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 June 30, 2020

OR

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

For the transition period from _____ to _____

Commission File Number: 001-38958

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.)**
33 Arch Street, Suite 3110 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 July 31, 2020, the registrant had 26,615,908 shares of common stock, $0.0001 par value per share, outstanding.

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PART I—FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements.

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

	June 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 133,873	$ 208,929
Short-term investments	233,712	180,468
Prepaid expenses and other current assets	6,933	3,309
Deferred offering costs	338	—
Total current assets	374,856	392,706
Restricted cash	157	123
Property and equipment, net	433	195
Right-of-use lease assets - operating, net	2,370	—
Total assets	$ 377,816	$ 393,024
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable (includes $0 and $51 at June 30, 2020 and December 31, 2019, respectively, due to related parties)	$ 773	$ 547
Accrued expenses	2,622	2,353
Current portion of deferred lease obligation	—	58
Current portion of operating lease liability	674	—
Total current liabilities	4,069	2,958
Deferred lease obligation, net of current portion	—	150
Operating lease liability, net of current portion	1,944	—
Total liabilities	6,013	3,108
Commitments and Contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized and 0 shares outstanding as of June 30, 2020 and December 31, 2019	—	—
Common stock, $0.0001 par value; 150,000,000 shares authorized at June 30, 2020 and December 31, 2019; 26,580,533 and 26,012,754 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	3	3
Additional paid-in capital	472,119	465,420
Accumulated deficit	(101,216)	(75,512)
Accumulated other comprehensive income	897	5
Total stockholders' equity	371,803	389,916
Total liabilities and stockholders' equity	$ 377,816	$ 393,024

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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenue	—	—	—	—
Operating expenses:				
Research and development	$ 10,819	$ 6,784	$ 15,239	$ 13,751
General and administrative	7,006	8,286	12,641	12,892
Total operating expenses	17,825	15,070	27,880	26,643
Loss from operations	(17,825)	(15,070)	(27,880)	(26,643)
Other income (expense):				
Interest income	779	452	2,176	567
Interest income, net (Note 4)	—	—	—	11
Accretion of debt discount (Note 4)	—	(522)	—	(945)
Change in fair value of derivative (Note 4)	—	—	—	(135)
Total other income (expense), net	779	(70)	2,176	(502)
Net loss before income taxes	(17,046)	(15,140)	(25,704)	(27,145)
Income tax provision	—	—	—	—
Net loss attributable to common stockholders	$ (17,046)	$ (15,140)	$ (25,704)	$ (27,145)
Net loss per share, basic and diluted (Note 7)	$ (0.65)	$ (146.02)	$ (0.98)	$ (507.76)
Weighted average common shares outstanding used in computing net loss per share, basic and diluted	26,186,493	103,684	26,114,464	53,460

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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Net loss	$ (17,046)	$ (15,140)	$ (25,704)	$ (27,145)
Other comprehensive income (loss):				
Unrealized (losses) gains on short-term investments	(674)	71	892	71
Comprehensive loss	$ (17,720)	$ (15,069)	$ (24,812)	$ (27,074)

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

KARUNA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(In thousands, except share data)
(Unaudited)

	Series Seed, A and B Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Value	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	—	—	—	—	1,634	—	—	1,634
Exercise of common options	—	—	82,138	—	517	—	—	517
Other comprehensive income	—	—	—	—	—	—	1,566	1,566
Net loss	—	—	—	—	—	(8,658)	—	(8,658)
Balance, March 31, 2020	—	$ —	26,094,892	$ 3	$ 467,537	$ (84,170)	$ 1,571	$ 384,941
Stock-based compensation expense	—	—	—	—	3,226	—	—	3,226
Exercise of common options	—	—	485,641	—	1,356	—	—	1,356
Other comprehensive loss	—	—	—	—	—	—	(674)	(674)
Net loss	—	—	—	—	—	(17,046)	—	(17,046)
Balance, June 30, 2020	—	$ —	26,580,533	$ 3	$ 472,119	$ (101,216)	$ 897	$ 371,803

	Series Seed, A and B Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Value	Shares	Value	Capital	Deficit	Income	Deficit
Balance, December 31, 2018	7,539,200	$ 41,965	12	$ —	$ 1,633	$ (31,555)	$ —	$ (29,922)
Issuance of Series B redeemable convertible preferred stock, net of issuance costs of $175	5,285,102	79,841	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	3,104	—	—	3,104
Exercise of common warrants	—	—	19,986	—	58	—	—	58
Net loss	—	—	—	—	—	(12,005)	—	(12,005)
Balance, March 31, 2019	12,824,302	$ 121,806	19,998	$ —	$ 4,795	$ (43,560)	$ —	$ (38,765)
Issuance of Series B redeemable convertible preferred stock	137,743	2,086	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	6,841	—	—	6,841
Exercise of common warrants	—	—	38,961	—	4	—	—	4
Vesting of restricted stock units	—	—	105,163	—	—	—	—	—
Other comprehensive income	—	—	—	—	—	—	71	71
Net loss	—	—	—	—	—	(15,140)	—	(15,140)
Balance, June 30, 2019	12,962,045	$ 123,892	164,122	$ —	$ 11,640	$ (58,700)	$ 71	$ (46,989)

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

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

	Six Months Ended June 30,	
	2020	**2019**
Cash flows from operating activities		
Net loss	$ (25,704)	$ (27,145)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	4,860	9,945
Non-cash interest income	(104)	(282)
Non-cash interest income, net (Note 4)	—	(11)
Accretion of debt discount (Note 4)	—	945
Change in fair value of derivative liability (Note 4)	—	135
Depreciation and amortization expense	54	22
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(3,624)	(8)
Right-of-use assets	273	—
Accounts payable	166	253
Accrued expenses	182	327
Deferred lease obligation	—	132
Operating lease liability	(233)	—
Net cash used in operating activities	(24,130)	(15,687)
Cash flows from investing activities		
Purchases of short-term investments	(132,248)	(64,468)
Maturities of short-term investments	80,000	5,000
Acquisition of property and equipment	(233)	(70)
Net cash used in investing activities	(52,481)	(59,538)
Cash flows from financing activities		
Proceeds from issuance of Series B redeemable convertible preferred stock, net of issuance costs	—	74,825
Proceeds from issuance of convertible notes	—	3,128
Proceeds from exercise of stock options	1,873	4
Proceeds from exercise of warrant	—	58
Payment of deferred offering costs	(284)	(1,199)
Net cash provided by financing activities	1,589	76,816
Net increase (decrease) in cash, cash equivalents and restricted cash	(75,022)	1,591
Cash, cash equivalents and restricted cash at beginning of period	209,052	9,027
Cash, cash equivalents and restricted cash at end of period	$ 134,030	$ 10,618
Supplemental disclosures of cash flows information		
Lease liabilities arising from obtaining right-of-use assets	$ 2,851	$ —
Purchases of property and equipment included in accrued expenses	$ 59	$ —
Deferred offering costs included in accrued expenses and accounts payable	$ 88	$ 833
Conversion of convertible notes, accrued interest and discount upon conversion to preferred stock	$ —	$ 7,102

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 focused on developing novel therapies with the potential to transform the lives of people with disabling and potentially fatal neuropsychiatric disorders.

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 COVID-19 coronavirus pandemic, and the need to obtain adequate additional financing to fund the development of its product candidates.

On June 14, 2019, the Company effected a one-for-1.2987 stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios for each series of the Company's redeemable convertible preferred stock. Accordingly, all share and per share amounts for all periods presented in the accompanying consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this stock split and adjustment of the redeemable convertible preferred stock conversion ratios.

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 approximately $234.2 million after deducting underwriting discounts and commissions of $15.0 million and offering expenses of $0.4 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 $24.1 million for the six months ended June 30, 2020 and had an accumulated deficit of $101.2 million as of June 30, 2020. The Company expects to continue to generate operating losses for the foreseeable future.

The Company expects that its cash, cash equivalents and short-term investments of $367.6 million as of June 30, 2020 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. The future viability of the Company beyond that point is dependent on its ability to raise additional capital to fund its operations.

If the Company is unable to obtain funding, 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 June 30, 2020, the consolidated statements of operations, comprehensive loss, and redeemable convertible preferred stock and stockholders' equity (deficit) for the three and six months ended June 30, 2020 and 2019 and the consolidated statements of cash flows for the six months ended June 30, 2020 and 2019 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 June 30, 2020 and the results of its operations for the three and six months ended June 30, 2020 and 2019 and the results of its cash flows for the six months ended June 30, 2020 and 2019. 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, 2019. The results for the three and six months ended June 30, 2020 are not necessarily indicative of results to be expected for the year ending December 31, 2020, 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, 2019, and the notes thereto, which are included in the Company's Annual Report on Form 10-K. During the three and six months ended June 30, 2020, there were no material changes to the Company's significant accounting policies, except for the adoption of ASU 2016-02, *Leases (Topic 842)*, as described more fully below.

Recently Adopted Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02, *Leases*, which replaces the guidance in ASC 840, "Leases." In addition, in July 2018, the FASB issued ASU 2018-11, *Leases (Topic 842): Targeted Improvements*, and in March 2019 issued ASU 2019-01, *Leases (Topic 842): Codification Improvements*. The new leasing standard generally requires lessees to recognize operating and financing lease liabilities and corresponding right-of-use ("ROU") assets on the consolidated balance sheet and to provide enhanced disclosures surrounding the amount, timing and uncertainty of cash flows arising from leasing arrangements. The Company adopted the new standard effective January 1, 2020 and did not restate comparative periods. The Company elected the package of practical expedients permitted under the transition guidance and, as such, the adoption of this ASU did not change the classification of any of our existing leases. The Company elected to combine lease and non-lease components, elected not to record leases with an initial term of 12 months or less on the balance sheet and recognized the associated lease payments in the consolidated statements of operations on a straight-line basis over the lease term. As of January 1, 2020, the Company recognized $1.5 million as total lease liabilities and $1.2 million as total right-of-use assets on its consolidated balance sheet as a result of the adoption. The deferred lease obligation of $0.2 million outstanding as of December 31, 2019 was recorded as a reduction of the right-of-use asset.

The Company determines if an arrangement contains a lease at inception. Operating leases are included in ROU lease assets, current portion of operating lease liability, and operating lease liability, net of current portion, on the Company's balance sheets.

ROU lease assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating ROU lease assets and liabilities are recognized at the commencement date based on the present value of lease payments over the lease term. As most of the Company's leases do not provide an implicit rate, the Company uses its incremental borrowing rate based on the information available at the commencement date in determining the present value of lease payments. The ROU lease asset excludes lease incentives. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense for lease payments is recognized on a straight-line basis over the lease term. Changes to terms and conditions of an arrangement that contains a lease are evaluated to determine if a modification had occurred and a lease continues to exist. Lease modifications are accounted for as a separate contract or are treated as a change in accounting for the existing lease.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820)*. ASU 2018-13 modifies fair value disclosure requirements, specifically around level transfers and valuation of Level 3 assets and liabilities. ASU 2018-13 is effective for financial statements issued for annual and interim periods beginning after December 15, 2019 for all entities. Early adoption of all or part of ASU 2018-13 is permitted. Effective January 1, 2020, the Company adopted the standard. The adoption did not have a material impact on the Company's consolidated financial statements.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*. The new standard simplifies the accounting for income taxes by removing certain exceptions within the guidance and making various other amendments. ASU 2019-12 is effective for financial statements issued for annual and interim periods beginning after December 15, 2020. Early adoption is permitted, including adoption in any interim period for which financial statements have not yet been issued. An entity that elects to early adopt in an interim period should reflect any adjustments as of the beginning of the annual period that includes that interim period. In addition, an entity that early adopts must adopt all amendments of ASU 2019-12 in the same period and apply each amendment on either a retrospective modified-retrospective basis as applicable. Effective January 1, 2020, the Company elected to early adopt the standard. The adoption did not have a material impact on the Company's consolidated financial statements.

Recently Issued Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses (Topic 326)*. The new standard adjusts the accounting for assets held at amortized cost basis, including marketable securities accounted for as available-for-sale. The standard eliminates the probable initial recognition threshold and requires an entity to reflect its current estimate of all expected credit losses. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis of the financial assets to present the net amount expected to be collected. In November 2019, the FASB issued ASU 2019-10, which deferred the effective date of the new standard for certain entities. Under this ASU, the standard is effective for public business entities, excluding entities eligible to be smaller reporting companies as defined by the SEC, for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. For all other entities, the standard is effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. Early application is allowed. The Company has not adopted the standard as it currently meets the designation as a smaller reporting company. The Company does not believe the guidance will have a material impact on its consolidated financial statements.

Note 3. Prepaid Expenses and Other Current Assets and Accrued Expenses

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

	June 30, 2020	December 31, 2019
Prepaid insurance	$ 23	$ 2,130
Prepaid research and development expenses	6,655	694
Other	255	485
Total prepaid expenses and other current assets	$ 6,933	$ 3,309

Accrued expenses consisted of the following (in thousands):

	June 30, 2020	December 31, 2019
Accrued payroll and related expenses	$ 1,090	$ 1,823
Accrued research and development expenses	1,036	344
Professional fees	338	142
Other	158	44
Total accrued expenses	$ 2,622	$ 2,353

Note 4. Convertible Notes Payable

In June 2018, the Company entered into a Company Funding Agreement with The Wellcome Trust, Limited ("Wellcome Trust") to receive up to $8.0 million in gross proceeds from the issuance of a convertible note (the "2018 Convertible Note"). The Company received $2.0 million of proceeds in July 2018, $2.7 million in November 2018, $1.6 million in March 2019, and $1.6 million in April 2019.

The 2018 Convertible Note had a stated interest rate of 2% per annum above the three-month Dollar LIBOR rate, which was not payable until settlement of the principal. The note was subject to redemption upon written demand by Wellcome Trust any time after the fifth anniversary of the effective date. The principal due under the 2018 Convertible Note was convertible into the class of the Company's stock issued in the Company's next qualified financing or upon an event of default at a discounted conversion price between 0% and 25% of the purchase price per share of such securities issued. The accrued interest in such a circumstance would be forgiven.

At inception, the Company concluded that the 2018 Convertible Note contained a conversion option at a significant discount that was deemed to be an embedded derivative, which was required to be bifurcated and accounted for separately from the debt host. There were no debt issuance costs associated with the 2018 Convertible Note.

The Company recognized the following changes in the debt related to the 2018 Convertible Note during the three and six months ended June 30, 2019 (in thousands):

			Financial statement impacted
Balance, December 31, 2018	$	2,516	
Issuance of 2018 Convertible Note		1,564	Balance sheet
Allocation of proceeds to derivative liability		(228)	Balance sheet
Accretion to settlement value		423	Statement of operations
Accrued interest		29	Statement of operations
Interest forgiven upon conversion		(40)	Statement of operations
Conversion of Wellcome Trust Convertible Notes to redeemable convertible preferred stock		(4,264)	Balance sheet
Balance, March 31, 2019		—	
Issuance of 2018 Convertible Note		1,564	Balance sheet
Allocation of proceeds to derivative liability		(522)	Balance sheet
Accretion to settlement value		522	Statement of operations
Conversion of Wellcome Trust Convertible Notes to redeemable convertible preferred stock		(1,564)	Balance sheet
Balance, June 30, 2019	$	—	

In March and April 2019, all outstanding principal under the 2018 Convertible Note was converted into Series B redeemable convertible preferred stock in connection with the Company's Series B preferred stock financing.

Note 5. Redeemable Convertible Preferred Stock

As of December 31, 2018, the Company had 7,539,200 shares of preferred stock issued and outstanding which were redeemable and convertible by the holders under specified conditions. The redeemable convertible preferred stock was classified outside of stockholders' equity (deficit) because the shares contained redemption features that were not solely within the control of the Company.

In March 2019, the Company authorized 5,422,845 shares of Series B Preferred Stock. The Company then issued and sold 4,953,758 shares of Series B Preferred Stock at an issuance price of $15.14 per share resulting in gross proceeds of approximately $75.0 million. There were $0.2 million of issuance costs associated with the Series B Preferred Stock.

In conjunction with the March 2019 issuance of Series B Preferred Stock, all outstanding principal under the 2018 Convertible Note converted into 331,344 shares of Series B Preferred Stock. In April 2019, the Company received an additional $1.6 million pursuant to the 2018 Convertible Note, which was subsequently converted into 137,743 shares of Series B Preferred Stock.

Upon closing of the Company's IPO on July 2, 2019, the then-outstanding shares of the redeemable convertible preferred stock converted into common stock. There were no shares of redeemable convertible preferred stock authorized, issued or outstanding as of June 30, 2020 or December 31, 2019.

Note 6. 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 June 30, 2020 or December 31, 2019.

Common Stock

As of June 30, 2020, 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 June 30, 2020, no cash dividends have been declared or paid.

Upon completion of the Company's IPO on July 2, 2019, all outstanding shares of redeemable convertible preferred stock converted into common stock. As of June 30, 2020, there were 26,580,533 shares of common stock outstanding.

Note 7. 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 six months ended June 30, 2020 and 2019 (in thousands, except share and per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Net Loss	$ (17,046)	$ (15,140)	$ (25,704)	$ (27,145)
Weighted-average shares used in computing net loss per share	26,186,493	103,684	26,114,464	53,460
Net loss per share, basic and diluted	$ (0.65)	$ (146.02)	$ (0.98)	$ (507.76)

The Company's potentially dilutive securities, which include stock options and convertible preferred stock, 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.

Prior to the IPO, the Company's outstanding shares of redeemable convertible preferred stock contractually entitled the holders of such shares to participate in distributions but contractually did not require the holders of such shares to participate in losses of the Company. Accordingly, these shares have not been included in the denominator used to calculate net loss per share.

Common Stock Equivalents

The following common stock equivalents, presented based on amounts outstanding at each period end, have been excluded from the calculation of diluted net loss per share because including them would have had an anti-dilutive impact:

	June 30,	
	2020	2019
Redeemable convertible preferred stock (as converted to common stock)	—	16,833,790
Stock options to purchase common stock	4,767,515	4,702,906
	4,767,515	21,536,696

Note 8. 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 aggregate common shares issuable were 3,911,138 under the 2009 Plan, as amended. 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 June 30, 2020, there were 3,039,491 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 June 30, 2020, there were 1,158,680 common shares available for issuance and 1,728,024 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. In general, 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, 2019	4,614,544	$ 8.94	8.3	$ 306,395
Granted	769,750	93.41		
Exercised	(567,779)	3.30		
Forfeited	(49,000)	16.00		
Outstanding as of June 30, 2020	4,767,515	$ 23.18	8.4	$ 420,877
Options vested and expected to vest as of June 30, 2020	4,767,515	$ 23.18	8.4	$ 420,877
Options exercisable as of June 30, 2020	2,999,686	$ 9.73	8.1	$ 305,172

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 June 30, 2020.

As of June 30, 2020, there was $41.6 million of unrecognized compensation cost, which is expected to be recognized over a weighted-average period of 3.3 years.

Warrants

In October 2016, PureTech Health LLC, a related party ("PureTech Health"), agreed to provide management services to the Company in exchange for a warrant to purchase up to 19,998 shares of the Company's common stock. As of December 31, 2018, the warrant was fully vested and PureTech Health had partially exercised the warrant to purchase 12 shares of the Company's common stock.

In March 2019, PureTech Health exercised the remaining portion of the warrant to purchase 19,986 shares of the Company's common stock, resulting in proceeds to the Company of $0.1 million. There were no outstanding warrants as of June 30, 2020 or December 31, 2019.

Stock-based Compensation Expense

Stock-based compensation expense is classified in the statements of operations for the three and six months ended June 30, 2020 and 2019 as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Research and development	$ 918	$ 144	$ 1,268	$ 224
General and administrative	2,308	6,697	3,592	9,721
Total stock based compensation expense	$ 3,226	$ 6,841	$ 4,860	$ 9,945

Note 9. Fair Value of Financial Assets and Liabilities

The following tables present information about the Company's assets and liabilities as of June 30, 2020 and December 31, 2019 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 June 30, 2020 Using			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents (Money Market Fund)	$ 116,456	$ —	$ —	$ 116,456
Cash equivalents (Corporate Bonds)	—	3,999	—	3,999
Short-term investments (US Treasuries)	201,802	—	—	201,802
Short-term investments (Corporate Bonds)	—	31,910	—	31,910
Total	$ 318,258	$ 35,909	$ —	$ 354,167

	Fair Value Measurement at December 31, 2019 Using			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents (Money Market Fund)	$ 197,303	$ —	$ —	$ 197,303
Short-term investments (US Treasuries)	180,468	—	—	180,468
Total	$ 377,771	$ —	$ —	$ 377,771

The fair values of the Company's corporate bonds 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 estimated fair value and amortized cost of the Company's short-term investments by contractual maturity are summarized as follows (in thousands):

	June 30, 2020			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Due in one year or less	$ 232,815	$ 897	$ —	$ 233,712
Total	$ 232,815	$ 897	$ —	$ 233,712

	December 31, 2019			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Due in one year or less	$ 180,463	$ 5	$ —	$ 180,468
Total	$ 180,463	$ 5	$ —	$ 180,468

As of December 31, 2018, the Company had recorded a derivative liability of $0.4 million in connection with the 2018 Convertible Note. The derivative liability was considered a Level 3 liability because its fair value measurement was based, in part, on significant inputs not observed in the market. In March and April 2019, additional derivative liabilities of $0.8 million in the aggregate were recognized in connection with the 2018 Convertible Note (see Note 4). For the six months ended June 30, 2019, the Company recognized a change in fair value of derivative of $0.1 million in the consolidated statement of operations. Upon the Company's issuance of Series B redeemable convertible preferred stock in March and April 2019, all outstanding principal under the 2018 Convertible Note was converted into redeemable convertible preferred stock.

There was no derivative liability recorded as of June 30, 2020 or December 31, 2019.

Note 10. Commitments and Contingencies

Leases

The Company entered into an agreement to lease approximately 7,050 square feet of office space in Boston, Massachusetts ("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 Lease Agreement") to gain access to approximately 4,175 square feet of additional office space ("Expansion Premises") beginning in March 2020, and to extend the maturity of the agreement for the Original Premises to December 2023. The Amended Lease Agreement provides for future minimum annual rental payments as defined within the agreement. Under the terms of the amended 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 June 30, 2020 and December 31, 2019. The amended agreement also provides for approximately $0.1 million in leasehold incentives which may be applied to base rent or improvements to the Expansion Premises, subject to limitations.

The Company determined the Amended Lease Agreement represented a lease modification, and the Original Premises and Expansion Premises were identified as separate lease components. The extension of maturity with respect to the 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 asset as of February 1, 2020, the effective date of the modification. The addition of the 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.

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.

In addition to the lease liabilities arising from ROU assets recognized upon adoption of ASC 842, *Leases* (see Note 2), the Company recognized approximately $1.4 million in incremental lease liabilities arising from obtaining ROU assets as a result of the Amended Lease Agreement and Indiana Lease Agreement.

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

	Six Months Ended June 30, 2020
Lease Cost	
Operating lease cost	$ 348
Short-term lease cost	—
Total lease cost	$ 348
Other Information	
Cash paid for amounts included in the measurement of lease liabilities	$ 308
Operating lease liabilities arising from obtaining right-of-use assets	$ 2,851
Weighted-average remaining lease term	3.44 years
Weighted-average discount rate	6.16%

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 June 30, 2020 (in thousands):

Year ended:	
December 31, 2020	$ 392
December 31, 2021	845
December 31, 2022	860
December 31, 2023	804
Total future minimum lease payments	2,901
Less imputed interest	(283)
Present value of lease liabilities	$ 2,618

Future minimum lease payments under non-cancelable operating lease agreements as of December 31, 2019 (under ASC 840, prior to the adoption of ASC 842 effective January 1, 2020), were as follows (in thousands):

Year ended:	
December 31, 2020	$ 499
December 31, 2021	506
December 31, 2022	514
December 31, 2023	86
December 31, 2024 and thereafter	—
	$ 1,605

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 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 us 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 June 30, 2020, 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 we receive 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 six months ended June 30, 2020 or 2019. The Company had no outstanding liabilities to PureTech Health related to the Patent License Agreement as of June 30, 2020 and December 31, 2019.

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 June 30, 2020.

Note 11. Related Party Transactions

PureTech Health Management Consulting Services and Overhead Agreement

The Company previously engaged PureTech Health, a related party, to provide, among other things, management expertise, strategic advice, administrative support, computer and telecommunications services and office infrastructure. In exchange for providing such services, the Company paid PureTech Health a monthly fee. In addition, PureTech Health periodically invoiced the Company for out-of-pocket expenses reasonably incurred in connection with providing such business services.

The Company incurred general and administrative costs for management services provided by PureTech Health totaling less than $0.1 million in the six months ended June 30, 2019. In addition, the Company had outstanding current liabilities to PureTech Health of less than $0.1 million as of December 31, 2019, which were recorded as accounts payable in the consolidated balance sheets. As of and for the six months ended June 30, 2020, the Company had no outstanding liabilities to PureTech Health and no general and administrative costs for management services were incurred.

Note 12. 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 matching expense for the Company was $0.1 million and less than $0.1 million for the six months ended June 30, 2020 and 2019, respectively.

Note 13. Subsequent Events

On July 2, 2020, the Company filed a shelf registration statement on Form S-3 (the "Shelf") with the SEC which registers 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 Shelf. The Shelf was filed and declared automatically effective by the SEC on July 2, 2020.

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, 2019 included in our Annual Report on Form 10-K, or the Annual Report, filed with the Securities and Exchange Commission, or the SEC, on March 24, 2020. This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act 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 an innovative clinical-stage biopharmaceutical company committed to developing novel therapies with the potential to transform the lives of people with disabling and potentially fatal neuropsychiatric disorders. 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. In November 2019, we completed a Phase 2 clinical trial of KarXT for the treatment of acute psychosis in patients with schizophrenia, in which KarXT met the trial's primary endpoint and was observed to be well tolerated. We are also developing KarXT as a potential treatment for dementia-related psychosis, or DRP. In the fourth quarter of 2019, we initiated a Phase 1b clinical trial of KarXT evaluating the safety and tolerability of KarXT in healthy elderly volunteers in order to select the most appropriate dose for future KarXT trials to assess efficacy and safety in a DRP patient population. We have assembled a team whose members have extensive expertise in the research, development and commercialization of numerous CNS agents, as well as deep familiarity with the biology of neuropsychiatric disorders, such as schizophrenia and DRP, including the role of muscarinic receptors in potential treatment of these diseases. We plan to leverage this expertise to develop a pipeline of product candidates targeting a broad range of psychiatric and neurological conditions.

We are on track to initiate the first Phase 3 trial within our EMERGENT program, the clinical program evaluating KarXT for the treatment of acute psychosis in adults with schizophrenia, by the end of 2020. The EMERGENT program includes the completed positive Phase 2 clinical trial (EMERGENT-1) and additional planned efficacy and safety trials to support an NDA filing, including EMERGENT-2 through EMERGENT-5. EMERGENT-2 is a five-week, inpatient, 1:1 randomized, flexible-dose, double-blind, placebo-controlled trial evaluating the efficacy and safety of KarXT in approximately 250 adults with schizophrenia in the U.S., which we expect to commence by the end of 2020. EMERGENT-3 is a five-week, inpatient trial evaluating the safety and efficacy of KarXT in adults with schizophrenia, with additional details of the trial to be finalized by the end of 2020 and initiation expected in the first half of 2021. EMERGENT-4 is a 52-week, outpatient, open-label long-term safety and tolerability extension study of EMERGENT-2 and EMERGENT-3 which will initiate upon patient rollover from EMERGENT-2. EMERGENT-5 is a 52-week, outpatient, open-label long-term study evaluating the safety of KarXT in adults with schizophrenia who have not been enrolled in the EMERGENT-2 or EMERGENT-3 trials, which we expect to commence the first half of 2021. The formal minutes from our End-of-Phase 2 meeting with the FDA for KarXT for the treatment of acute psychosis in patients with schizophrenia confirmed that our completed Phase 2 trial (EMERGENT-1), 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.

We also plan to initiate a Phase 2 trial evaluating KarXT as an adjunctive therapy with the standard of care for the treatment of psychosis in patients with schizophrenia who remain symptomatic on existing therapies. We previously planned to initiate a Phase 1b trial assessing potential Drug-Drug Interactions with a selection of currently marketed antipsychotics in healthy volunteers, but based on multiple considerations, including the evaluation of existing preclinical and clinical data supporting the potential of KarXT to augment traditional antipsychotic drugs, we will move forward

directly to initiate a Phase 2 trial. The trial will evaluate the efficacy and safety of KarXT when dosed in conjunction with background antipsychotic treatment and its potential to improve symptoms in patients who had not achieved an adequate response on their current antipsychotic treatment. Data evaluating KarXT as an adjunctive therapy is intended to support a supplemental NDA filing assuming the successful development of KarXT as a monotherapy for the treatment of adults with schizophrenia. We plan to initiate this trial following the initiation of the Phase 3 trials within the EMERGENT program.

The use of KarXT for the treatment of negative and cognitive symptoms in patients with schizophrenia remains of interest. We will collect data on the potential benefit of KarXT on negative and cognitive symptoms of schizophrenia as part of the EMERGENT program and our adjunctive therapy trial. We continue to evaluate the timing of potential trial designs specifically directed towards the negative and cognitive symptoms of schizophrenia.

In the fourth quarter of 2019, we initiated a Phase 1b clinical trial of KarXT evaluating the effect of KarXT on experimentally induced pain in healthy volunteers. On August 3, 2020, we announced that the topline results from this exploratory trial were inconclusive and did not provide sufficient evidence of an analgesic benefit of KarXT compared to placebo. As a result, we will not move forward to develop KarXT in pain.

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 approximately $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.

We have never generated revenue and have incurred significant net losses since inception. Our net losses were $25.7 million and $27.1 million for the six months ended June 30, 2020 and 2019, respectively. As of June 30, 2020, we had an accumulated deficit of $101.2 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 June 30, 2020, we had cash, cash equivalents and short-term investments of $367.6 million. We believe that our existing cash, cash equivalents and short-term investments will be sufficient to meet our anticipated operating and capital expenditure requirements through at least the next 36 months. 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.”

Special Note About Coronavirus (COVID-19)

Since March 2020, we have been evaluating the potential business impacts related to the outbreak of SARS-CoV-2 (severe acute respiratory syndrome 2), or coronavirus, a novel strain of virus which causes coronavirus disease, or COVID-19. We have managed to continue operations and maintain adherence to previously announced timelines to date. However, we may experience disruptions, pauses and/or delays that could adversely impact our business operations, including the conduct of our clinical trials and other research and development operations.

In 2019, we initiated a Phase 1b clinical trial evaluating the safety and tolerability of KarXT in healthy elderly volunteers in order to select the most appropriate dose for future KarXT trials to assess efficacy and safety in a DRP patient population. We remain on track to announce topline results from this trial in the second half of 2020. However, if negative developments relating to the COVID-19 pandemic (such as a so-called “resurgence”) were to occur, we may face enrollment delays or may elect to pause recruitment in this trial out of an abundance of caution for the health and safety of the elderly volunteers in this trial.

The ultimate impact of the coronavirus pandemic on our business operations remains uncertain and subject to change and will depend on future developments, which cannot be accurately predicted. We will continue to monitor the situation closely.

Components of Our Results of Operations

Revenue

To date, we have not generated any revenue and do not expect to 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.

We do not track certain research and development expenses on an indication-by-indication basis as they primarily relate to personnel, early research and consumable costs 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. Other 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 costs as well as preclinical 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. The following table summarizes our research and development expenses:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
	(in thousands)			
Schizophrenia clinical trials	$ 2,636	$ 4,019	$ 2,696	$ 8,817
Pain clinical trials	485	—	790	—
DRP clinical trials	(2)	—	483	—
Formulation and CMC	2,732	770	3,477	1,360
Preclinical	434	696	531	1,487
Unallocated expenses	4,534	1,299	7,262	2,087
Total research and development expense	$ 10,819	$ 6,784	$ 15,239	$ 13,751

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;
- assess the potential impact of COVID-19, if any, 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 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. 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. We will also 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 (Expense)

Interest Income. Interest income consists of interest income from our cash equivalents and short-term investments.

Interest Income, Net. Interest income, net, consists of interest accrued, net of any interest forgiven, on the principal balance of convertible notes that were issued and outstanding during 2019. In March 2019 and April 2019, all outstanding convertible notes were converted into redeemable convertible preferred stock. A portion of the accrued interest was forgiven with respect to certain of the convertible notes upon their conversion into redeemable convertible preferred stock, and the forgiven interest was recorded as a reduction to interest expense in the year ended December 31, 2019.

Accretion of Debt Discount. Upon issuance of our convertible notes, each note was recorded at cost, net of the derivative liability. This discount on each outstanding note, if any, was amortized as interest expense to the date such note was expected to convert using the effective interest rate method and is reflected in the statements of operations as accretion of debt discount.

Change in Fair Value of Derivative. Our convertible notes contained conversion options at a significant premium that were deemed to be embedded derivatives which are required to be bifurcated and accounted for separately from the convertible note. We remeasured the derivative liability to fair value at each reporting date, and we recognized changes in the fair value of the derivative liabilities in our statements of operations. As part of the conversion of outstanding convertible notes into redeemable convertible preferred stock, all derivatives were settled in March and April 2019.

Results of Operations

Comparison of the Three Months Ended June 30, 2020 and 2019

	Three Months Ended June 30,		
	2020	2019	Change
		(in thousands)	
Revenue	$ —	$ —	$ —
Operating expenses:			
Research and development	10,819	6,784	4,035
General and administrative	7,006	8,286	(1,280)
Total operating expenses	17,825	15,070	2,755
Loss from operations	(17,825)	(15,070)	(2,755)
Total other income (expense), net	779	(70)	849
Net loss attributable to common stockholders	$ (17,046)	$ (15,140)	$ (1,906)

Research and Development Expenses

	Three Months Ended June 30,		
	2020	2019	Change
		(in thousands)	
Direct research and development expenses:			
Schizophrenia clinical trials	$ 2,636	$ 4,019	$ (1,383)
Pain clinical trials	485	—	485
DRP clinical trials	(2)	—	(2)
Formulation and CMC	2,732	770	1,962
Preclinical	434	696	(262)
Unallocated expenses:			
Personnel related expenses (including stock-based compensation)	2,503	877	1,626
Consultant fees and other expenses	2,031	422	1,609
Total research and development expense	$ 10,819	$ 6,784	$ 4,035

Expenses related to our schizophrenia clinical trials decreased by $1.4 million in the three months ended June 30, 2020 as compared to the three months ended June 30, 2019 due to the conclusion of our Phase 2 trial, which was partially offset by expenses related to start-up activities for our planned Phase 3 trials. The $0.5 million in expenses related to pain clinical trials consists of enrollment, dosing and study close out activities for our Phase 1 trial incurred in the three months ended June 30, 2020. The decrease in expenses related to our DRP clinical trials during the three months ended June 30, 2020 relates to the reconciliation of payments made and services rendered for these clinical trials. Formulation and CMC expenses increased by $2.0 million due to an increase in manufacturing activities to obtain sufficient supply to support clinical trial activities, including our planned Phase 3 clinical trials in schizophrenia. Preclinical expenses decreased by $0.3 million due to the conclusion of several toxicology studies in 2019. The increase of $1.6 million in personnel-related costs was primarily a result of an increase in headcount. The increase of $1.6 million in consultant fees and other expenses was due an increase in costs related to our discovery programs as well as other consulting costs not specifically allocated to preclinical, clinical, formulation and CMC activities.

General and Administrative Expenses

	Three Months Ended June 30,		
	2020	2019	Change
	(in thousands)		
Personnel-related expenses (including stock-based compensation)	$ 4,349	$ 7,626	$ (3,277)
Professional and consultant fees	908	200	708
Other	1,749	460	1,289
Total general and administrative expense	$ 7,006	$ 8,286	$ (1,280)

The decrease of $3.3 million in personnel-related costs in the three months ended June 30, 2020 as compared to the three months ended June 30, 2019 was primarily due to the acceleration of option awards which fully vested prior to the end of 2019 as a result of our IPO and was partially offset by expenses related to our increased headcount. The increase of $0.7 million in professional and consultant fees was primarily due to an increase in accounting fees, legal costs, and consulting fees related to our ongoing business activities as a public company. The increase of $1.3 million in other costs was primarily due to insurance costs, the expansion of our facility lease in Boston, Massachusetts and the entry into a new office lease in Carmel, Indiana.

Other Income (Expense), Net

	Three Months Ended June 30,		
	2020	2019	Change
	(in thousands)		
Interest income	$ 779	$ 452	$ 327
Interest income, net	—	—	—
Accretion of debt discount	—	(522)	522
Change in fair value of derivative	—	—	—
Total other income (expense), net	$ 779	$ (70)	$ 849

Interest income is attributable to interest earned on our cash equivalents and short-term investments, the balance of which increased significantly subsequent to our IPO in July 2019 and our follow-on offering in November 2019.

There was no interest income, net, accretion of debt discount, or change in fair value of derivative recorded during the three months ended June 30, 2020 because there were no convertible notes outstanding during the period.

In April 2019, we received $1.6 million from a convertible note, or the 2018 Convertible Note, issued to The Wellcome Trust, Limited, or Wellcome Trust, pursuant to a Company Funding Agreement with Wellcome Trust. The outstanding principal under the 2018 Convertible Note was subsequently converted into shares of Series B convertible preferred stock in our Series B preferred stock financing. Accordingly, due to the insignificant period of time during which the debt was outstanding, no interest expense was accrued or forgiven in connection with the conversion of this portion of the note, and no change in fair value of derivative was recognized for the three months ended June 30, 2019. The associated debt discount that had been recognized was fully accreted upon conversion.

Comparison of the Six Months Ended June 30, 2020 and 2019

	Six Months Ended June 30,		
	2020	2019	Change
	(in thousands)		
Revenue	$ —	$ —	$ —
Operating expenses:			
Research and development	15,239	13,751	1,488
General and administrative	12,641	12,892	(251)
Total operating expenses	27,880	26,643	1,237
Loss from operations	(27,880)	(26,643)	(1,237)
Total other income (expense), net	2,176	(502)	2,678
Net loss attributable to common stockholders	$ (25,704)	$ (27,145)	$ 1,441

Research and Development Expenses

	Six Months Ended June 30,		
	2020	2019	Change
	(in thousands)		
Direct research and development expenses:			
Schizophrenia clinical trials	$ 2,696	$ 8,817	$ (6,121)
Pain clinical trials	790	—	790
DRP clinical trials	483	—	483
Formulation and CMC	3,477	1,360	2,117
Preclinical	531	1,487	(956)
Unallocated expenses:			
Personnel related expenses (including stock-based compensation)	3,908	1,298	2,610
Consultant fees and other expenses	3,354	789	2,565
Total research and development expense	$ 15,239	$ 13,751	$ 1,488

Expenses related to our schizophrenia clinical trials decreased by $6.1 million in the six months ended June 30, 2020 as compared to the six months ended June 30, 2019 due to the conclusion of our Phase 2 trial, which was partially offset by expenses related to start-up activities for our planned Phase 3 trials. The $0.8 million and $0.5 million in expenses related to pain and DRP clinical trials consist of enrollment and dosing activities for Phase 1 trials incurred in the six months ended June 30, 2020. Formulation and CMC expenses increased by $2.1 million due to an increase in manufacturing activities to obtain sufficient supply to support clinical trial activities, including our planned Phase 3 clinical trials in schizophrenia. Preclinical expenses decreased by $1.0 million due to the conclusion of several toxicology studies in 2019. The increase of $2.6 million in personnel-related costs was primarily a result of an increase in headcount. The increase of $2.6 million in consultant fees and other expenses was due to an increase in costs related to our discovery programs as well as other consulting costs not specifically allocated to preclinical, clinical, formulation and CMC activities.

General and Administrative Expenses

	Six Months Ended June 30,		
	2020	2019	Change
	(in thousands)		
Personnel-related expenses (including stock-based compensation)	$ 7,239	$ 11,353	$ (4,114)
Professional and consultant fees	2,108	714	1,394
Other	3,294	825	2,469
Total general and administrative expense	$ 12,641	$ 12,892	$ (251)

The decrease of $4.1 million in personnel-related costs in the six months ended June 30, 2020 as compared to the six months ended June 30, 2019 was primarily due to the acceleration of option awards which fully vested prior to the end of 2019 as a result of our Series B preferred stock financing and IPO and was partially offset by expenses related to our increased headcount. The increase of $1.4 million in professional and consultant fees was primarily due to an increase in accounting fees, legal costs, and consulting fees related to our ongoing business activities as a public company. The increase of $2.5 million in other costs was primarily due to insurance costs, the expansion of our facility lease in Boston, Massachusetts and the entry into a new office lease in Carmel, Indiana.

Other Income (Expense), Net

	Six Months Ended June 30,		
	2020	2019	Change
		(in thousands)	
Interest income	$ 2,176	$ 567	$ 1,609
Interest income, net	—	11	(11)
Accretion of debt discount	—	(945)	945
Change in fair value of derivative	—	(135)	135
Total other income (expense), net	$ 2,176	$ (502)	$ 2,678

Interest income is attributable to interest earned on our cash equivalents and short-term investments, the balance of which increased significantly subsequent to our IPO in July 2019 and our follow-on offering in November 2019.

There was no interest income, net, accretion of debt discount, or change in fair value of derivative recorded during the six months ended June 30, 2020 because there were no convertible notes outstanding during the period.

Interest income, net, for the six months ended June 30, 2019 represents the excess of interest forgiven over interest accrued on the 2018 Convertible Note when all outstanding principal under the 2018 Convertible Note was converted into shares of Series B convertible preferred stock in March 2019.

Accretion of debt discount for the six months ended June 30, 2019 represents the full accretion of debt discount when all outstanding principal under the 2018 Wellcome Trust Note was converted into shares of Series B convertible preferred stock in March and April 2019.

The change in fair value of derivative for the six months ended June 30, 2019 reflects the mark-to-market of the convertible note derivative liabilities prior to the conversion of the outstanding principal under the 2018 Convertible Note in March 2019 into shares of our Series B convertible preferred stock.

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 June 30, 2020, our operations have been financed by gross 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 initial public offering, and $234.2 million from the sale of our common stock in a follow-on public offering. As of June 30, 2020, we had $367.6 million in cash, cash equivalents and short-term investments, and an accumulated deficit of $101.2 million.

On July 2, 2020, we filed a shelf registration statement on Form S-3, or the Shelf, with the SEC which registers 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 our issuance and sale of up to $150.0 million of common stock from time to time in “at-the-market” offerings under the Shelf, or the ATM Program. The Shelf was filed and declared automatically effective by the SEC on July 2, 2020, so as of June 30, 2020, 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 accounts payable and accrued expenses.

Cash Flows

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

	Six Months Ended June 30,	
	2020	2019
	(in thousands)	
Net cash used in operating activities	$ (24,130)	$ (15,687)
Net cash used in investing activities	(52,481)	(59,538)
Net cash provided by financing activities	1,589	76,816
Net increase in cash, cash equivalents and restricted cash	$ (75,022)	$ 1,591

Cash Flows from Operating Activities

Cash used in operating activities for the six months ended June 30, 2020 was $24.1 million, consisting of a net loss of $25.7 million partially offset by non-cash items, including stock-based compensation expense of $4.9 million and $0.1 million of non-cash interest income. The change in our net operating assets and liabilities was due to an increase in prepaid expenses and other current assets of $3.6 million and a decrease in operating lease liabilities of $0.2 million which were partially offset by a decrease of $0.3 million in right-of-use assets and an increase in accounts payable and accrued expenses of $0.4 million.

Cash used in operating activities for the six months ended June 30, 2019 was $15.7 million, consisting of a net loss of $27.1 million partially offset by non-cash items, including stock-based compensation expense of $9.9 million, the accretion of debt discount related to the convertible notes of $0.9 million, and $0.1 million resulting from the change in fair value of the convertible note derivative liabilities. The change in our net operating assets and liabilities was due primarily to an increase in accounts payable and accrued expenses of $0.6 million, primarily driven by timing of payments to CROs and CMOs, and $0.1 million related to an increase in deferred lease obligation.

Cash Flows from Investing Activities

Cash used in investing activities for the six months ended June 30, 2020 was $52.5 million, primarily attributable to the purchases of short-term investments of $132.3 million and acquisition of $0.2 million in property and equipment, which were partially offset by maturities of short-term investments of $80.0 million.

Cash used in investing activities for the six months ended June 30, 2019 was $59.5 million, primarily attributable to the purchases of short-term investments of $64.5 million and offset by maturities of short-term investments of $5.0 million.

Cash Flows from Financing Activities

Cash provided by financing activities for the six months ended June 30, 2020 was $1.6 million, attributable to proceeds from the exercise of stock options of $1.9 million, offset by $0.3 million in payments of deferred offering costs associated with the filing of our Shelf and the ATM Program prospectus.

Cash provided by financing activities for the six months ended June 30, 2019 was $76.8 million and was related primarily to the $74.8 million of net proceeds from the issuance of redeemable convertible preferred stock as well as $3.1 million related to proceeds from the issuance of convertible notes, partially offset by $1.2 million in payments of deferred offering costs.

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. In addition, we expect to incur additional costs associated with operating as a public company.

As of June 30, 2020, we had cash and cash equivalents and short-term investments of $367.6 million. Based on our current plans, we believe that our existing cash, cash equivalents and short-term investments will be sufficient to meet our anticipated operating and capital expenditure requirements through at least the next 36 months.

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 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 office space in Boston, Massachusetts to acquire approximately 4,175 in additional square feet and to extend the original lease term through December 2023. Remaining lease payments from June 30, 2020 through the end of the lease term total $2.5 million for both the original space and the 2,422 square feet of the January 2020 lease expansion which we took possession of in February 2020. We took possession of the remaining 1,753 square feet on August 3, 2020.

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 will total approximately $0.4 million over the term of the lease.

During the six months ended June 30, 2020, 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 involve the most judgment and complexity:

- research and development contract costs and accruals; and
- stock-based compensation expense.

There have been no material changes to these critical accounting policies from those described in the Annual Report.

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

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. Other exemptions and reduced reporting requirements under the JOBS Act for emerging growth companies include an exemption from the requirement to provide an auditor’s report on internal controls over financial reporting pursuant to the Sarbanes-Oxley Act of 2012, and an exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation. We have elected to use the extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that (i) we are no longer an emerging growth company or (ii) we affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

We will cease to be an emerging growth company upon the earliest of: (1) the last day of the fiscal year ending after the fifth anniversary of our initial public offering; (2) the last day of the fiscal year in which we have more than $1.07 billion in annual gross revenue; (3) the last day of the fiscal year in which we qualify as a “large accelerated filer,” with at least $700.0 million of equity securities held by non-affiliates as of the prior June 30th; or (4) the issuance, in any three-year period, by our company of more than $1.0 billion in non-convertible debt securities held by non-affiliates. As of June 30, 2020, the last business day of our most recently completed second fiscal quarter, the market value of our common stock that was held by non-affiliates exceeded $700.0 million. As such, we will cease to be an “emerging growth company” as of December 31, 2020 and will be a “large accelerated filer” for our fiscal year ending December 31, 2021.

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

We are not currently exposed to significant market risk related to changes in foreign currency exchange rates; however, we have contracted with and may continue to contract with 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 six months ended June 30, 2020 and 2019.

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 June 30, 2020.

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 six months ended June 30, 2020 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 other information set forth in this Form 10-Q, you should carefully consider the factors discussed in Part I, Item 1A, subsection “Risk Factors” in our 2019 Annual Report on Form 10-K filed with the SEC on March 24, 2020, as they could materially affect our business, financial condition or future results of operations. The risks described in our Annual Report on Form 10-K are not the only risks that we face. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial may also materially adversely affect our business, financial condition and future results of operations. The following information updates, and should be read in conjunction with, the risk factors previously disclosed in Item 1A, subsection “Risk Factors” to Part I of our 2019 Annual Report on Form 10-K filed with the SEC on March 24, 2020. Except as set forth below, there have been no material changes to the risk factors previously disclosed under the caption “Risk Factors” in our 2019 Annual Report on Form 10-K.

A pandemic, epidemic or outbreak of an infectious disease in the United States may adversely affect our business.

If a pandemic, epidemic or outbreak of an infectious disease occurs in the United States or worldwide, our business may be adversely affected. In March 2020, SARS-CoV-2 (severe acute respiratory syndrome 2), or coronavirus, a novel strain of virus which causes coronavirus disease, or COVID-19, was declared a pandemic by the World Health Organization. The continued worldwide spread of COVID-19 has impacted the global economy and may impact our operations, including the potential interruption of our clinical trial activities, regulatory reviews and our supply chain. We are monitoring the global outbreak and spread of the novel strain of COVID-19 and have taken steps to identify and mitigate the adverse impacts on, and risks to, our business posed by its spread and actions taken by governmental and health authorities to address this pandemic. To date, our financial condition and operations have not been significantly impacted by the COVID-19 pandemic; however the spread of COVID-19 has caused us to modify our business practices, including implementing a work from home policy for all employees who are able to perform their duties remotely and restricting all nonessential travel, and we expect to continue to take actions as may be required or recommended by government authorities or as we determine are in the best interests of our employees and other business partners in light of COVID-19.

In addition, the COVID-19 outbreak may delay enrollment in our clinical trials due to prioritization of hospital resources toward the outbreak or other factors, and some patients may be unwilling to enroll in our trials or be unable to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services, which would delay our ability to conduct clinical trials or release clinical trial results and could delay our ability to obtain regulatory approval and commercialize our product candidates. In particular, there is a risk that such impacts may be seen in our ongoing Phase 1b clinical trial evaluating the safety and tolerability of KarXT in healthy elderly volunteers,. While we remain on track to announce topline results from this trial in the second half of 2020, given that this is a population that is particularly vulnerable to COVID-19, if negative developments relating to the COVID-19 pandemic (such as a so-called “resurgence”) were to occur, we may face enrollment delays or may elect to pause recruitment in this trial out of an abundance of caution for the health and safety of the elderly volunteers in this trial. Furthermore, the spread of the virus may affect the operations of key governmental agencies, such as the FDA, which may delay the development of our product candidates. The spread of an infectious disease, including COVID-19, may also result in the inability of our suppliers to deliver components or raw materials on a timely basis or at all. In addition, hospitals may reduce staffing and reduce or postpone certain treatments in response to the spread of an infectious disease. Such events may result in a period of business disruption, and in reduced operations, or doctors and medical providers may be unwilling to participate in our clinical trials, any of which could materially affect our business, financial condition and results of operations.

The extent to which the coronavirus impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others. The coronavirus and other infectious diseases could result in a widespread health crisis that could adversely affect the economies and financial markets worldwide, resulting in an economic downturn that could impact our business, financial condition and results of operations.

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

On July 2, 2019, we closed our initial public offering of 6,414,842 shares of our common stock at a public offering price of $16.00 per share for aggregate gross proceeds of $102.6 million. The offer and sale of all of the shares in the offering were registered under the Securities Act of 1933, as amended, or the Securities Act, pursuant to a registration statement on Form S-1 (File No. 333-231863), which was declared effective by the SEC on June 27, 2019. Goldman Sachs & Co. LLC and Citigroup Global Markets Inc. acted as representatives of the underwriters for the offering. The offering commenced on June 27, 2019 and did not terminate until the sale of all of the shares offered.

We received aggregate net proceeds from the offering of $93.0 million, after deducting underwriting discounts and commissions of $7.2 million and offering expenses of $2.4 million payable by us. None of the underwriting discounts and commissions or offering expenses were incurred by or paid to our directors or officers or their associates or to persons owning 10% or more of our common stock or to any of our affiliates.

Our planned “Use of Proceeds” as described in the final prospectus dated as of June 27, 2019 and filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on June 28, 2019 included the planned use of approximately $20.0 million to fund the completion of a Phase 1b and Phase 2 clinical trial for the treatment of pain, and approximately $5.0 million to fund the completion of our planned Phase 1b clinical trials for cognitive and negative symptoms in schizophrenia. As previously announced on August 3, 2020, based on the topline results of our Phase 1b clinical trial evaluating the analgesic effects of KarXT on experimentally induced pain in healthy volunteers, we decided not to move forward to develop KarXT in pain. Additionally, we have determined that the planned Phase 1b clinical trial for the cognitive and negative symptoms of schizophrenia is not required based on multiple considerations, including our evaluation of existing data supporting the potential of KarXT to augment traditional antipsychotic drugs. We will instead move forward directly to initiate a Phase 2 clinical trial evaluating the efficacy and safety of KarXT when dosed in conjunction with background antipsychotic treatment to further improve positive symptoms in patients who had not achieved an adequate response on their current antipsychotic treatment. As such, the balance of the $20.0 million allocated to the clinical trials of KarXT for the treatment of pain that has not been spent to date, and the $5.0 million allocated to the planned Phase 1b clinical trials for the cognitive and negative symptoms in schizophrenia have been reallocated to our existing KarXT programs for the treatment of neuropsychiatric disorders.

Other than these reallocations, there has been no material change in our planned use of the net proceeds from the offering as described in the prospectus.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Not applicable.

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	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

+ 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: August 5, 2020

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

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

Date: August 5, 2020

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)) 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) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

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: August 5, 2020

/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)) 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) (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

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: August 5, 2020

/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 June 30, 2020, 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: August 5, 2020

/s/ Steven Paul, M.D.

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

Dated: August 5, 2020

/s/ Troy Ignelzi

Troy Ignelzi
Chief Financial Officer
(Principal Financial Officer)