46,911)
Cash flows from investing activities		
Purchases of investment securities	(289,504)	(263,974)
Maturities of investment securities	302,149	145,000
Sales of investment securities	8,990	—
Acquisition of property and equipment	(2,303)	(337)
Net cash provided by (used in) investing activities	19,332	(119,311)
Cash flows from financing activities		
Proceeds from public offering, net of underwriting discounts and commissions	270,250	—
Payment of offering costs	(233)	(439)
Proceeds from exercise of stock options	3,808	2,553
Net cash provided by financing activities	273,825	2,114
Net increase (decrease) in cash, cash equivalents and restricted cash	199,277	(164,108)
Cash, cash equivalents and restricted cash at beginning of period	53,205	209,052
Cash, cash equivalents and restricted cash at end of period	$ 252,482	$ 44,944
Supplemental disclosures of cash flows information		
Lease liabilities arising from obtaining right-of-use assets	$ 6,040	$ 3,259
Purchases of property and equipment included in accounts payable and accrued expenses	$ 499	$ 20

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

Note 1. Nature of the Business and Basis of Presentation

Description of the Business

Karuna Therapeutics, Inc. (the "Company") was incorporated under the laws of the State of Delaware in July 2009 as Karuna Pharmaceuticals, Inc. and is headquartered in Boston, Massachusetts. In March 2019, the Company changed its name to Karuna Therapeutics, Inc. The Company is an innovative clinical-stage biopharmaceutical company driven to create and deliver transformative medicines for people living with psychiatric and neurological conditions.

Since the Company's inception, it has focused substantially all of its efforts and financial resources on organizing and staffing the Company, acquiring and developing its technology, raising capital, building its intellectual property portfolio, undertaking preclinical studies and clinical trials and providing general and administrative support for these activities. The Company has not generated any product revenue related to its primary business purpose to date and is subject to a number of risks similar to those of other early stage companies, including dependence on key individuals, regulatory approval of products, uncertainty of market acceptance of products, competition from substitute products and larger companies, compliance with government regulations, protection of proprietary technology, dependence on third parties, product liability, the impact of the ongoing and evolving COVID-19 coronavirus pandemic, and the need to obtain adequate additional financing to fund the development of its product candidates.

On June 27, 2019, the Company's registration statement on Form S-1 relating to its initial public offering of its common stock ("IPO") was declared effective by the Securities and Exchange Commission ("SEC"). In the IPO, which closed on July 2, 2019, the Company issued and sold 6,414,842 shares of common stock, including full exercise of the underwriters' over-allotment option to purchase an additional 836,718 shares, at a public offering price of $16.00 per share. The aggregate net proceeds to the Company from the IPO, inclusive of proceeds from the over-allotment exercise, were approximately $93.0 million after deducting underwriting discounts and commissions of $7.2 million and offering expenses of $2.4 million. Upon closing of the IPO, all 12,962,045 shares of the Company's redeemable convertible preferred stock then outstanding converted into an aggregate of 16,833,790 shares of common stock.

On November 20, 2019, the Company's registration statement on Form S-1 relating to its follow-on public offering of its common stock was declared effective by the SEC. In this offering, which closed on November 25, 2019, the Company issued and sold 2,600,000 shares of common stock at a public offering price of $96.00 per share. The aggregate net proceeds were $234.2 million after deducting underwriting discounts and commissions of $15.0 million and offering expenses of $0.4 million.

On July 2, 2020, the Company filed an automatically effective registration statement on Form S-3 (the "Registration Statement") with the SEC which registered the offering, issuance and sale of an unspecified amount of common stock, preferred stock, debt securities, warrants and/or units of any combination thereof. The Company simultaneously entered into an equity distribution agreement with Goldman Sachs & Co. LLC, as sales agent, to provide for the issuance and sale by the Company of up to $150.0 million of common stock from time to time in "at-the-market" offerings under the Registration Statement and related prospectus filed with the Registration Statement (the "ATM Program"). As of September 30, 2021, no sales had been made pursuant to the ATM Program.

On March 4, 2021, the Company completed a follow-on public offering under the Registration Statement and a related prospectus supplement in which it issued and sold 2,395,834 shares of common stock, including full exercise of the underwriters' over-allotment option to purchase an additional 312,500 shares of common stock, at a public offering price of $120 per share. The aggregate net proceeds to the Company from the offering, inclusive of proceeds from the over-allotment exercise, were $270.0 million after deducting underwriting discounts and commissions of $17.3 million and offering expenses of $0.2 million.

The Company's consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities in the ordinary course of business. The Company experienced negative operating cash flows of $93.9 million for the nine months ended September 30, 2021 and had an accumulated deficit of $259.9 million as of September 30, 2021. The Company expects to continue to generate operating losses for the foreseeable future.

The Company expects that its cash, cash equivalents and available-for-sale investments of $498.9 million as of September 30, 2021 will be sufficient to fund its operating expenses and capital expenditure requirements through at least 12 months from the date of issuance of these consolidated financial statements.

If the Company is unable to obtain funding when needed, the Company could be forced to delay, reduce or eliminate some or all of its research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect its business prospects, or the Company may be unable to continue operations. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all.

Basis of Presentation

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

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiary, Karuna Securities Corporation, a Massachusetts corporation. All inter-company transactions and balances have been eliminated in consolidation.

The accompanying consolidated balance sheet as of September 30, 2021, the consolidated statements of operations, comprehensive loss, and stockholders' equity for the three and nine months ended September 30, 2021 and 2020 and the consolidated statements of cash flows for the nine months ended September 30, 2021 and 2020 are unaudited. The unaudited interim consolidated financial statements have been prepared on the same basis as the audited annual consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company's financial position as of September 30, 2021 and the results of its operations for the three and nine months ended September 30, 2021 and 2020 and the results of its cash flows for the nine months ended September 30, 2021 and 2020. Certain information and footnote disclosures typically included in annual financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. Accordingly, these unaudited consolidated interim financial statements should be read in conjunction with the Company's consolidated financial statements as of and for the year ended December 31, 2020. The results for the three and nine months ended September 30, 2021 are not necessarily indicative of results to be expected for the year ending December 31, 2021, any other interim periods, or any future year or period.

Note 2. Summary of Significant Accounting Policies

The significant accounting policies and estimates used in preparation of the consolidated financial statements are described in the Company's audited consolidated financial statements as of and for the year ended December 31, 2020, and the notes thereto, which are included in the Company's Annual Report on Form 10-K. During the three and nine months ended September 30, 2021, there were no material changes to the Company's significant accounting policies, notwithstanding the following policies.

Impairment of Long-Lived Assets

The Company continually evaluates long-lived assets for potential impairment when events or changes in circumstances indicate the carrying value of the assets may not be recoverable. Recoverability is measured by comparing the carrying values of the assets to the expected future net undiscounted cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the book values of the assets exceed their fair value.

Leases (Lessor Accounting)

Sublease income is recognized on a straight-line basis over the term of the sublease agreement and is recorded within other income (loss) on the consolidated statements of operations.

Recently Issued Accounting Pronouncements

New pronouncements issued but not effective until after September 30, 2021 are not expected to have a material impact on the Company's consolidated financial statements.

Note 3. Prepaid Expenses and Other Assets and Accrued Expenses

Prepaid expenses and other current assets consisted of the following (in thousands):

	September 30, 2021	December 31, 2020
Prepaid research and development expenses	$ 25,839	$ 18,660
Prepaid insurance	3,598	2,116
Other	697	1,088
Total prepaid expenses and other current assets	$ 30,134	$ 21,864

The Company also had other non-current assets of $0.5 million as of September 30, 2021, which consisted of a security deposit of $0.4 million and less than $0.1 million in prepaid research and development expenses, as well as less than $0.1 million in deferred rent.

Accrued expenses consisted of the following (in thousands):

	September 30, 2021	December 31, 2020
Accrued research and development expenses	$ 6,292	$ 1,829
Accrued payroll and related expenses	4,041	2,654
Professional fees	663	458
Other	662	203
Total accrued expenses	$ 11,658	$ 5,144

Note 4. Stockholders' Equity

Preferred Stock

On July 2, 2019, in connection with the closing of the Company's IPO, the Company filed its amended and restated Certificate of Incorporation, which authorizes the Company to issue up to 10,000,000 shares of preferred stock, $0.0001 par value per share. There were no shares of preferred stock outstanding as of September 30, 2021 or December 31, 2020.

Common Stock

As of September 30, 2021, the Company's amended and restated Certificate of Incorporation authorized the Company to issue 150,000,000 shares of common stock, $0.0001 par value per share.

Holders of the common stock are entitled to one vote for each share of common stock held at all meetings of stockholders and written actions in lieu of meetings. The holders of common stock are entitled to receive dividends out of funds legally available, as declared by the board of directors. These dividends are subject to the preferential dividend rights of the holders of the Company's preferred stock. Through September 30, 2021, no cash dividends have been declared or paid.

Note 5. Net Loss per Share

The following table sets forth the computation of basic and diluted net loss per share of common stock for the three and nine months ended September 30, 2021 and 2020 (in thousands, except share and per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net Loss	$ (50,932)	$ (18,841)	$ (115,845)	$ (44,545)
Weighted-average shares used in computing net loss per share	29,572,289	26,663,968	28,953,654	26,298,969
Net loss per share, basic and diluted	$ (1.72)	$ (0.71)	$ (4.00)	$ (1.69)

The Company's potentially dilutive securities, which consist of stock options, have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same.

Common Stock Equivalents

As of September 30, 2021 and 2020, stock options outstanding to purchase common stock of 5,231,877 and 4,676,732, respectively, have been excluded from the calculation of diluted net loss per share because including them would have had an anti-dilutive impact.

Note 6. Stock-based Compensation

Stock Options

In September 2009, the Company's board of directors approved the 2009 Stock Incentive Plan (the "2009 Plan") which provided for the grant of incentive stock options to employees and non-statutory stock options to directors, consultants, and non-employees of the Company. The 2009 Plan terminated in July 2019 effective upon the completion of the Company's IPO. No additional options will be granted under the 2009 Plan. As of September 30, 2021, there were 2,496,265 options outstanding under the 2009 Plan.

In May 2019, the Company's board of directors approved the 2019 Stock Option and Incentive Plan (the "2019 Plan") which became effective on June 26, 2019, the date immediately prior to the date on which the registration statement related to the IPO was declared effective by the SEC. The 2019 Plan will expire in May 2029. Under the 2019 Plan, the Company may grant incentive stock options, non-statutory stock options, restricted stock awards, restricted stock units and other stock-based awards. There were 1,709,832 shares of the Company's common stock initially reserved for issuance under the 2019 Plan. The number of shares of common stock that may be issued under the 2019 Plan automatically increases on January 1 of each calendar year, commencing on January 1, 2020 and each January 1 thereafter, by 4% of the number of shares of common stock outstanding on the immediately preceding December 31 or such lesser amount determined by the Company's board of directors or the compensation committee of the board of directors. In addition, any shares of common stock underlying any awards from the 2009 Plan that are forfeited, cancelled, held back, reacquired, or otherwise terminated shall be added back to the shares of stock available for issuance under the 2019 Plan. As of September 30, 2021, there were 1,230,630 common shares available for issuance and 2,735,612 options outstanding under the 2019 Plan.

Options under the 2019 Plan generally vest based on the grantee's continued service with the Company during a specified period following a grant as determined by the board of directors and expire ten years from the grant date. Awards typically vest in four years, but vesting conditions can vary based on the discretion of the Company's board of directors.

A summary of the Company's stock option activity and related information is as follows:

	Number of Shares	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2020	4,612,790	$ 28.63	8.3	$ 336,740
Granted	892,925	125.93		
Exercised	(221,713)	17.18		
Forfeited	(52,125)	64.83		
Outstanding as of September 30, 2021	5,231,877	$ 45.36	7.8	$ 408,369
Options vested and expected to vest as of September 30, 2021	5,231,877	$ 45.36	7.8	$ 408,369
Options exercisable as of September 30, 2021	3,361,643	$ 18.91	7.3	$ 347,644

The aggregate intrinsic values of options outstanding, exercisable, vested and expected to vest were calculated as the difference between the exercise price of the options and the fair value of the Company's common stock as of September 30, 2021.

As of September 30, 2021, there was $85.5 million of unrecognized compensation cost, which is expected to be recognized over a weighted-average period of 2.98 years.

Stock-based Compensation Expense

Stock-based compensation expense is classified in the statements of operations for the three and nine months ended September 30, 2021 and 2020 as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
General and administrative	$ 4,996	$ 2,986	$ 13,388	$ 6,578
Research and development	3,207	1,158	8,103	2,426
Total stock-based compensation expense	$ 8,203	$ 4,144	$ 21,491	$ 9,004

Note 7. Fair Value of Financial Assets and Liabilities

The following tables present information about the Company's assets as of September 30, 2021 and December 31, 2020 that are measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values (in thousands):

	Fair Value Measurement at September 30, 2021 Using			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market fund	$ 248,208	$ —	$ —	$ 248,208
Investment securities:				
U.S. Treasuries	50,186	—	—	50,186
Corporate debt securities	—	66,771	—	66,771
Commercial paper	—	129,725	—	129,725
Total	$ 298,394	$ 196,496	$ —	$ 494,890

	Fair Value Measurement at December 31, 2020 Using			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market fund	$ 50,141	$ —	$ —	$ 50,141
Investment securities:				
U.S. Treasuries	172,295	—	—	172,295
Corporate debt securities	—	36,817	—	36,817
Commercial paper	—	60,170	—	60,170
Total	$ 222,436	$ 96,987	$ —	$ 319,423

The fair values of the Company's commercial paper and corporate debt securities are based on prices obtained from independent pricing sources. Securities with validated quotes from pricing services are reflected within Level 2, as they are primarily based on observable pricing for similar assets or other market observable inputs. Typical inputs used by these pricing services include, but are not limited to, reported trades, benchmark yields, issuer spreads, bids, offers or estimates of cash flow, prepayment spreads and default rates.

The Company does not hold any securities classified as Level 3, which are securities valued using unobservable inputs. The Company has not transferred any investment securities between the classification levels.

The estimated fair value and amortized cost of the Company's available-for-sale investments, by contractual maturity and security type, are summarized as follows (in thousands):

	September 30, 2021			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
U.S. Treasuries (due after one year and less than two years)	$ 50,211	$ —	$ (25)	$ 50,186
Corporate debt securities (due within one year)	39,912	4	(16)	39,900
Corporate debt securities (due after one year and less than two years)	26,888	4	(21)	26,871
Commercial paper (due within one year)	129,706	23	(4)	129,725
Total	$ 246,717	$ 31	$ (66)	$ 246,682

	December 31, 2020			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
U.S. Treasuries (due within one year)	$ 172,265	$ 37	$ (7)	$ 172,295
Corporate debt securities (due within one year)	36,823	3	(9)	36,817
Commercial paper (due within one year)	60,155	16	(1)	60,170
Total	$ 269,243	$ 56	$ (17)	$ 269,282

The Company has classified all of its available-for-sale investment securities, including those with maturities beyond one year, as current assets on its condensed consolidated balance sheets based on the highly liquid nature of the investment securities and because these investment securities are considered available for use in current operations.

The Company is required to determine whether a decline in the fair value below the amortized cost basis of available-for-sale securities is due to credit-related factors. At each reporting date, the Company performs an evaluation of impairment to determine if any unrealized losses are the result of credit losses. Impairment is assessed at the individual security level. Factors considered in determining whether a loss resulted from a credit loss or other factors include the Company's intent and ability to hold the investment until the recovery of its amortized cost basis, the extent to which the fair value is less than the amortized cost basis, the length of time and extent to which fair value has been less than the cost basis, the financial condition of the issuer, any historical failure of the issuer to make scheduled interest or principal payments, any changes to the rating of the security by a rating agency, any adverse legal or regulatory events affecting the issuer or issuer's industry, and any significant deterioration in economic conditions.

Unrealized losses on available-for-sale securities presented in the previous table have not been recognized in the consolidated statements of operations because the securities are high credit quality, investment grade securities that the Company does not intend to sell and will not be required to sell prior to their anticipated recovery, and the decline in fair value is attributable to factors other than credit losses. Based on its evaluation, the Company determined its year-to-date credit losses related to its available-for-sale securities were immaterial at September 30, 2021 and December 31, 2020.

Note 8. Commitments and Contingencies

Leases

The Company entered into an agreement to lease approximately 7,050 square feet of office space in Boston, Massachusetts ("Arch Street Original Premises") that began in December 2018 and had an original expiry in February 2023. In January 2020, the Company entered into an amended agreement ("Amended Arch Street Lease Agreement") to gain access to approximately 4,175 square feet of additional office space ("Arch Street Expansion Premises") beginning in March 2020, and to extend the maturity of the agreement for the Arch Street Original Premises to December 2023. The Amended Arch Street Lease Agreement provides for future minimum annual rental payments as defined within the agreement. Under the terms of the Amended Arch Street Lease Agreement, the Company is required to maintain a cash balance of approximately $0.2 million to secure a letter of credit associated with this lease. The amount was classified as restricted cash in the consolidated balance sheets as of September 30, 2021 and December 31, 2020. The Amended Arch Street Lease Agreement also provides for approximately $0.1 million in leasehold incentives which may be applied to base rent or improvements to the Arch Street Expansion Premises, subject to limitations.

The Company determined the Amended Arch Street Lease Agreement represented a lease modification, and the Arch Street Original Premises and Arch Street Expansion Premises were identified as separate lease components. The extension of maturity with respect to the Arch Street Original Premises was treated as a modification not accounted for as a separate contract, in which the lease classification was reassessed, and the lease liability was remeasured. The effect of the remeasurement, in the amount of $0.4 million, was recorded as an adjustment to the right-of-use ("ROU") lease asset as of February 1, 2020, the effective date of the modification. The addition of the Arch Street Expansion Premises was accounted for as a separate contract which granted the Company an additional right of use not included in the original lease, in which the lease payments increased commensurate with the standalone price for the additional right of use. As the leasehold incentives were not paid or payable at commencement, the Company will account for the incentives once the contingency is resolved.

In February 2020, the Company entered into an agreement to lease approximately 5,050 square feet of office space, and furniture within the office space, in Carmel, Indiana ("Indiana Lease Agreement"), which began in June 2020 and expires in July 2023, with the option to renew for an additional three-year term. In addition, the agreement provides an option to purchase the office furniture at the expiration of the agreement.

The office space and office furniture within the Indiana Lease Agreement were each determined to represent separate lease components. Consideration for the contract was allocated to each lease component based on their relative stand-alone selling price. The options to renew the lease for an additional three-year term as well as purchase the office furniture at the expiration of the agreement were excluded from the determination of lease liabilities arising from obtaining the ROU assets, as they were not considered probable of being exercised at commencement.

In March 2021, the Company entered into an agreement ("High Street Lease") to sublease from a third party approximately 25,445 square feet of office space in Boston, Massachusetts, beginning on April 1, 2021 and expiring December 31, 2025. The initial fixed rental rate is $60 per rentable square foot of the premises per annum and will increase at a rate of $1 per rentable square foot each year, with base rent first becoming due on July 1, 2021. Upon signing of the High Street Lease, the Company was also required to pay the first full monthly installment of base rent of $0.1 million and a security deposit of $0.4 million. The security deposit was recorded within other non-current assets on the consolidated balance sheet as of September 30, 2021. The first monthly installment was included as an adjustment to the ROU asset recognized upon commencement of the lease. The Company recognized an ROU asset and corresponding lease liability of approximately $6.2 million and $6.0 million, respectively, on its consolidated balance sheet as of April 1, 2021, upon commencement of the High Street Lease.

For each of the lease agreements entered into or modified, the Company identified certain non-lease components. Lease and non-lease components were combined into a single lease component. In addition, all identified leases were assessed as operating leases.

As the Company's leases do not provide an implicit rate, the Company used its incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a term equal to the lease payments in a similar economic environment, in determining the present value of lease payments for each identified lease at the lease commencement date.

Simultaneous with the High Street Lease, the Company entered into an agreement ("Arch Street Original Premises Sublease") to sublease approximately 7,050 square feet of its former Arch Street Boston headquarters to a third party from July 1, 2021 through the remainder of its current lease term, which ends on December 31, 2023. The initial fixed rental rate is $59 per rentable square foot of the premises per annum, and will increase at a rate of 2% per year, with base rent first becoming due on October 1, 2021. Upon signing of the Arch Street Original Premises Sublease, the agreement required a security deposit of $0.1 million and payment of the first full monthly installment of base rent of less than $0.1 million, which have been recorded as on offset to deferred rent within other non-current assets and other non-current liabilities, respectively, on the consolidated balance sheet as of September 30, 2021.

On April 30, 2021, the Company entered into an agreement to sublease approximately 1,751 square feet of the Arch Street Expansion Premises to another third party from June 1, 2021 through the remainder of its current lease term, which ends on December 31, 2023. The initial fixed rental rate is $61 per rentable square foot per annum and will increase at a rate of 2% per year, with base rent commencing on June 1, 2021.

The components of lease cost were as follows (dollar amounts in thousands):

	Nine Months Ended September 30,	
	2021	2020
Lease Cost		
Operating lease cost	$ 1,288	$ 564
Short-term lease cost	—	—
Sublease income	(131)	—
Total lease cost	$ 1,157	$ 564
Other Information		
Cash paid for amounts included in the measurement of lease liabilities	$ 991	$ 491
Operating lease liabilities arising from obtaining right-of-use assets	$ 6,040	$ 3,259
Weighted-average remaining lease term	3.72 years	3.19 years
Weighted-average discount rate	5.90%	6.21%

The following is a maturity analysis of the annual undiscounted cash flows of the operating lease liabilities and a reconciliation to present value of lease liabilities as of September 30, 2021 (in thousands):

Year ended:	
December 31, 2021	$ 627
December 31, 2022	2,547
December 31, 2023	2,520
December 31, 2024	1,597
December 31, 2025	1,622
Total future minimum lease payments	8,913
Less imputed interest	(894)
Present value of lease liabilities	$ 8,019

The following summarizes the annual undiscounted cash flows to be received from subleases (in thousands):

Year ended:	
December 31, 2021	$ 96
December 31, 2022	528
December 31, 2023	539
Total future sublease payments to be received	$ 1,163

Historically, all Company assets and liabilities belonged to a single corporate office asset group. The circumstances described above triggered a reassessment of asset grouping, such that the ROU assets associated with the Arch Street Original Premises and Arch Street Expansion Premises had their own separately identifiable cash flows and therefore their own separate asset grouping. Further, sublease income associated with the Arch Street office space is projected to be lower than lease payments owed by the Company for this space, and therefore impairment was indicated for this new asset group.

The carrying value of these ROU assets immediately before impairment was $2.0 million, and the fair value of these operating lease ROU assets immediately subsequent to the impairment, calculated as the present value of the estimated future cash flows attributable to the assets, was $1.3 million. The Company recognized approximately $0.7 million in impairment losses on ROU assets within other income (loss) on the statement of operations for the nine months ended September 30, 2021.

Intellectual Property License with Eli Lilly and Company

In May 2012, the Company entered into an exclusive license agreement (the "Lilly License Agreement"), with Eli Lilly and Company ("Eli Lilly"), pursuant to which Eli Lilly assigned to the Company all of its rights to certain patents (now expired), regulatory documentation, data records and materials related to xanomeline. The Company is also entitled to sublicense or otherwise transfer the rights granted in connection with the Lilly License Agreement.

Under the Lilly License Agreement, the Company is obligated to use commercially reasonable efforts to develop, manufacture, commercialize and seek and maintain regulatory approval for xanomeline, in any formulation, for use in humans.

The Company paid Eli Lilly an upfront payment of $0.1 million and has agreed to make milestone payments to Eli Lilly of up to an aggregate of $16 million upon the achievement of specified regulatory milestones and up to an aggregate of $54 million in commercial milestones. In addition, the Company is obligated to pay Eli Lilly tiered royalties, at rates in the low to mid single-digit percentages, on the worldwide net sales of any commercialized product on a country-by-country basis until the expiration of the applicable royalty term, which is the longer of six years from the date of first commercial sale of each licensed product within a country or data package exclusivity in such country. During the royalty term, Eli Lilly is prohibited from granting any third party rights to the patents, regulatory documentation, data records and materials that have been licensed to the Company under the Lilly License Agreement.

The Lilly License Agreement will expire on the later of (i) the expiration of the last-to-expire royalty term on a licensed product-by-licensed product basis or (ii) the date on which the Company has made all milestone payments pursuant to the terms of the Lilly License Agreement, unless terminated earlier by the parties. In no event will the term of the Lilly License Agreement exceed 15 years past the anniversary of the first commercial sale of a xanomeline product. The Company may terminate the Lilly License Agreement for any reason with proper prior notice to Eli Lilly. Either party may terminate the Lilly License Agreement upon an uncured material breach by the other party.

The initial upfront payment of $0.1 million was expensed when incurred in May 2012. As of September 30, 2021, no milestones have been reached and, accordingly, no milestone payments have been made.

Intellectual Property License with PureTech Health

In March 2011, the Company entered into an exclusive license agreement (the "Patent License Agreement") with PureTech Health, pursuant to which PureTech Health granted the Company an exclusive license to patent rights relating to combinations of a muscarinic activator with a muscarinic inhibitor for the treatment of central nervous system disorders.

In connection with the Patent License Agreement, the Company has agreed to make milestone payments to PureTech Health of up to an aggregate of $10 million upon the achievement of specified development and regulatory milestones. In addition, the Company is obligated to pay PureTech Health low single-digit royalties on the worldwide net sales of any commercialized product covered by the licenses granted under the Patent License Agreement. In the event that the Company sublicenses any of the patent rights granted under the Patent License Agreement, the Company will be obligated to pay PureTech Health royalties within the range of 15% to 25% on any income the Company receives from the sublicensee, excluding royalties.

The Company may terminate the Patent License Agreement for any reason with proper prior notice to PureTech Health. Either party may terminate the Patent License Agreement upon an uncured material breach by the other party.

The Company incurred no expenses related to the Patent License Agreement provided by PureTech Health during the nine months ended September 30, 2021 and 2020. In December 2020, the Company paid $2.0 million to PureTech Health, having reached the milestone of Phase 3 clinical trial commencement. The Company had no outstanding liabilities to PureTech Health related to the Patent License Agreement as of September 30, 2021 and December 31, 2020.

Indemnification

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnification obligations. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future but have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may incur charges in the future as a result of these indemnification obligations.

Contingencies

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of its business activities. The Company accrues a liability for such matters when it is probable that future expenditures will be made, and such expenditures can be reasonably estimated.

Litigation

The Company is not a party to any litigation and does not have contingency reserves established for any litigation liabilities as of September 30, 2021.

Note 9. 401(k) Savings Plan

The Company has a 401(k) retirement plan in which substantially all U.S. employees are eligible to participate. Eligible employees may elect to contribute up to the maximum limits, as set by the Internal Revenue Service, of their eligible compensation. The total contribution expense for the Company was $0.4 million and $0.2 million for the nine months ended September 30, 2021 and 2020, respectively.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our audited consolidated financial statements and related notes for the year ended December 31, 2020 included in our Annual Report on Form 10-K, or the Annual Report, filed with the Securities and Exchange Commission, or the SEC, on February 25, 2021. This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements are often identified by the use of words such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "project," "will," "would" or the negative or plural of these words or similar expressions or variations. Such forward-looking statements are subject to a number of risks, uncertainties, assumptions and other factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified and discussed in the section titled "Risk Factors," set forth in Part II, Item 1A of this Quarterly Report on form 10Q, Part I, Item 1A of our Annual Report, and in subsequent SEC filings. You should not rely upon forward-looking statements as predictions of future events. Furthermore, such forward-looking statements speak only as of the date of this report. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

Overview

We are a clinical-stage biopharmaceutical company driven to create and deliver transformative medicines for people living with psychiatric and neurological conditions. Our pipeline is built on the broad therapeutic potential of our lead product candidate, KarXT, an oral modulator of muscarinic receptors that are located both in the central nervous system, or CNS, and various peripheral tissues. KarXT is our proprietary product candidate that combines xanomeline, a novel muscarinic agonist, with trospium, an approved muscarinic antagonist, to preferentially stimulate muscarinic receptors in the CNS.

We are initially developing our lead product candidate, KarXT, for the treatment of acute psychosis in patients with schizophrenia. KarXT combines xanomeline, a muscarinic receptor agonist that preferentially stimulates M1 and M4 muscarinic receptors, and trospium, an approved muscarinic receptor antagonist that does not measurably cross the blood-brain barrier, confining its effects to peripheral tissues. M1 and M4 muscarinic receptors are the receptor subtypes believed to mediate the antipsychotic and procognitive effects of xanomeline and other muscarinic agonists.

In November 2019, we announced positive results from the first trial in our EMERGENT program, the clinical program evaluating KarXT for the treatment of schizophrenia. In this Phase 2 trial, EMERGENT-1, we evaluated KarXT for the treatment of acute psychosis in adults with schizophrenia. KarXT met the trial's primary endpoint with a statistically significant ($p<0.0001$) and clinically meaningful 11.6 point mean reduction in total Positive and Negative Syndrome Scale, or PANSS, scores over placebo at week 5 (-17.4 KarXT vs. -5.9 placebo). Following the positive results of EMERGENT-1, we had an End-of-Phase 2 meeting with the U.S. Food and Drug Administration, or FDA, in which the FDA confirmed that our completed EMERGENT-1 trial, along with one successful Phase 3 efficacy and safety trial, and additional safety data to meet regulatory requirements, would be acceptable to support a New Drug Application, or NDA, filing.

In addition to our completed positive Phase 2 EMERGENT-1 trial, our EMERGENT program includes two Phase 3 trials evaluating the efficacy and safety of KarXT compared to placebo (EMERGENT-2 & EMERGENT-3, which are similar in design to EMERGENT-1), and two Phase 3 trials evaluating the long-term safety of KarXT (EMERGENT-4 & EMERGENT-5). All Phase 3 trials within our EMERGENT program are currently enrolling, with details as follows:

- EMERGENT-2: A five-week inpatient trial evaluating the efficacy and safety of KarXT compared to placebo in 246 adults with schizophrenia in the U.S. Enrollment for this trial began in December 2020 and we anticipate reporting topline data in mid-2022.
- EMERGENT-3: A five-week inpatient trial evaluating the efficacy and safety of KarXT compared to placebo in 246 adults with schizophrenia in the U.S. and Ukraine. Enrollment for this trial began in the second quarter of 2021 and we anticipate reporting topline data in the second half of 2022.
- EMERGENT-4: A 52-week outpatient, open-label extension trial evaluating the long-term safety and tolerability of KarXT in 350 adults with schizophrenia who completed EMERGENT-2 or EMERGENT-3. Enrollment for this trial began in the first quarter of 2021.
- EMERGENT-5: A 52-week outpatient, open-label trial evaluating the long-term safety and tolerability of KarXT in 400 adults with schizophrenia in the U.S. in patients who were not enrolled in EMERGENT-2 or EMERGENT-3. Enrollment for this trial began in the second quarter of 2021.

We are on track to initiate our initial Phase 3 ARISE trial evaluating the safety and efficacy of KarXT compared to placebo as an adjunctive treatment in adults with schizophrenia who have an inadequate response to their current antipsychotic therapy in the fourth quarter of 2021. This six-week, 1:1 randomized, double-blind, placebo-controlled Phase 3 trial will enroll approximately 400 adults with schizophrenia who have not achieved an adequate response to their current atypical antipsychotic treatment. Participants in this trial will continue their currently prescribed atypical antipsychotic therapy at the same dose or regimen schedule as prior to entry in the study, and will receive a flexible dose of KarXT or placebo based on tolerability and clinical response as determined by a clinician. The primary outcome measure of the trial is change in Positive and Negative Syndrome Scale (PANSS) total score of KarXT compared to placebo at week 6. Upon completion of the trial at week 6, participants will have the opportunity to enroll in a 52-week outpatient, open-label Phase 3 extension trial evaluating the long-term safety and tolerability of KarXT when dosed with atypical antipsychotic treatment.

In June 2021 we announced results from our multi-cohort, placebo-controlled Phase 1b trial evaluating the safety and tolerability of KarXT in healthy elderly volunteers. Results from the trial suggest that potentially therapeutic doses of KarXT can be administered to elderly adults while maintaining a favorable tolerability profile, and support the advancement of KarXT into a Phase 3 program. Our evaluation of KarXT for the treatment of dementia-related psychosis will initially focus on psychosis in Alzheimer’s disease, the most prevalent subtype of dementia-related psychosis. Dementia affects an estimated 8.4 million people in the United States, with Alzheimer's disease accounting for 60% to 80% of all cases. Up to 50% of Alzheimer's disease patients exhibit psychiatric symptoms. Our initial focus on the Alzheimer’s disease dementia subtype reflects various strategic development, regulatory and commercial considerations, and we remain interested in exploring KarXT in other dementia subtypes in future development programs. Details of our Phase 3 Alzheimer’s disease psychosis program will be available in the first half of 2022 prior to the program’s initiation in mid-2022.

Since our inception in 2009, we have focused substantially all of our efforts and financial resources on organizing and staffing our company, acquiring and developing our technology, raising capital, building our intellectual property portfolio, undertaking preclinical studies and clinical trials and providing general and administrative support for these activities.

On July 2, 2019, we issued and sold 6,414,842 shares of our common stock, including full exercise of the underwriters’ over-allotment option to purchase an additional 836,718 shares, at a public offering price of $16.00 per share, in our initial public offering, or IPO. The aggregate net proceeds to us from the IPO were $93.0 million.

On November 25, 2019, we issued and sold 2,600,000 shares of our common stock at a public offering price of $96.00 per share in a follow-on offering in which we received net proceeds of $234.2 million. Prior to the IPO and follow-on public offering, we funded our operations primarily with proceeds from the sales of redeemable convertible preferred stock and the issuance of convertible notes.

On July 2, 2020, we filed an automatically effective registration statement on Form S-3, or the Registration Statement, with the SEC which registered the offering, issuance and sale of an unspecified amount of common stock, preferred stock, debt securities, warrants and/or units of any combination thereof. We simultaneously entered into an equity distribution agreement with Goldman Sachs & Co. LLC, as sales agent, to provide for the issuance and sale by the Company of up to $150.0 million of common stock from time to time in "at-the-market" offerings under the Registration Statement and related prospectus filed with the Registration Statement, or the ATM Program. As of September 30, 2021, no sales had been made pursuant to the ATM Program.

On March 4, 2021, we issued and sold 2,395,834 shares of our common stock, including full exercise of the underwriters' over-allotment option to purchase an additional 312,500 shares, at a public offering price of $120 per share under the Registration Statement and a related prospectus supplement. The aggregate net proceeds from the offering were $270.0 million.

We have never generated revenue and have incurred significant net losses since inception. Our net losses were $115.9 million and $44.6 million for the nine months ended September 30, 2021 and 2020, respectively. As of September 30, 2021, we had an accumulated deficit of $259.9 million. Our net losses may fluctuate significantly from quarter to quarter and year to year. We expect to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our operating expenses and capital expenditures will increase substantially, particularly as we:

- invest significantly to further develop KarXT for our current and future indications;
- advance additional product candidates into preclinical and clinical development;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- require the manufacture of larger quantities of our product candidates for clinical development and potential commercialization;
- hire additional clinical, scientific, management and administrative personnel;
- maintain, expand and protect our intellectual property portfolio;
- acquire or in-license other assets and technologies; and
- add additional operational, financial and management information systems and processes to support our ongoing development efforts, any future manufacturing or commercialization efforts and our ongoing operations as a public company.

We do not expect to generate revenue from product sales unless and until we successfully complete development and obtain regulatory approval for a product candidate, which we expect will take a number of years, if ever, and the outcome of which is subject to significant uncertainty. Additionally, we currently use third parties such as contract research organizations, or CROs, and contract manufacturing organizations, or CMOs, to carry out our preclinical and clinical development activities, and we do not yet have a sales organization. If we obtain regulatory approval for any product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of private and public equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution, or licensing arrangements with third parties. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our product candidates.

As of September 30, 2021, we had cash, cash equivalents and available-for-sale investments of $498.9 million. We believe that our existing cash, cash equivalents and available-for-sale investments will be sufficient to meet our anticipated operating and capital expenditure requirements for at least twelve months following the potential submission of a new drug application, or NDA, with the U.S. Food and Drug Administration for KarXT for the treatment of acute psychosis in patients with schizophrenia. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See "Liquidity and Capital Resources."

Components of Our Results of Operations

Revenue

To date, we have not generated any revenue and may not generate any revenue in the foreseeable future, if at all. If our development efforts for our product candidates are successful and result in regulatory approval, we may generate revenue in the future from product sales. If we enter into license or collaboration agreements for any of our product candidates or intellectual property, we may generate revenue in the future from payments as a result of such license or collaboration agreements. We cannot predict if, when, or to what extent we will generate revenue from the commercialization and sale of our product candidates. We may never succeed in obtaining regulatory approval for any of our product candidates.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for the development of our product candidates and our drug discovery efforts, which include:

- personnel costs, including salaries and the related costs, and stock-based compensation expense for employees engaged in research and development functions;
- expenses incurred in connection with the preclinical and clinical development of our product candidates, including under agreements with CROs;
- expenses incurred in connection with CMOs that manufacture drug products for use in our preclinical and clinical trials;
- formulation costs and chemistry, manufacturing and controls, or CMC, costs; and
- expenses incurred under agreements with consultants who supplement our internal capabilities.

We expense all research and development costs in the periods in which they are incurred. Costs for certain development activities are recognized based on an evaluation of the progress to completion of specific tasks using information and data provided to us by our vendors and third-party service providers.

Most research and development costs, such as fees paid to consultants, central laboratories, contractors, CMOs and CROs in connection with our clinical development activities, are tracked on an indication-by-indication basis. Formulation and CMC, preclinical, and discovery expenses consist of costs associated with activities to support our current and future clinical programs, but are not allocated on an indication-by-indication basis due to the overlap of the potential benefit of those efforts across multiple indications that utilize KarXT and future product and development candidates. We similarly do not track certain research and development expenses on an indication-by-indication basis as they primarily relate to personnel or other consulting costs which are deployed across multiple projects under development. These costs are included in unallocated research and development expenses in the table below. The following table summarizes our research and development expenses:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	(in thousands)		(in thousands)	
Schizophrenia clinical trials	$ 21,520	$ 4,020	$ 39,220	$ 6,716
Dementia-related psychosis clinical trials	198	537	1,596	1,020
Pain clinical trial	(34)	465	143	1,255
Formulation and CMC	3,883	2,133	9,460	5,610
Preclinical	993	289	1,736	820
Discovery	3,538	1,608	9,680	3,529
Unallocated expenses	8,677	3,533	21,273	8,874
Total research and development expense	$ 38,775	$ 12,585	$ 83,108	$ 27,824

We expect our research and development expenses to increase substantially for the foreseeable future as we continue to invest in research and development activities related to developing our product candidates, including investments in manufacturing, as our programs advance into later stages of development and we continue to conduct clinical trials. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain.

Because of the numerous risks and uncertainties associated with conducting product development, we cannot determine with certainty the duration and completion costs of our current or future preclinical studies and clinical trials or if, when, or to what extent we will generate revenues from the commercialization and sale of our product candidates. We may never succeed in achieving regulatory approval for our product candidates. The duration, costs and timing of preclinical studies and clinical trials and development of our product candidates will depend on a variety of factors, if and as we:

- continue to develop and conduct clinical trials for KarXT for our current and future indications;
- initiate and continue research, preclinical and clinical development efforts for future product candidates;
- seek to identify additional product candidates;
- seek regulatory approvals for KarXT for our current and future indications as well as any other product candidates that successfully complete clinical development;
- add operational, financial and management information systems and personnel, including personnel to support our product development;
- hire and retain additional personnel, such as clinical, quality control, scientific, commercial and administrative personnel;
- maintain, expand and protect our intellectual property portfolio;
- establish sales, marketing, distribution, manufacturing, supply chain and other commercial infrastructure in the future to commercialize various products for which we may obtain regulatory approval, if any;
- continue to assess the impact of the ongoing and evolving COVID-19 pandemic on the ability to execute research and development activities;
- add equipment and physical infrastructure to support our research and development; and
- acquire or in-license other product candidates and technologies.

A change in the outcome of any of these variables with respect to the development of any of our product candidates would significantly change the costs and timing associated with the development of that product candidate. We may never succeed in obtaining regulatory approval for any of our product candidates.

We do not believe that it is possible at this time to accurately project total indication-specific 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 consist primarily of employee-related costs for personnel in executive, finance, commercial, and administrative functions, costs related to maintenance and filing of intellectual property, facility-related costs, insurance costs, and other expenses for outside professional services, including legal, human resources, data management, audit and accounting services, and costs incurred as we prepare for commercialization. Personnel costs consist of salaries, benefits, travel expense and stock-based compensation expense.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research activities and development of our product candidates, and if and as we commercialize. We will also continue to incur increased accounting, audit, legal, regulatory, compliance and director and officer insurance costs as well as investor and public relations expenses associated with operating as a public company.

Other Income (Loss), Net

Other income (loss), net, consists of interest income from our cash equivalents and available-for-sale investments and sublease income recognized in connection with the sublease of office space, offset by impairment loss on our right-of-use lease assets at our Arch Street facility, due to their carrying value exceeding their estimated fair value.

Results of Operations

Comparison of the three months ended September 30, 2021 and 2020

	Three Months Ended September 30,		
	2021	2020	Change
		(in thousands)	
Revenue	$ —	$ —	$ —
Operating expenses:			
Research and development	38,775	12,585	26,190
General and administrative	12,393	6,944	5,449
Total operating expenses	51,168	19,529	31,639
Loss from operations	(51,168)	(19,529)	(31,639)
Total other income, net	236	688	(452)
Net loss attributable to common stockholders	$ (50,932)	$ (18,841)	$ (32,091)

Research and Development Expenses

	Three Months Ended September 30,		
	2021	2020	Change
		(in thousands)	
Direct research and development expenses:			
Schizophrenia clinical trials	$ 21,520	$ 4,020	$ 17,500
Dementia-related psychosis clinical trials	198	537	(339)
Pain clinical trial	(34)	465	(499)
Formulation and CMC	3,883	2,133	1,750
Preclinical	993	289	704
Discovery	3,538	1,608	1,930
Unallocated expenses:			
Personnel related expenses (including stock-based compensation)	8,175	3,130	5,045
Consultant fees and other expenses	502	403	99
Total research and development expense	$ 38,775	$ 12,585	$ 26,190

Expenses related to our schizophrenia clinical trials increased by $17.5 million in the three months ended September 30, 2021 as compared to the three months ended September 30, 2020 due to expenses related to ongoing enrollment activities for our EMERGENT Phase 3 trials as well as start-up activities related to our ARISE Phase 3 trials. The decrease of $0.3 million related to our dementia-related psychosis, or DRP, clinical trial is primarily due to unrepeated costs for enrollment and dosing activities for the Phase 1b trials incurred in the three months ended September 30, 2020, compared to close out costs incurred in the three months ended September 30, 2021. The decrease of $0.5 million in expenses related to our pain clinical trial is primarily due to unrepeated costs for enrollment and dosing activities for the Phase 1b trial incurred in the three months ended September 30, 2020, compared to a credit amount of less than $0.1 million due to the final reconciliation and overpayment compared to actual costs in the three months ended September 30, 2021. Formulation and CMC expenses increased by $1.8 million due to the timing of manufacturing activities necessary in the current period to support ongoing and future clinical trial activities as well as activities to support a potential future NDA filing. Preclinical expenses increased by $0.7 million due to the initiation of new studies in the three months ended September 30, 2021. The increase of $1.9 million in discovery costs is due to an increase in ongoing discovery efforts, including ongoing collaborations with Charles River Labs and Psychogenics, Inc. The increase of $5.1 million in personnel related costs was primarily a result of an increase in headcount and an increase of $2.0 million related to stock-based compensation expense. The increase of $0.1 million in consultant fees and other expenses was due to timing of consulting costs not specifically allocated to discovery, preclinical, clinical, formulation and CMC activities.

General and Administrative Expenses

	Three Months Ended September 30,		Change
	2021	2020	
		(in thousands)	
Personnel related expenses (including stock-based compensation)	$ 7,067	$ 4,380	$ 2,687
Professional and consultant fees	2,971	945	2,026
Other	2,355	1,619	736
Total general and administrative expense	$ 12,393	$ 6,944	$ 5,449

The increase of $2.7 million in personnel related costs in the three months ended September 30, 2021 as compared to the three months ended September 30, 2020 was primarily a result of an increase in headcount and an increase of $2.0 million related to stock-based compensation expense. The increase of $2.0 million in professional and consultant fees was primarily due to an increase in recruiting fees, accounting fees, pre-commercial costs, legal costs and consulting fees related to our ongoing business activities. The increase of $0.7 million in other costs was primarily due to additional lease costs for our High Street lease in Boston, Massachusetts as well as other infrastructure and administrative related costs to support increased headcount.

Other Income, Net

	Three Months Ended September 30,		Change
	2021	2020	
		(in thousands)	
Interest income	$ 114	$ 688	$ (574)
Sublease income	122	—	122
Total other income, net	$ 236	$ 688	$ (452)

Interest income is attributable to interest earned on our cash equivalents and available-for-sale investments. The decrease of $0.6 million in interest income is primarily due to lower market interest rates.

Sublease income is due to the sublease of a portion of our Arch Street office space in Boston, Massachusetts during the three months ended September 30, 2021.

Comparison of the nine months ended September 30, 2021 and 2020

	Nine Months Ended September 30,		Change
	2021	2020	
		(in thousands)	
Revenue	$ —	$ —	$ —
Operating expenses:			
Research and development	83,108	27,824	55,284
General and administrative	32,554	19,585	12,969
Total operating expenses	115,662	47,409	68,253
Loss from operations	(115,662)	(47,409)	(68,253)
Total other income (loss), net	(183)	2,864	(3,047)
Net loss attributable to common stockholders	$ (115,845)	$ (44,545)	$ (71,300)

Research and Development Expenses

	Nine Months Ended September 30,		Change
	2021	2020	
		(in thousands)	
Direct research and development expenses:			
Schizophrenia clinical trials	$ 39,220	$ 6,716	$ 32,504
Dementia-related psychosis clinical trials	1,596	1,020	576
Pain clinical trial	143	1,255	(1,112)
Formulation and CMC	9,460	5,610	3,850
Preclinical	1,736	820	916
Discovery	9,680	3,529	6,151
Unallocated expenses:			
Personnel related expenses (including stock-based compensation)	19,800	7,038	12,762
Consultant fees and other expenses	1,473	1,836	(363)
Total research and development expense	$ 83,108	$ 27,824	$ 55,284

Expenses related to our schizophrenia clinical trials increased by $32.5 million in the nine months ended September 30, 2021, as compared to the nine months ended September 30, 2020, due to expenses related to start-up and ongoing enrollment activities for our EMERGENT and ARISE Phase 3 trials. The increase of $0.6 million in expenses related to our DRP clinical trial during the nine months ended September 30, 2021 is primarily driven by enrollment and dosing activities related to our completed Phase 1b clinical trial in healthy elderly volunteers. The decrease of $1.1 million in expenses related to our pain clinical trial is primarily due to unrepeated costs for enrollment and dosing activities incurred in the nine months ended September 30, 2020 for our Phase 1b trial compared to close out costs for that trial incurred in the nine months ended September 30, 2021. Formulation and CMC expenses increased by $3.9 million due to an increase in manufacturing activities in 2021 to obtain sufficient supply to support current and future clinical trial activities as well as activities to support a potential future NDA filing. Preclinical expenses increased by $0.9 million due to the initiation of new studies in late 2020 and into 2021. The increase of $6.2 million in discovery costs is due to an increase in ongoing discovery efforts, including ongoing collaborations with Charles River Labs and Psychogenics, Inc. The increase of $12.8 million in personnel related costs was primarily a result of an increase in headcount and an increase of $5.7 million related to in stock-based compensation expense. The decrease of $0.4 million in consultant fees and other expenses was due to timing of consulting costs not specifically allocated to discovery, preclinical, clinical, formulation and CMC activities.

General and Administrative Expenses

	Nine Months Ended September 30,		Change
	2021	2020	
		(in thousands)	
Personnel related expenses (including stock-based compensation)	$ 19,658	$ 11,619	$ 8,039
Professional and consultant fees	6,676	3,053	3,623
Other	6,220	4,913	1,307
Total general and administrative expense	$ 32,554	$ 19,585	$ 12,969

The increase of $8.0 million in personnel related costs in the nine months ended September 30, 2021 as compared to the nine months ended September 30, 2020 was primarily a result of an increase in headcount and an increase of $6.8 million related to stock-based compensation expense. The increase of $3.6 million in professional and consultant fees was primarily due to an increase in recruiting fees, accounting fees, pre-commercial costs, legal costs and consulting fees related to our ongoing business activities. The increase of $1.3 million in other costs was primarily due to increased lease costs for our Arch Street lease and High Street Lease in Boston, Massachusetts as well as other infrastructure and administrative related costs to support increased headcount.

Other Income (Loss), Net

	Nine Months Ended September 30,		Change
	2021	2020	
		(in thousands)	
Impairment loss on right-of-use assets	$ (677)	$ —	$ (677)
Interest income	363	2,864	(2,501)
Sublease income	131	—	131
Total other income (loss), net	$ (183)	$ 2,864	$ (3,047)

Impairment loss on right-of-use assets for the nine months ended September 30, 2021 represents impairment recognized on our right-of-use lease assets to the extent their carrying value exceeded their estimated fair value for our Arch Street facility leases in Boston, Massachusetts. See Note 8 to our consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

Interest income is attributable to interest earned on our cash equivalents and available-for-sale investments. The decrease of $2.5 million in interest income is primarily due to lower market interest rates.

Sublease income is due to the sublease of a portion of our Arch Street office space in Boston, Massachusetts during 2021.

Liquidity and Capital Resources

Since our inception, we have incurred significant operating losses. We have not yet commercialized any of our product candidates and we do not expect to generate revenue from sales of any product candidates for several years, if at all. To date, we have funded our operations primarily with proceeds from the sale of redeemable convertible preferred stock, issuance of convertible notes, and sales of our common stock. Through September 30, 2021, our operations have been financed by net proceeds of $25.7 million from the issuance of convertible notes, $91.0 million from the sale of shares of our redeemable convertible preferred stock, $93.0 million from the sale of our common stock in our IPO, $234.2 million from the sale of our common stock in a follow-on public offering in November 2019, and $270.0 million from the sale of our common stock in a follow-on public offering in March 2021. As of September 30, 2021, we had $498.9 million in cash, cash equivalents and available-for-sale investments, and an accumulated deficit of $259.9 million.

On July 2, 2020, we filed the Registration Statement with the SEC and simultaneously entered into an equity distribution agreement with Goldman Sachs & Co. LLC, as sales agent, for the ATM Program. As of September 30, 2021, no sales had been made pursuant to the ATM Program.

Our primary use of cash has been to fund operating expenses, which consist of research and development and general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding prepaid expenses, accounts payable and accrued expenses.

Cash Flows

The following table summarizes our sources and uses of cash for each of the periods presented:

	Nine Months Ended September 30,	
	2021	2020
	(in thousands)	
Net cash used in operating activities	$ (93,880)	$ (46,911)
Net cash provided by (used in) investing activities	19,332	(119,311)
Net cash provided by financing activities	273,825	2,114
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 199,277	$ (164,108)

Cash Flows from Operating Activities

Cash used in operating activities for the nine months ended September 30, 2021 was $93.9 million, consisting of a net loss of $115.9 million, partially offset by non-cash items, including stock-based compensation expense of $21.5 million, accretion of discounts, partially offset by amortization of premiums, on our available-for-sale investments of $0.7 million, and impairment loss on right-of-use assets of $0.7 million. The change in our net operating assets and liabilities was mainly due to an increase in prepaid expenses and other current assets of $8.4 million, primarily driven by upfront payments made to CROs and CMOs in connection with our clinical trials, offset by an increase in accounts payable and accrued expenses of $7.1 million, driven by the timing of payments to our vendors.

Cash used in operating activities for the nine months ended September 30, 2020 was $46.9 million, consisting of a net loss of $44.6 million, partially offset by non-cash items, including stock-based compensation expense of $9.0 million. The change in our net operating assets and liabilities was mainly due to an increase in prepaid expenses and other current assets of $12.6 million, which was primarily driven by upfront payments made to CROs and CMOs in connection with our clinical trials.

Cash Flows from Investing Activities

Cash provided by investing activities for the nine months ended September 30, 2021 was $19.3 million, primarily attributable to maturities and sales of investment securities of $302.1 million and $9.0 million, respectively, which were partially offset by purchases of investment securities of $289.5 million.

Cash used in investing activities for the nine months ended September 30, 2020 was $119.3 million, primarily attributable to the purchases of investment securities of $264.0 million, which was partially offset by maturities of investment securities of $145.0 million.

Cash Flows from Financing Activities

Cash provided by financing activities for the nine months ended September 30, 2021 was $273.8 million, which was primarily attributable to $270.0 million in net proceeds received from the sale of our common stock in our follow-on public offering and $3.8 million attributable to proceeds received from the exercise of stock options.

Cash provided by financing activities for the nine months ended September 30, 2020 was $2.1 million, attributable to proceeds from the exercise of stock options.

Future Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing activities, in particular as we continue to advance our product candidates through clinical trials and prepare for the potential commercialization of KarXT, if approved by the FDA. In addition, we expect to incur additional costs associated with operating as a public company.

As of September 30, 2021, we had cash and cash equivalents and available-for-sale investments of $498.9 million. Based on our current plans, we believe that our existing cash, cash equivalents and available-for-sale investments will be sufficient to meet our anticipated operating and capital expenditure requirements for at least twelve months following the potential submission of an NDA for KarXT for the treatment of acute psychosis in patients with schizophrenia.

We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical product candidates, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on and could increase significantly as a result of many factors, including:

- the scope, progress, results and costs of researching and developing KarXT for our current and future indications as well as other product candidates we may develop;
- the timing of, and the costs involved in, obtaining marketing approvals for KarXT for our current and future indications as well as future product candidates we may develop and pursue;
- the number of future indications and product candidates that we pursue and their development requirements;
- if approved, the costs of commercialization activities for KarXT for the approved indication, or any other product candidate that receives regulatory approval to the extent such costs are not the responsibility of any future collaborators, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;
- subject to receipt of regulatory approval, revenue, if any, received from commercial sales of KarXT for any indication or revenue received from any future product candidates;
- the extent to which we in-license or acquire rights to other products, product candidates or technologies;
- our headcount growth and associated costs as we expand our research and development and establish a commercial infrastructure;
- the costs of preparing, filing and prosecuting patent applications, and maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property related claims; and
- the ongoing costs of operating as a public company.

A change in the outcome of any of these or other variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. Further, our operating plans may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such operating plans.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity financings, debt financings, collaborations with other companies or other strategic transactions. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect their rights as common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution 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 grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, 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.

Further, our operating plans may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials and other research and development activities. We currently have no credit facility or committed sources of capital. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated product development programs.

Contractual Obligations and Other Commitments

In January 2020, we amended our current lease for 7,050 square feet of office space in Boston, Massachusetts, or the Arch Street Original Premises, to acquire approximately 4,175 in additional square feet, or the Arch Street Expansion Premises, and to extend the original lease term through December 2023. Remaining lease payments from July 1, 2021 through the end of the lease term total $1.9 million for both the Arch Street Original Premises and the Arch Street Expansion Premises, of which we took possession of 2,424 square feet and 1,751 square feet in March 2020 and August 2020, respectively.

In February 2020, we entered into an agreement to lease approximately 5,050 square feet of office space in Carmel, Indiana. The term of the lease commenced in June 2020 and expires in July 2023. Remaining lease payments total approximately $0.3 million through the end of the lease term.

In March 2021, we entered into an agreement to sublease approximately 25,445 square feet of office space from a third party in Boston, Massachusetts as part of the relocation of our corporate headquarters. The term of the sublease extends from April 1, 2021 through December 31, 2025 and provides for escalating annualized base rent payments starting at approximately $1.5 million and increasing to $1.6 million in the final year of the sublease. Remaining lease payments from October 1, 2021 through the end of the lease term total $6.7 million.

Simultaneously, in March 2021, we entered into an agreement to sublease the Arch Street Original Premises to a third party. The term of the sublease extends from July 1, 2021 through December 31, 2023.

In April 2021, we entered into an agreement to sublease approximately 1,751 square feet of the Arch Street Expansion Premises to another third party from June 1, 2021 through December 31, 2023.

During the nine months ended September 30, 2021, there were no other material changes to our contractual obligations and commitments described in our Annual Report, as filed with the SEC.

Critical Accounting Polices and Estimates

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States. The preparation of our consolidated financial statements and related disclosures requires us to make estimates, assumptions and judgments that affect the reported amount of assets, liabilities, revenue, costs and expenses, and related disclosures. We believe that of our critical accounting policies described under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Estimates” in our Annual Report, the following involves the most judgment and complexity:

- Research and development contract costs and accruals

Accordingly, we believe the policies set forth above are critical to fully understand and evaluate our financial condition and results of operations. If actual results or events differ materially from the estimates, judgments and assumptions used by us in applying these policies, our reported financial condition and results of operations could be materially affected.

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 in the rules and regulations of the SEC.

JOBS Act Accounting Election

As of June 30, 2020, the market value of our common stock held by non-affiliates exceeded $700 million, and as a result, as of January 1, 2021, we qualified as a “large accelerated filer” and no longer qualified as an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As a large accelerated filer, we are subject to certain disclosure requirements that are applicable to other public companies that were not applicable to us as an emerging growth company, including compliance with the auditor attestation requirements in the assessment of our internal control over financial reporting imposed by the Sarbanes-Oxley Act of 2002, compliance with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements and full disclosure obligations regarding executive compensation. Additionally, we are no longer able to take advantage of transition periods for complying with new or revised accounting standards that are available to emerging growth companies.

Recently Issued or Adopted Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to changes in interest rates. We had cash, cash equivalents and available-for-sale investment securities of $498.9 million as of September 30, 2021, which consisted primarily of money market funds and investment securities, largely composed of U.S. Treasuries and investment grade, short to intermediate term fixed income securities.

The primary objective of our investment activities is to preserve capital to fund our operations. We also seek to maximize income from our investments without assuming significant risk. To achieve our objectives, we maintain a portfolio of investments in a variety of securities of high credit quality and short-term duration, according to our board-approved investment policy. Our investments are subject to interest rate risk and could fall in value if market interest rates increase. A hypothetical 10% relative change in interest rates during any of the periods presented would not have had a material impact on our condensed consolidated financial statements.

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 vendors that are located outside of the United States. As a result, our operations may be subject to fluctuations in foreign currency exchange rates in the future.

Inflation generally affects us by increasing our cost of labor. We do not believe that inflation had a material effect on our business, financial condition, or results of operations during the three and nine months ended September 30, 2021 and 2020.

Item 4. Limitations on Effectiveness of Controls and Procedures.

The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, refers to controls and procedures 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 the company’s management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act of 1934). Based on that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2021.

Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) has occurred during the three and nine months ended September 30, 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We are not currently subject to any material legal proceedings.

Item 1A. Risk Factors.

In addition to the risks described in our Annual Report, you should carefully consider the other information set forth in this Form 10-Q and the information in our other filings with the SEC, as they could materially affect our business, financial condition or future results of operations. There have been no material changes to the risk factors previously disclosed in Part I, Item 1A (Risk Factors) of our Annual Report.

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.

None.

Item 6. Exhibits.

The exhibits listed on the Exhibit Index immediately preceding such exhibits, which is incorporated herein by reference, are filed or furnished as part of this Quarterly Report on Form 10-Q.

Exhibit Number	Description
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 and 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 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)

+ The certification furnished in Exhibit 32.1 hereto is deemed to accompany this Quarterly Report on Form 10-Q and will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference. Such certification will not be deemed to be incorporated by reference into any filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, except to the extent that the Registrant specifically incorporates it by reference.

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.

KARUNA THERAPEUTICS, INC.

Date: November 4, 2021

By: /s/ Steven Paul, M.D.

Steven Paul, M.D.
Chief Executive Officer, President and Chairman (Principal Executive Officer)

Date: November 4, 2021

By: /s/ Troy Ignelzi

Troy Ignelzi
Chief Financial Officer (Principal Financial and Accounting Officer)

Exhibit 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 SARBANES-OXLEY ACT OF 2002

I, Steven Paul, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Karuna Therapeutics, 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

d) 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.

Dated: November 4, 2021

/s/ Steven Paul, M.D.

Steven Paul, M.D.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 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 SARBANES-OXLEY ACT OF 2002

I, Troy Ignelzi, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Karuna Therapeutics, 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

d) 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.

Dated: November 4, 2021

/s/ Troy Ignelzi

Troy Ignelzi
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER 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 on Form 10-Q of Karuna Therapeutics, Inc. (the "Company") for the quarterly period ended September 30, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Steven Paul and Troy Ignelzi, Chief Executive Officer of the Company and Chief Financial Officer of the Company, respectively, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to their knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 4, 2021

/s/ Steven Paul, M.D.

Steven Paul, M.D.
Chief Executive Officer
(Principal Executive Officer)

Dated: November 4, 2021

/s/ Troy Ignelzi

Troy Ignelzi
Chief Financial Officer
(Principal Financial Officer)