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, 2023

OR

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

For the transition period from _____ to _____

Commission File Number: 001-38958

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

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

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

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	KRTX	Nasdaq Global Market

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

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

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

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

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

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

As of July 31, 2023, the registrant had 37,667,845 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, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 263,603	$ 248,329
Investment securities, available-for-sale	1,170,874	875,715
Short-term investments, other	2,033	—
Accounts receivable	—	57
Prepaid expenses and other current assets	14,812	30,100
Deferred offering costs	625	568
Total current assets	1,451,947	1,154,769
Restricted cash	—	261
Right-of-use lease assets - operating, net	15,435	4,674
Property and equipment, net	4,182	3,201
Other non-current assets	539	429
Total assets	$ 1,472,103	$ 1,163,334
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,102	$ 2,379
Accrued expenses	35,524	29,285
Current portion of operating lease liability	1,977	2,282
Total current liabilities	38,603	33,946
Operating lease liability, net of current portion	13,833	3,046
Other non-current liabilities	104	104
Total liabilities	52,540	37,096
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, 2023 and December 31, 2022	—	—
Common stock, $0.0001 par value; 150,000,000 shares authorized at June 30, 2023 and December 31, 2022; 37,644,294 and 34,473,905 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	4	3
Additional paid-in capital	2,188,145	1,693,732
Accumulated deficit	(764,944)	(564,207)
Accumulated other comprehensive loss	(3,642)	(3,290)
Total stockholders' equity	1,419,563	1,126,238
Total liabilities and stockholders' equity	$ 1,472,103	$ 1,163,334

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,	
	2023	**2022**	**2023**	**2022**
License and other revenue	$ —	$ 5,278	$ 654	$ 5,278
Operating expenses:				
Research and development	92,490	52,487	177,957	96,293
General and administrative	27,417	17,843	51,670	32,631
Total operating expenses	119,907	70,330	229,627	128,924
Loss from operations	(119,907)	(65,052)	(228,973)	(123,646)
Other income, net:				
Interest income	16,597	490	27,942	727
Sublease income	147	147	294	286
Total other income, net	16,744	637	28,236	1,013
Net loss before income taxes	(103,163)	(64,415)	(200,737)	(122,633)
Income tax provision	—	(528)	—	(528)
Net loss attributable to common stockholders	$ (103,163)	$ (64,943)	$ (200,737)	$ (123,161)
Net loss per share, basic and diluted (Note 6)	$ (2.75)	$ (2.17)	$ (5.55)	$ (4.13)
Weighted average common shares outstanding used in computing net loss per share, basic and diluted	37,524,640	29,896,332	36,170,166	29,851,396

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,	
	2023	2022	2023	2022
Net loss	$ (103,163)	$ (64,943)	$ (200,737)	$ (123,161)
Other comprehensive loss:				
Unrealized losses on available-for-sale investments	(2,027)	(460)	(352)	(2,498)
Comprehensive loss	$ (105,190)	$ (65,403)	$ (201,089)	$ (125,659)

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

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

	Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Value	Capital	Deficit	Loss	Equity
Balance, December 31, 2022	34,473,905	$ 3	$ 1,693,732	$ (564,207)	$ (3,290)	$ 1,126,238
Issuance of common stock upon public offering, net of $23,000 in under-writing discounts and commissions and $281 in offering costs	2,851,299	1	436,719	—	—	436,720
Stock-based compensation expense	—	—	15,507	—	—	15,507
Exercise of common options	72,815	—	5,569	—	—	5,569
Other comprehensive gain	—	—	—	—	1,675	1,675
Net loss	—	—	—	(97,574)	—	(97,574)
Balance, March 31, 2023	37,398,019	$ 4	$ 2,151,527	$ (661,781)	$ (1,615)	$ 1,488,135
Stock-based compensation expense	—	—	18,003	—	—	18,003
Exercise of common options	246,275	—	18,615	—	—	18,615
Other comprehensive loss	—	—	—	—	(2,027)	(2,027)
Net loss	—	—	—	(103,163)	—	(103,163)
Balance, June 30, 2023	37,644,294	$ 4	$ 2,188,145	$ (764,944)	$ (3,642)	$ 1,419,563

	Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Value	Capital	Deficit	Loss	Equity
Balance, December 31, 2021	29,770,558	$ 3	$ 790,391	$ (287,871)	$ (497)	$ 502,026
Stock-based compensation expense	—	—	10,636	—	—	10,636
Exercise of common options	60,700	—	1,282	—	—	1,282
Other comprehensive loss	—	—	—	—	(2,038)	(2,038)
Net loss	—	—	—	(58,218)	—	(58,218)
Balance, March 31, 2022	29,831,258	$ 3	$ 802,309	$ (346,089)	$ (2,535)	$ 453,688
Stock-based compensation expense	—	—	12,132	—	—	12,132
Exercise of common options	101,845	—	4,992	—	—	4,992
Other comprehensive loss	—	—	—	—	(460)	(460)
Net loss	—	—	—	(64,943)	—	(64,943)
Balance, June 30, 2022	29,933,103	$ 3	$ 819,433	$ (411,032)	$ (2,995)	$ 405,409

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,	
	2023	**2022**
Cash flows from operating activities		
Net loss	$ (200,737)	$ (123,161)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	33,510	22,768
Amortization of premiums and accretion of discounts on investment securities	(16,656)	463
Depreciation and amortization expense	796	517
Changes in operating assets and liabilities:		
Accrued interest on investment securities	(1,306)	67
Accounts receivable	57	(3,000)
Prepaid expenses and other current assets	15,288	9,649
Right-of-use assets	1,059	873
Other non-current assets	(110)	76
Accounts payable	(1,310)	1,967
Accrued expenses	5,984	1,544
Operating lease liability	(1,338)	(1,066)
Net cash used in operating activities	(164,763)	(89,303)
Cash flows from investing activities		
Purchases of investment securities	(924,447)	(90,507)
Purchase of short-term investments (certificates of deposit)	(2,033)	—
Maturities of investment securities	646,898	103,199
Acquisition of property and equipment	(1,489)	(451)
Net cash (used in) provided by investing activities	(281,071)	12,241
Cash flows from financing activities		
Proceeds from public offering, net of underwriting discounts and commissions	436,720	—
Payment of offering costs	(57)	(69)
Proceeds from exercise of stock options	24,184	6,274
Net cash provided by financing activities	460,847	6,205
Net increase (decrease) in cash, cash equivalents and restricted cash	15,013	(70,857)
Cash, cash equivalents and restricted cash at beginning of period	248,590	207,214
Cash, cash equivalents and restricted cash at end of period	$ 263,603	$ 136,357
Supplemental disclosures of cash flows information		
Lease liabilities arising from obtaining right-of-use assets	$ 11,820	$ —
Purchases of property and equipment included in accounts payable and accrued expenses	$ 288	$ 53
Deferred offering costs included in accounts payable and accrued expenses	$ —	$ 4

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

Note 1. Nature of the Business and Basis of Presentation

Description of the Business

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

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

In March 2023, the Company completed a follow-on public offering under an effective registration statement on Form S-3 (File No. 333-239657) and a related prospectus supplement in which it issued and sold 2,851,299 shares of common stock, which included the full exercise of the underwriters’ option to purchase an additional 371,908 shares of common stock, at a public offering price of $161.33 per share. The aggregate net proceeds to the Company from the offering, inclusive of proceeds from the option exercise, were $436.7 million after deducting underwriting discounts and commissions of $23.0 million and offering expenses of $0.3 million. On June 21, 2023, the Company filed an automatically effective registration statement on Form S-3 (File No. 333- 272813) with the Securities and Exchange Commission (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’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 $164.8 million for the six months ended June 30, 2023 and had an accumulated deficit of $764.9 million as of June 30, 2023. The Company expects to continue to generate operating losses for the foreseeable future.

The Company expects that its cash, cash equivalents and available-for-sale investments of $1,434.5 million as of June 30, 2023 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.

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 Karuna Therapeutics, Inc. 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, 2023 and the consolidated statements of operations, comprehensive loss, and stockholders' equity for the three and six months ended June 30, 2023 and 2022, and the statements of cash flow for the six months ended June 30, 2023 and 2022 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, 2023 and the results of its operations for the three and six months ended June 30, 2023 and 2022 and cash flows for the six months ended June 30, 2023 and 2022. 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, 2022. The results for the three and six months ended June 30, 2023 are not necessarily indicative of results to be expected for the year ending December 31, 2023, 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, 2022, 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, 2023, there were no material changes to the Company's significant accounting policies, except for the addition of the following policy:

Acquired In-Process Research and Development (IPR&D) and Development Milestones

Acquired IPR&D and development milestones include the initial costs of externally developed IPR&D projects, acquired directly in a transaction other than a business combination, that do not have an alternative future use. Prior to regulatory approval of the compound, initial costs are expensed when incurred, and milestone payment obligations related to these transactions are expensed when the event triggering an obligation to pay the milestone occurs. Milestone payments made upon or after regulatory approval are capitalized and amortized over the remaining useful life of the related asset.

Recently Issued Accounting Pronouncements

New pronouncements issued but not effective until after June 30, 2023 are not expected to have a material impact on the Company's consolidated financial statements.

Note 3. Prepaid Expenses and Other Assets and Accrued Expenses

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

	June 30, 2023	December 31, 2022
Research and development expenses	$ 8,107	$ 25,285
Insurance	12	2,472
Other	6,693	2,343
Total prepaid expenses and other current assets	$ 14,812	$ 30,100

Accrued expenses consisted of the following (in thousands):

	June 30, 2023	December 31, 2022
Research and development expenses	$ 22,334	$ 11,962
Payroll and related expenses	5,952	11,950
Professional fees	6,494	2,943
Other	744	2,430
Total accrued expenses	$ 35,524	$ 29,285

Note 4. Stockholders' Equity

Preferred Stock

On July 2, 2019, in connection with the closing of the Company's initial public offering of its common stock ("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. Through June 30, 2023, no preferred stock has been issued.

Common Stock

As of June 30, 2023, 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, 2023, no cash dividends have been declared or paid.

As of June 30, 2023, there were 37,644,294 shares of common stock outstanding.

Note 5. Zai License Agreement

Terms of Agreement

On November 8, 2021, the Company and Zai Lab (Shanghai) Co., Ltd. ("Zai") entered into a license agreement (the "Zai License Agreement"), pursuant to which Karuna granted to Zai the right to exclusively develop, manufacture and commercialize KarXT in Greater China, including mainland China, Hong Kong, Macau, and Taiwan (the "Licensed Territory"). Zai will fund substantially all development, regulatory, and commercialization activities in the Licensed Territory.

Under the terms of the Zai License Agreement, the Company received a non-refundable $35.0 million upfront payment and payment of certain taxes on its behalf. The Zai License Agreement also provides that the Company is eligible to receive total development and regulatory milestone payments of up to $80.0 million, total sales milestone payments of up to $72.0 million and low double-digit to high-teens tiered royalties based on annual net sales of KarXT in the Licensed Territory, subject to reduction under specified circumstances. Receipt of sales milestone payments and royalties are not contingent on any further participation by the Company in the development of KarXT in the Licensed Territory.

The Zai License Agreement will expire upon the latest of the following dates with respect to the last licensed product in any region in the Licensed Territory: (i) the date of expiration of the last valid claim covering such licensed product in such region, (ii) the date that is a specific period after the date of the first commercial sale of such licensed product in such region and (iii) the expiration date of any regulatory exclusivity for such licensed product in such region. Zai may terminate the Zai License Agreement for convenience, subject to the terms thereto, by providing written notice to the Company, which termination will be effective following a prescribed notice period. In addition, the Company may terminate the Zai License Agreement under specified circumstances if Zai or certain other parties challenge the Company's patent rights or if Zai or its affiliates fail to complete certain development activities with respect to the licensed product for a specified period of time, subject to specified exceptions. Either party may terminate the Zai License Agreement for the other party's uncured material breach, with a customary notice and cure period, or insolvency.

After termination or expiration, the Company is entitled to retain a worldwide, exclusive, and perpetual license from Zai to exploit the licensed product, which license would be non-exclusive after expiration (but not termination), subject to a reasonable royalty to be agreed by the parties if terminated for the Company's uncured material breach.

Revenue Recognition

The Company concluded that the distinct units of account within the agreement are reflective of a vendor-customer relationship and therefore within the scope of ASC 606, Revenue From Contracts with Customers.

Under the provisions of ASC 606, the Company identified one performance obligation. The Company provided an exclusive license to intellectual property, bundled with the associated know-how and certain professional services that are not substantive.

Under the terms of the Zai License Agreement, Zai has the sole right to manufacture, or have manufactured, KarXT for use in development and commercialization in the Licensed Territory. At the election of Zai, the Company may supply KarXT to Zai at the fully burdened manufacturing cost plus a specified margin, as defined within the Zai License Agreement. This provision was determined to be an option to acquire additional goods or services at a price that approximates the stand-alone selling price for that good or service, and therefore does not represent a material right, or separate performance obligation, within the context of the Zai License Agreement. For the six months ended June 30, 2023, the Company recognized $0.7 million in revenue associated with sales of clinical drug supply to Zai. For the three months ended June 30, 2023, and for the three and six months ended June 30, 2022, no revenue was recognized for sales of clinical drug supply.

The Company determined the transaction price of the Zai License Agreement was equal to $37.0 million, which includes the upfront fee of $35.0 million and payments to taxing authorities on the Company's behalf. In estimating the stand-alone selling price, the Company determined that there were no significant financing components, noncash consideration or amounts that may be refunded to the customer, and as such the total unconstrained consideration of $37.0 million was included in the total transaction price.

License of Intellectual Property. The license to the Company's intellectual property represents a distinct performance obligation. The license and associated know-how was transferred to Zai in the fourth quarter of 2021 to satisfy this performance obligation. The Company allocated the full transaction price to the license of the Company's intellectual property and accordingly recognized revenue of $37.0 million as license revenue in its Consolidated Statement of Operations for the year ended December 31, 2021.

Milestone Payments. The potential development and regulatory milestone payments, as well as sales milestone payments, are paid upon achievement of certain milestones as defined in the Zai License Agreement. For the three and six months ended June 30, 2023, there was no revenue related to milestone payments recognized pursuant to the Zai License Agreement. For the three and six months ended June 30, 2022, the Company recognized $5.3 million in license revenue for certain development milestones and related payments to taxing authorities on the Company's behalf. The Company recorded $0.5 million in foreign tax expense to income tax provision for the three and six months ended June 30, 2022.

For all remaining development and regulatory milestones, which, as of June 30, 2023, can total up to $70.0 million, it was determined that their achievement is highly dependent on factors outside of the Company's control. These payments have been fully constrained until the Company concludes that achievement of the milestone is probable, and that recognition of revenue related to the milestone will not result in a significant reversal in amounts recognized in future periods, and as such have been excluded from the transaction price. At the end of each subsequent reporting period, the Company will re-evaluate the probability of achievement of each milestone and any related constraint and, if necessary, adjust its estimate of the overall transaction price.

As of June 30, 2023, the Company has not recognized any revenue associated with sales milestones.

Royalties. Any consideration related to royalties will be recognized if and when the related sales occur, as they were determined to relate predominantly to the license granted to Zai and, therefore, have also been excluded from the transaction price. As of June 30, 2023, the Company has not recognized any revenue associated with royalties.

There was no deferred revenue as of June 30, 2023 or December 31, 2022 related to the Zai License Agreement.

Note 6. 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, 2023 and 2022 (in thousands, except share and per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Net Loss	$ (103,163)	$ (64,943)	$ (200,737)	$ (123,161)
Weighted-average shares used in computing net loss per share	37,524,640	29,896,332	36,170,166	29,851,396
Net loss per share, basic and diluted	$ (2.75)	$ (2.17)	$ (5.55)	$ (4.13)

The Company's potentially dilutive securities, which consist of stock options and restricted stock units ("RSUs"), have been excluded from the computation of diluted net loss per share because including them would have had an anti-dilutive impact. 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.

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:

	June 30,	
	2023	2022
Stock options to purchase common stock	5,590,892	5,912,840
Restricted stock units	247,003	—
	5,837,895	5,912,840

Note 7. License Agreements

Acquisition of KAR-2618 and other TRPC4/5 candidates

In January 2023, the Company entered into an exclusive license agreement (the "GFB Agreement"), with GFB (ABC), LLC ("GFB"), assignee of the assignment estate of Goldfinch Bio, Inc., pursuant to which GFB granted to the Company the exclusive right and license to develop, manufacture, and commercialize GFB's TRPC4/5 candidates (the "GFB Compounds"), including the lead clinical-stage candidate known as KAR-2618 (formerly GFB-887). The Company agreed to use commercially reasonable efforts to develop, obtain regulatory approval for, and commercialize at least one licensed product that contains or comprises a GFB Compound in at least two indications in the United States.

Under the terms of the GFB Agreement, the Company paid to GFB a $15.0 million upfront payment, and agreed to pay a total of up to $520.0 million for each GFB Compound upon the achievement of certain development, regulatory and commercial milestones with respect to such GFB Compound, of which $110.0 million, $150.0 million, and $260.0 million are related to development, regulatory, and commercial sales milestones, respectively. The Company also agreed to pay GFB a flat low-single digit royalty on aggregate net sales of each licensed product on a country-by-country basis until the expiration of the applicable royalty term, which ends on the later of (i) the expiration date of the last valid claim covering the licensed product in such country, (ii) the expiration date of regulatory exclusivity with respect to such licensed product in such country, and (iii) the date that is a specific period after the first commercial sale of such licensed product in such country. The royalty rate is subject to reduction on a licensed product-by-licensed product and country-by-country basis under certain circumstances. In the event that the Company sublicenses to a third party any of the rights to the licensed intellectual property granted under the GFB Agreement, the Company will be obligated to pay GFB royalties within the range of 25% to 35% on any consideration the Company receives from the sublicensee, excluding royalties and certain other payments.

Unless earlier terminated, the GFB Agreement will expire on the expiration of the last to expire royalty term. Unless the GFB Agreement is earlier terminated, on expiration of each applicable royalty term, the Company will have a fully paid-up, irrevocable and perpetual license to develop, manufacture and commercialize each applicable licensed product in the applicable country. Either party may terminate the GFB Agreement for the other party's material breach, following a customary notice and cure period, or insolvency. The Company may terminate the GFB Agreement for any reason upon 90 days written notice to GFB.

The upfront payment of $15.0 million was accounted for as an asset acquisition and recorded within research and development expense in the consolidated statement of operations for the six months ended June 30, 2023, as KAR-2618 is prior to regulatory approval and has no alternative future use. The Company did not incur or recognize any milestone payments under the GFB Agreement during the three and six months ended June 30, 2023.

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 $16.0 million upon the achievement of specified regulatory milestones and up to an aggregate of $54.0 million in commercial milestones. In addition, the Company is obligated to pay Eli Lilly tiered royalties, at rates in the low to mid single-digit percentages, on the worldwide net sales of any commercialized product on a country-by-country basis until the expiration of the applicable royalty term, which is the longer of six years from the date of first commercial sale of each licensed product within a country or data package exclusivity in such country. During the royalty term, Eli Lilly is prohibited from granting any third party rights to the patents, regulatory documentation, data records and materials that have been licensed to the Company under the Lilly License Agreement.

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

The initial upfront payment of $0.1 million was expensed when incurred in May 2012. As of June 30, 2023, no regulatory or commercial 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 $10.0 million upon the achievement of specified development and regulatory milestones. In addition, the Company is obligated to pay PureTech Health low single-digit royalties on the worldwide net sales of any commercialized product covered by the licenses granted under the Patent License Agreement.

In the event that the Company sublicenses any of the patent rights granted under the Patent License Agreement, the Company will be obligated to pay PureTech Health royalties within the range of 15% to 25% on any income the Company receives from the sublicensee, excluding royalties.

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

The Company incurred no expenses related to the Patent License Agreement during the three and six months ended June 30, 2023 and 2022. As of June 30, 2023, the remaining development and regulatory milestone payments under the Patent License Agreement total up to $8.0 million. The Company had no outstanding liabilities to PureTech Health related to the Patent License Agreement as of June 30, 2023 and December 31, 2022.

Note 8. Stock-based Compensation

In September 2009, the Company’s board of directors approved the 2009 Stock Incentive Plan (the “2009 Plan”) which provided for the grant of incentive stock options to employees and non-statutory stock options to directors, consultants, and non-employees of the Company. The 2009 Plan terminated in July 2019 effective upon the completion of the Company’s IPO. No additional options will be granted under the 2009 Plan. As of June 30, 2023, there were 2,032,757 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, RSUs, 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 underlying awards that expire, or are terminated, surrendered, canceled or forfeited without having been fully exercised under the 2009 Plan will be added to the shares of common stock available for issuance under the 2019 Plan. In addition, 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, 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. As of June 30, 2023, there were 2,730,882 common shares available for issuance, 3,558,135 options outstanding, and 247,003 RSUs outstanding under the 2019 Plan.

Stock Options

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

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

	Number of Shares	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2022	5,570,355	$ 63.82	7.2	$ 744,097
Granted	485,456	194.50		
Exercised	(319,090)	75.79		
Forfeited	(145,829)	140.49		
Outstanding as of June 30, 2023	5,590,892	$ 72.48	6.9	$ 809,191
Options vested and expected to vest as of June 30, 2023	5,590,892	$ 72.48	6.9	$ 809,191
Options exercisable as of June 30, 2023	3,807,562	$ 38.22	6.1	$ 680,144

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 publicly traded stock price of the Company's common stock as of June 30, 2023.

As of June 30, 2023, there was $139.6 million of unrecognized compensation cost, which is expected to be recognized over a weighted-average period of 2.8 years.

The weighted-average fair values of options granted during the six months ended June 30, 2023 and 2022 was $114.35 and $67.55, respectively. The intrinsic value of options exercised during the six months ended June 30, 2023 and 2022 was $42.7 million and $13.3 million, respectively.

Restricted Stock Units

RSUs are granted to certain employees and are payable in shares of our common stock. RSU shares are accounted for at fair value based upon the closing stock price on the date of grant. The corresponding expense is amortized over the vesting period, which is typically four years.

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

	Number of Shares	Weighted-Average Grant Date Fair Value
Unvested as of December 31, 2022	—	$ —
Granted	251,418	194.47
Vested	—	—
Forfeited	(4,415)	192.10
Unvested as of June 30, 2023	247,003	$ 194.51

As of June 30, 2023, the total remaining unrecognized compensation cost related to nonvested RSUs was $43.7 million, which will be amortized over the weighted-average remaining requisite service period of 3.5 years.

Stock-based Compensation Expense

Stock-based compensation expense is classified in the statements of operations for the three and six months ended June 30, 2023 and 2022 as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Research and development	$ 10,240	$ 5,179	$ 19,075	$ 9,709
General and administrative	7,763	6,953	14,435	13,059
Total stock-based compensation expense	$ 18,003	$ 12,132	$ 33,510	$ 22,768

Note 9. Fair Value of Financial Assets and Liabilities

The following tables present information about the Company's assets as of June 30, 2023 and December 31, 2022 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, 2023 Using			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market fund	$ 202,009	$ —	$ —	$ 202,009
Commercial paper	—	34,038	—	34,038
Short-term investments, other:				
Certificate of deposit	—	2,033	—	2,033
Investment securities:				
US Treasuries	678,675	—	—	678,675
US government agencies	208,917	—	—	208,917
Corporate debt securities	—	40,979	—	40,979
Commercial paper	—	242,303	—	242,303
Total	$ 1,089,601	$ 319,353	$ —	$ 1,408,954

	Fair Value Measurement at December 31, 2022 Using			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market fund	$ 160,158	$ —	$ —	$ 160,158
Commercial paper	—	61,277	—	61,277
Investment securities:				
US Treasuries	423,688	—	—	423,688
US government agencies	210,188	—	—	210,188
Corporate debt securities	—	63,728	—	63,728
Commercial paper	—	178,111	—	178,111
Total	$ 794,034	$ 303,116	$ —	$ 1,097,150

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

Certificates of deposit held for investment with an original maturity greater than three months and less than twelve months are carried at amortized cost and reported as short-term investments on the Company's consolidated balance sheet, which approximates their fair value based on Level 2 inputs.

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

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

	June 30, 2023			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
US Treasuries (due within one year)	$ 572,486	$ 22	$ (1,626)	$ 570,882
US Treasuries (due after one year and less than three years)	108,695	—	(903)	107,792
US government agencies (due within one year)	169,322	49	(410)	168,961
US government agencies (due after one year and less than three years)	40,343	—	(387)	39,956
Corporate debt securities (due within one year)	32,456	—	(100)	32,356
Corporate debt securities (due after one year and less than three years)	8,715	—	(91)	8,624
Commercial paper (due within one year)	242,499	—	(196)	242,303
Total	$ 1,174,516	$ 71	$ (3,713)	$ 1,170,874

	December 31, 2022			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
US Treasuries (due within one year)	$ 329,533	$ 17	$ (2,044)	$ 327,506
US Treasuries (due after one year and less than three years)	96,802	—	(620)	96,182
US government agencies (due within one year)	178,319	54	(108)	178,265
US government agencies (due after one year and less than three years)	32,104	—	(181)	31,923
Corporate debt securities (due within one year)	51,952	1	(170)	51,783
Corporate debt securities (due after one year and less than three years)	11,983	—	(38)	11,945
Commercial paper (due within one year)	178,312	16	(217)	178,111
Total	$ 879,005	$ 88	$ (3,378)	$ 875,715

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

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

Unrealized losses on available-for-sale securities presented in the previous table have not been recognized in the consolidated statements of operations because the securities are high credit quality, investment grade securities that the Company does not intend to sell and will not be required to sell prior to their anticipated recovery, and the decline in fair value is attributable to factors other than credit losses. Based on its evaluation, the Company determined its year-to-date credit losses related to its available-for-sale securities were immaterial at June 30, 2023 and December 31, 2022.

Note 10. Commitments and Contingencies

Leases

The Company has 25,445 square feet of office space on High Street in Boston, Massachusetts (“High Street Sublease”). The term of the sublease extends from April 1, 2021 through December 31, 2025 and provides for escalating annualized base rent payments starting at approximately $1.5 million and increasing to $1.6 million in the final year of the sublease.

In April 2023, the Company entered into an agreement ("High Street Lease") to lease approximately 50,890 square feet of additional office space located at 99 High Street in Boston, MA. The Company took possession of the premises in June 2023. The initial term of the lease is ten years from the date alterations are substantially complete, estimated to occur no later than April 2024, with the option to renew for an additional five-year term. Annual base rent under the lease is approximately $3.5 million and is subject to annual increases in accordance with the terms of the lease agreement. Lease payments begin on the earlier of January 1, 2025 or nine months from the date alterations are substantially complete. The Company recognized a right-of-use ("ROU") asset and corresponding lease liability of approximately $11.7 million and $11.4 million, respectively, on its consolidated balance sheet as of June 8, 2023 upon commencement of the High Street Lease. The lease provides for a tenant improvement allowance of $9.2 million, which was recognized as a reduction in the ROU asset and lease liability recognized at commencement, as the Company is reasonably certain to incur reimbursable costs related to alterations equal to or exceeding this amount. The option to renew the lease for an additional five-year term was excluded from the determination of lease liabilities arising from obtaining the ROU assets, as it was not considered reasonably certain of being exercised at commencement. Upon signing of the High Street Lease, the Company was also required to pay the first full monthly installment of base rent of $0.3 million, which was included as an adjustment to the ROU asset recognized upon commencement of the lease. The agreement requires a security deposit of $2.0 million, which is in the form of a line of credit collateralized by a certificate of deposit with a six month maturity which will be continually reinvested for the duration of the lease term. This certificate of deposit has been recorded within "short-term investments, other" on the consolidated balance sheet as of June 30, 2023.

The Company also has office space at 33 Arch Street in Boston, MA ("Arch Street Lease"), which expires in December 2023, as amended. The associated space is entirely subleased to third parties through the remainder of the current lease term ("Arch Street Subleases"). We additionally have office space in Carmel, IN.

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.

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

	Six Months Ended June 30,	
	2023	2022
Lease Cost		
Operating lease cost	$ 1,300	$ 1,075
Short-term lease cost	—	—
Sublease income	(294)	(286)
Total lease cost	$ 1,006	$ 789
Other Information		
Cash paid for amounts included in the measurement of lease liabilities	$ 1,579	$ 1,269
Operating lease liabilities arising from obtaining right-of-use assets	11,820	—
Weighted-average remaining lease term	8.98 years	3.06 years
Weighted-average discount rate	10.38%	5.88%

The following is a maturity analysis of the remaining annual undiscounted cash flows of the operating lease liabilities and a reconciliation to present value of lease liabilities as of June 30, 2023 (in thousands):

Year ended:		
December 31, 2023	$	1,285
December 31, 2024		1,704
December 31, 2025		4,818
December 31, 2026		3,591
December 31, 2027		3,698
Thereafter		29,188
Total future minimum lease payments		44,284
Less lease incentive		(9,184)
Less imputed interest		(19,290)
Present value of lease liabilities	$	15,810

Cash inflows related to the $9.2 million lease incentive under the High Street Lease are expected to be received in the years ended December 31, 2023 and 2024 and are expected to exceed cash outflows relating to our operating leases during those years.

The annual undiscounted cash flows to be received from subleases is $0.3 million as of June 30, 2023. The Arch Street Lease and Arch Street Subleases mature in December 2023 and will not be extended.

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 indemnifications. 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, 2023.

Note 11. 401(k) Savings Plan

The Company has a 401(k) retirement plan in which substantially all U.S. employees are eligible to participate. Eligible employees may elect to contribute up to the maximum limits, as set by the Internal Revenue Service, of their eligible compensation. The total contribution expense for the Company was $1.0 million and $0.5 million for the six months ended June 30, 2023 and 2022, respectively.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our audited consolidated financial statements and related notes for the year ended December 31, 2022 included in our Annual Report on Form 10-K, or the Annual Report, filed with the Securities and Exchange Commission, or the SEC, on February 23, 2023. This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements are often identified by the use of words such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "project," "will," "would" or the negative or plural of these words or similar expressions or variations. Such forward-looking statements are subject to a number of risks, uncertainties, assumptions and other factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified and discussed in the section titled "Risk Factors," set forth in Part II, Item 1A of this Quarterly Report on Form 10-Q, Part I, Item 1A of our Annual Report, and in subsequent SEC filings. You should not rely upon forward-looking statements as predictions of future events. Furthermore, such forward-looking statements speak only as of the date of this report. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

Overview

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

We are initially developing KarXT for the treatment of acute psychosis in adults with schizophrenia, as well as for the treatment of psychosis in Alzheimer's disease, or AD. KarXT combines xanomeline, a muscarinic receptor agonist that preferentially stimulates M1 and M4 muscarinic receptors, and trospium, an approved muscarinic receptor antagonist that does not measurably cross the blood-brain barrier, confining its effects to peripheral tissues. M1 and M4 muscarinic receptors are the receptor subtypes believed to mediate the antipsychotic and procognitive effects of xanomeline and other muscarinic agonists. Results from preclinical studies and clinical trials conducted by third parties support the hypothesis that xanomeline can reduce psychosis and improve cognition. To our knowledge, xanomeline is the only muscarinic orthosteric agonist that has demonstrated therapeutic benefit in clinical trials in both schizophrenia and AD. Like all muscarinic orthosteric agonists studied to date, however, xanomeline's tolerability has been limited by side effects arising from muscarinic receptor stimulation in peripheral tissues, which leads to nausea, vomiting, diarrhea and increased salivation and sweating, collectively referred to as cholinergic adverse events. Trospium is a muscarinic receptor antagonist approved in the United States and Europe for the treatment of overactive bladder that inhibits all five muscarinic receptor subtypes in peripheral tissues. We believe that the combination of xanomeline and trospium in KarXT has the potential to preferentially stimulate M1 and M4 muscarinic receptors in the brain without stimulating muscarinic receptors in peripheral tissues in order to achieve meaningful therapeutic benefit in patients with psychotic and cognitive disorders.

The EMERGENT program is our clinical program evaluating KarXT for the treatment of schizophrenia as a monotherapy and includes our completed positive Phase 2 EMERGENT-1 and Phase 3 EMERGENT-2 and EMERGENT-3 trials, as well as two ongoing Phase 3 trials evaluating the long-term safety of KarXT:

- EMERGENT-4: A 52-week outpatient, open-label extension trial evaluating the long-term safety and tolerability of KarXT in adults with schizophrenia who completed EMERGENT-2 or EMERGENT-3. Enrollment for this trial completed in the fourth quarter of 2022 and topline data is anticipated in 2024.
- EMERGENT-5: A 52-week outpatient, open-label trial conducted in the United States and Puerto Rico evaluating the long-term safety and tolerability of KarXT in adults with schizophrenia who were not enrolled in EMERGENT-2 or EMERGENT-3. Enrollment for this trial completed in the second quarter of 2023 and topline data is anticipated in 2024.

Following a pre-New Drug Application, or pre-NDA, meeting with the U.S. Food and Drug Administration, or FDA, in April 2023, we remain on track to submit our NDA for KarXT for the treatment of schizophrenia to the FDA in the third quarter of 2023. If approved, we are targeting a potential commercial launch of KarXT for the treatment of schizophrenia in the second half of 2024.

In the first quarter of 2023, we initiated a Phase 1b Ambulatory Blood Pressure Monitoring, or ABPM, trial to further characterize the impact of KarXT on blood pressure. Enrollment for this trial completed in the second quarter of 2023, and we expect topline data in the fourth quarter of 2023.

Given the unique mechanism of action of KarXT in comparison to existing standard of care therapies, we believe there is the potential for therapeutic benefit as both a monotherapy and as an adjunctive therapy for the treatment of schizophrenia. In November 2021, we initiated our Phase 3 ARISE trial evaluating the efficacy and safety of KarXT compared to placebo as an adjunctive treatment in adults with schizophrenia who have an inadequate response to their current antipsychotic therapy. This six-week, 1:1 randomized, double-blind, placebo-controlled Phase 3 outpatient trial is designed to enroll approximately 400 adults with schizophrenia who have not achieved an adequate response to their current atypical antipsychotic treatment. The primary outcome measure of the trial is change in Positive and Negative Syndrome Scale, or PANSS, total score of KarXT compared to placebo at week 6. Upon completion of the trial at week 6, participants have the opportunity to enroll in our ARISE-2 trial, an ongoing 52-week outpatient, open-label extension trial evaluating the long-term safety and tolerability of KarXT when dosed with atypical antipsychotic treatment. We anticipate topline data from the ARISE trial in the second half of 2024.

We are also developing KarXT as a potential treatment for psychosis related to AD. The ADEPT program, which is the clinical program evaluating KarXT as a potential treatment for psychosis related to AD, consists of three Phase 3 trials: ADEPT-1, ADEPT-2 and ADEPT-3. The Phase 3 ADEPT-1 trial is evaluating the efficacy and safety of KarXT compared to placebo in adults with moderate to severe psychosis related to AD. Enrollment for this trial began in the third quarter of 2022 and topline data is anticipated in 2025. This trial consists of a 12-week, single-blind treatment period, followed by a 26-week, double-blind, randomized withdrawal period in which subjects who meet the response criteria will be randomized to receive KarXT or placebo. The single-blind treatment period is designed to enroll approximately 400 adults with AD between 55 and 90 years old, with moderate to severe hallucinations or delusions, who are living at home or at an assisted living facility. The primary objective of this trial is to evaluate relapse prevention as measured by time from randomization to relapse during the 26-week, double-blind period. Our Phase 3 ADEPT-2 trial will be a 14-week, flexible-dose, double-blind, placebo-controlled trial evaluating the efficacy and safety of KarXT versus placebo. We expect to initiate ADEPT-2 in the second half of 2023, with topline data anticipated in 2025. Our Phase 3 ADEPT-3 trial is an open-label extension trial of ADEPT-1 and ADEPT-2 evaluating the long-term safety of KarXT in adults with psychosis related to AD. Enrollment for this trial commenced in the third quarter of 2023.

In January 2023, we entered into an exclusive global license agreement for Goldfinch Bio, Inc.'s, or Goldfinch Bio's, investigational transient receptor potential canonical 4 and 5 (TRPC4/5) channel candidates, including the lead clinical-stage TRPC4/5 candidate, KAR-2618 (formerly GFB-887), after confirming select properties of KAR-2618 under a material transfer agreement. KAR-2618 has been dosed in over 100 humans across Goldfinch Bio's clinical trials. We intend to develop KAR-2618 for the treatment of mood and anxiety disorders, and plan to provide details regarding the expected development of KAR-2618 in the second half of 2023.

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, preparing for the potential commercialization of KarXT, and providing general and administrative support for these activities.

We have never generated revenue from product sales and have incurred significant net losses since inception. Our net losses were $200.7 million and $123.2 million for the six months ended June 30, 2023 and 2022, respectively. As of June 30, 2023, we had an accumulated deficit of $764.9 million. Our net losses may fluctuate significantly from quarter to quarter and year to year. We expect to incur significant expenses and increasing operating losses for the foreseeable future. We anticipate that our operating expenses and capital expenditures will increase substantially, particularly as we:

- invest significantly to further develop and potentially commercialize KarXT for our current and future indications;
- advance additional product candidates, such as KAR-2618, 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, 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, manufacturing 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 may 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, 2023, we had cash, cash equivalents and available-for-sale investments of $1,434.5 million. We believe that our existing cash, cash equivalents and available-for-sale investments will be sufficient to meet our anticipated operating and capital expenditure requirements through the end of 2026. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See “Liquidity and Capital Resources.”

Components of Our Results of Operations

Revenue

To date, we have not generated any revenue from product sales. 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. 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.

Our revenue to date has been derived from payments under our license agreement, or the Zai License Agreement, with Zai Lab (Shanghai) Co., Ltd., or Zai. We may generate additional revenue in the future from payments under the Zai License Agreement or as a result of any other license or collaboration agreements we may enter into for any of our product candidates or intellectual property. For the six months ended June 30, 2023, we recognized revenue of $0.7 million under the Zai License Agreement associated with the sale of clinical drug supply to Zai and did not recognize any revenue for the three months ended June 30, 2023. We cannot provide assurance as to the timing of future milestone or royalty payments under the Zai License Agreement, or that we will receive any of these payments at all. We generated $5.3 million of revenue under the Zai License Agreement in the three and six months ended June 30, 2022.

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 license agreements related to in-process R&D or 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.

Research and development costs directly related to our clinical development activities, such as fees paid to consultants, central laboratories, contractors, CMOs and CROs, are tracked on an indication-by-indication basis. Other costs that are indirectly related to our clinical development activities, such as formulation and CMC, preclinical, discovery and other unallocated expenses in the table below, 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. Unallocated expenses primarily relate to personnel or other consulting costs which are deployed across multiple projects under development. For the six months ended June 30, 2023, unallocated expenses also include $15.0 million in license fees related to the acquisition of KAR-2618 paid in February 2023. The following table summarizes our research and development expenses:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
	(in thousands)		(in thousands)	
Schizophrenia clinical trials	$ 36,141	$ 24,195	$ 58,095	$ 44,999
Dementia-related psychosis clinical trials	10,560	1,262	14,138	1,948
CMC and formulation	4,697	7,820	16,426	13,373
Preclinical	5,211	819	6,194	996
Medical affairs	2,990	394	5,289	683
Discovery	3,842	3,639	8,104	8,349
Unallocated expenses	29,049	14,358	69,711	25,945
Total research and development expense	$ 92,490	$ 52,487	$ 177,957	$ 96,293

We expect our research and development expenses to continue to increase for the foreseeable future as we continue to invest in research and development activities related to developing our product candidates, 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 our early stage and future product candidates, such as KAR-2618;
- 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;
- continue to assess the impact of the ongoing and evolving COVID-19 pandemic on the ability to execute research and development activities;
- add equipment and physical infrastructure to support our research and development; and
- acquire or in-license other product candidates and technologies.

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

We do not believe that it is possible at this time to accurately project total indication-specific expenses through commercialization. There are numerous factors associated with the successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control will impact our clinical development programs and plans.

General and Administrative Expenses

General and administrative expenses consist primarily of employee-related costs for personnel in executive, commercial, 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, and costs incurred as we prepare for commercialization. Personnel costs consist of salaries, short-term incentive compensation, benefits, travel expense and stock-based compensation expense. The following table summarizes our general and administrative expenses:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
	(in thousands)		(in thousands)	
Personnel related expenses (including stock-based compensation)	$ 14,670	$ 10,589	$ 27,344	$ 20,758
Professional and consultant fees	7,989	4,353	15,052	6,229
Other	4,758	2,901	9,274	5,644
Total general and administrative expense	$ 27,417	$ 17,843	$ 51,670	$ 32,631

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

Other Income, Net

Other income, net, consists of interest income from our cash equivalents, available-for-sale investments and other short-term investments, and sublease income recognized in connection with the sublease of office space. The following table summarizes our other income, net:

	Three Months Ended June 30,		For the Six Months Ended June 30,	
	2023	2022	2023	2022
	(in thousands)		(in thousands)	
Interest income	$ 16,597	$ 490	$ 27,942	$ 727
Sublease income	147	147	294	286
Total other income, net	$ 16,744	$ 637	$ 28,236	$ 1,013

Results of Operations

Comparison of the three months ended June 30, 2023 and 2022

	Three Months Ended June 30,		
	2023	2022	Change
	(in thousands)		
License and other revenue	$ —	$ 5,278	$ (5,278)
Operating expenses:			
Research and development	92,490	52,487	40,003
General and administrative	27,417	17,843	9,574
Total operating expenses	119,907	70,330	49,577
Loss from operations	(119,907)	(65,052)	(54,855)
Total other income, net	16,744	637	16,107
Income tax provision	—	(528)	528
Net loss attributable to common stockholders	$ (103,163)	$ (64,943)	$ (38,220)

Research and Development Expenses

	Three Months Ended June 30,		
	2023	2022	Change
	(in thousands)		
Direct research and development expenses:			
Schizophrenia clinical trials	$ 36,141	$ 24,195	$ 11,946
Dementia-related psychosis clinical trials	10,560	1,262	9,298
CMC and formulation	4,697	7,820	(3,123)
Preclinical	5,211	819	4,392
Medical affairs	2,990	394	2,596
Discovery	3,842	3,639	203
Unallocated expenses:			
Personnel related expenses (including stock-based compensation)	23,617	12,305	11,312
License fees	—	—	—
Consultant fees and other expenses	5,432	2,053	3,379
Total research and development expense	$ 92,490	$ 52,487	$ 40,003

Expenses related to our schizophrenia clinical trials increased by $12.0 million, primarily due to expenses related to our ongoing EMERGENT and ARISE Phase 3 trials as well as our ABPM Phase 1b trial. The increase of $9.3 million in expenses related to our dementia-related psychosis, or DRP, clinical trials is primarily driven by our ongoing ADEPT-1 Phase 3 trial which initiated in the third quarter of 2022. The decrease of $3.1 million in formulation and CMC expenses is primarily due to the timing of manufacturing activities in 2023. The increase of $4.4 million in expenses related to preclinical activities is primarily due to the timing and execution of studies for KarXT and early pipeline candidates. The increase of $0.2 million in discovery costs is due to an increase in costs associated with our portfolio of discovery programs, including ongoing collaborations with Charles River Labs and Psychogenics, Inc. The increase of $11.3 million in personnel related costs was primarily a result of an increase in headcount and an increase of $5.1 million related to stock-based compensation expense. The increase of $3.4 million in consultant fees and other expenses was due to an increase in consulting costs not specifically allocated to discovery, preclinical, clinical, formulation and CMC activities.

General and Administrative Expenses

	Three Months Ended June 30,		
	2023	2022	Change
	(in thousands)		
Personnel related expenses (including stock-based compensation)	$ 14,670	$ 10,589	$ 4,081
Professional and consultant fees	7,989	4,353	3,636
Other	4,758	2,901	1,857
Total general and administrative expense	$ 27,417	$ 17,843	$ 9,574

The increase of $4.1 million in personnel related costs was primarily a result of an increase in headcount and an increase of $0.8 million related to stock-based compensation expense. The increase of $3.6 million in professional and consultant fees was primarily due to an increase in pre-commercial costs, accounting fees, legal costs and consulting fees related to our ongoing business activities. The increase of $1.9 million in other costs was primarily due to infrastructure and administrative related costs to support increased headcount.

Other Income, Net

	Three Months Ended June 30,		
	2023	2022	Change
	(in thousands)		
Interest income	$ 16,597	$ 490	$ 16,107
Sublease income	147	147	—
Total other income, net	$ 16,744	$ 637	$ 16,107

Interest income is attributable to interest earned on our cash equivalents and available-for-sale investments. The increase of $16.1 million in interest income is primarily due to an increase in our cash equivalents and investment securities held, as well as an increase in interest rates on such instruments, during the three months ended June 30, 2023 compared to the three months ended June 30, 2022.

Comparison of the six months ended June 30, 2023 and 2022

	Six Months Ended June 30,		
	2023	2022	Change
	(in thousands)		
License and other revenue	$ 654	$ 5,278	$ (4,624)
Operating expenses:			
Research and development	177,957	96,293	81,664
General and administrative	51,670	32,631	19,039
Total operating expenses	229,627	128,924	100,703
Loss from operations	(228,973)	(123,646)	(105,327)
Total other income, net	28,236	1,013	27,223
Income tax provision	—	(528)	528
Net loss attributable to common stockholders	$ (200,737)	$ (123,161)	$ (77,576)

Research and Development Expenses

	Six Months Ended June 30,		
	2023	2022	Change
	(in thousands)		
Direct research and development expenses:			
Schizophrenia clinical trials	$ 58,095	$ 44,999	$ 13,096
Dementia-related psychosis clinical trials	14,138	1,948	12,190
CMC and formulation	16,426	13,373	3,053
Preclinical	6,194	996	5,198
Medical affairs	5,289	683	4,606
Discovery	8,104	8,349	(245)
Unallocated expenses:			
Personnel related expenses (including stock-based compensation)	44,845	23,257	21,588
License fees	15,000	—	15,000
Consultant fees and other expenses	9,866	2,688	7,178
Total research and development expense	$ 177,957	$ 96,293	$ 81,664

Expenses related to our schizophrenia clinical trials increased by $13.1 million, primarily due to expenses related to close out costs for our EMERGENT-3 trial, and costs related to our ongoing EMERGENT and ARISE Phase 3 trials as well as our ABPM Phase 1b trial. The increase of $12.2 million in expenses related to our DRP clinical trials is primarily driven by our ongoing ADEPT-1 Phase 3 trial which initiated in the third quarter of 2022. The increase of $3.1 million in formulation and CMC expenses is primarily due to an increase in manufacturing activities in 2023 to obtain sufficient supply of KarXT to support our planned NDA submission and potential commercialization, as well as current and future clinical trial activities. The increase of $5.2 million in expenses related to preclinical activities is primarily due to the timing and execution of studies for KarXT and early pipeline candidates. The increase of $0.3 million in discovery costs is due to the timing of activities associated with our portfolio of discovery programs, including ongoing collaborations with Charles River Labs and Psychogenics, Inc. The increase of $21.6 million in personnel related costs was primarily a result of an increase in headcount and an increase of $9.4 million related to stock-based compensation expense. License fees of $15.0 million are due to the upfront payment made in connection with the license agreement for Goldfinch Bio's TRPC4/5 channel candidates, including KAR-2618. The increase of $7.2 million in consultant fees and other expenses was due to an increase in consulting costs not specifically allocated to discovery, preclinical, clinical, formulation and CMC activities.

General and Administrative Expenses

	Six Months Ended June 30,		
	2023	2022	Change
	(in thousands)		
Personnel related expenses (including stock-based compensation)	$ 27,344	$ 20,758	$ 6,586
Professional and consultant fees	15,052	6,229	8,823
Other	9,274	5,644	3,630
Total general and administrative expense	$ 51,670	$ 32,631	$ 19,039

The increase of $6.6 million in personnel related costs was primarily a result of an increase in headcount and an increase of $1.4 million related to stock-based compensation expense. The increase of $8.8 million in professional and consultant fees was primarily due to an increase in pre-commercial costs, accounting fees, legal costs and consulting fees related to our ongoing business activities. The increase of $3.6 million in other costs was primarily due to other infrastructure and administrative related costs to support increased headcount.

Other Income (Loss), Net

	Six Months Ended June 30,		
	2023	2022	Change
	(in thousands)		
Interest income	$ 27,942	$ 727	$ 27,215
Sublease income	294	286	8
Total other income, net	$ 28,236	$ 1,013	$ 27,223

Interest income is attributable to interest earned on our cash equivalents, available-for-sale investments and short-term investments. The increase of $27.2 million in interest income is primarily due to an increase in our cash equivalents and investment securities held, as well as an increase in interest rates on such instruments, during the six months ended June 30, 2023 compared to the six months ended June 30, 2022.

The increase in sublease income is due to the sublease of our Arch Street office space in Boston, Massachusetts, in the first quarter of 2022.

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 until we receive FDA approval, which may take longer than we anticipate, or may not occur at all. Through June 30, 2023, our operations have been financed by net proceeds of $25.7 million from the issuance of convertible notes, $91.0 million from the sale of shares of our redeemable convertible preferred stock, $93.0 million from the sale of our common stock in our initial public offering in June 2019, $234.2 million from the sale of our common stock in a follow-on public offering in November 2019, $270.0 million from the sale of our common stock in a follow-on public offering in March 2021, $819.1 million from the sale of our common stock in a follow-on public offering in August 2022, $436.7 million from the sale of our common stock in a follow-on public offering in March 2023, and $45.0 million from the Zai License Agreement. As of June 30, 2023, we had $1,434.5 million in cash, cash equivalents and available-for-sale investments, and an accumulated deficit of $764.9 million.

On June 21, 2023, we and Goldman Sachs & Co. LLC, or Goldman Sachs, mutually terminated our Equity Distribution Agreement dated July 2, 2020, or the 2020 Distribution Agreement, in anticipation of the expiration of our automatic shelf Registration Statement on Form S-3 (File No. 333-239657) filed with the SEC on July 2, 2020, or the 2020 Registration Statement. The 2020 Distribution Agreement provided that we may sell shares of our common stock from time to time for an aggregate offering price of up to $150.0 million under the 2020 Registration Statement and related prospectus through an “at-the-market” equity offering program, or the 2020 ATM Program, for which Goldman Sachs would act as sales agent or principal. None of the shares of our common stock were sold under the 2020 Distribution Agreement and, as a result of the termination of the 2020 Distribution Agreement, we will not offer or sell any shares under the 2020 ATM Program.

Also on June 21, 2023, we filed an automatically effective registration statement on Form S-3, or the 2023 Registration Statement, 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, or the 2023 Distribution Agreement, with Goldman Sachs and Leerink Partners (f/k/a SVB Securities LLC), as sales agents, to provide for the issuance and sale by the Company of up to $400.0 million of common stock from time to time in “at-the-market” offerings under the 2023 Registration Statement and related prospectus, or the 2023 ATM Program. We may sell common stock pursuant to the 2023 Distribution Agreement from time to time in varying amounts, which may be limited, based upon factors including (among others) market conditions, investor demand, the trading price of our common stock, and determinations by us of our need for, and appropriate sources of, additional capital. As of June 30, 2023, no sales had been made pursuant to the 2023 ATM Program.

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

Cash Flows

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

	Six Months Ended June 30,	
	2023	2022
	(in thousands)	
Net cash used in operating activities	$ (164,763)	$ (89,303)
Net cash (used in) provided by investing activities	(281,071)	12,241
Net cash provided by financing activities	460,847	6,205
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 15,013	$ (70,857)

Cash Flows from Operating Activities

Cash used in operating activities for the six months ended June 30, 2023 was $164.8 million, consisting of a net loss of $200.7 million, partially offset by non-cash items, including stock-based compensation expense of $33.5 million and interest income resulting from the amortization of premiums and accretion of discounts on our available-for-sale investments of $16.7 million. The change in our net operating assets and liabilities was mainly due to an increase in accrued expenses of $6.0 million and a decrease in accounts payable of $1.3 million and prepaid expenses and other current assets of $15.3 million, primarily driven by timing of payments made and services rendered by CROs and CMOs in connection with our clinical trials.

Cash used in operating activities for the six months ended June 30, 2022 was $89.3 million, consisting of a net loss of $123.2 million, partially offset by non-cash items, including stock-based compensation expense of $22.8 million and interest expense resulting from the amortization of premiums and accretion of discounts on our available-for-sale investments of $0.4 million. The change in our net operating assets and liabilities was mainly due to an increase in accrued expenses of $1.6 million and accounts payable of $2.0 million, and a decrease in prepaid expenses and other current assets of $9.7 million, primarily driven by timing of payments made and services rendered by CROs and CMOs in connection with our clinical trials, partially offset by an increase in accounts receivable of $3.0 million pursuant to revenue earned under the Zai License Agreement.

Cash Flows from Investing Activities

Cash used in investing activities for the six months ended June 30, 2023 was $281.1 million, primarily attributable to purchases of investment securities of $924.5 million, which were partially offset by maturities of investment securities of $646.9 million.

Cash provided by investing activities for the six months ended June 30, 2022 was $12.2 million, primarily attributable to maturities of investment securities of $103.2 million, which were partially offset by purchases of investment securities of $90.5 million.

Cash Flows from Financing Activities

Cash provided by financing activities for the six months ended June 30, 2023 was $460.8 million, which was primarily attributable to $436.7 million in net proceeds received from the sale of common stock in our March 2023 follow-on public offering, and $24.2 million in proceeds received from the exercise of stock options.

Cash provided by financing activities for the six months ended June 30, 2022 was $6.2 million, which was primarily attributable to proceeds received from the exercise of stock options.

Future Funding Requirements

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

As of June 30, 2023, we had cash and cash equivalents and available-for-sale investments of $1,434.5 million. Based on our current plans, we believe that our existing cash, cash equivalents and available-for-sale investments will be sufficient to meet our anticipated operating and capital expenditure requirements through the end of 2026.

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, including KAR-2618;
- the timing of, and the costs involved in, obtaining marketing approvals for KarXT for our current and future indications as well as other product candidates we may develop and pursue, including KAR-2618;
- 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, the revenue received, if any, from commercial sales of KarXT for any program or revenues received from any other 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 commercial infrastructure;
- the costs of preparing, filing and prosecuting patent applications, and maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property related claims; and
- the ongoing costs of operating as a public company.

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

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

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

Cash Requirements due to Contractual Obligations and Other Commitments

We are currently under agreements to lease our Arch Street office space through December 2023. Remaining lease payments from July 1, 2023 through the end of the lease term total $0.4 million. As of January 21, 2022, all leases at our Arch Street office space in Boston, Massachusetts have been subleased through the end of their lease terms.

We are also under agreement to lease office space in Carmel, Indiana through August 2024. Remaining lease payments total $0.2 million through the end of the lease term.

In March 2021, we entered into an agreement to sublease approximately 25,445 square feet of office space, or the High Street Premises, from a third party in Boston, Massachusetts as part of the relocation of our corporate headquarters. The term of the sublease extends from April 1, 2021 through December 31, 2025 and provides for escalating annualized base rent payments starting at approximately $1.5 million and increasing to $1.6 million in the final year of the sublease. Remaining lease payments from July 1, 2023 through the end of the lease term total $4.0 million.

In April 2023, we entered into an agreement to lease approximately 50,890 square feet of additional office space located at 99 High Street in Boston, MA. We took possession of the premises in June 2023. The initial term of the lease is ten years from the date alterations are substantially complete, estimated to occur no later than April 2024, with the option to renew for an additional five-year term. Annual base rent under the lease is approximately $3.5 million and is subject to annual increases in accordance with the terms of the lease agreement. Lease payments begin on the earlier of January 1, 2025 or nine months from the date alterations are substantially complete and total $39.7 million through the end of the lease term. The lease provides for a tenant improvement allowance of $9.2 million.

We enter into contracts in the normal course of business with CROs, CMOs and other third parties for clinical trials, preclinical research studies and testing and manufacturing services. These contracts are generally cancelable by us upon prior written notice. Payments due upon cancellation consist of payments for services provided or expenses incurred, including noncancelable obligations of our service providers, up to the date of cancellation, and may also include termination penalties. As of June 30, 2023 the timing, amount or likelihood of such payments are not known.

We are also party to certain license and collaboration agreements with PureTech Health, Eli Lilly and Company, and GFB (ABC) LLC, assignee of the assignment estate of Goldfinch Bio, Inc. We may be obligated to make certain future payments which are contingent upon future events such as our achievement of specified regulatory and commercial milestones, or royalties on net product sales under these agreements. As of June 30, 2023, we were unable to estimate the timing or likelihood of achieving these milestones or generating future product sales.

Critical Accounting Polices and Estimates

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

- Research and development contract costs and accruals

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

Recently Issued or Adopted Accounting Pronouncements

New pronouncements issued but not effective until after June 30, 2023 are not expected to have a material impact on the Company’s consolidated financial statements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to changes in interest rates. We had cash, cash equivalents and available-for-sale investment securities of $1,434.5 million as of June 30, 2023, which consisted primarily of money market funds and investment securities, largely composed of U.S. Treasuries and Agencies and investment grade, short to intermediate term fixed income securities. Short-term investments consisted of a certificate of deposit with a maturity of less than twelve months.

The primary objective of our investment activities is to preserve capital to fund our operations. We also seek to maximize income from our investments without assuming significant risk. To achieve our objectives, we maintain a portfolio of investments in a variety of securities of high credit quality and short-term duration, according to our board-approved investment policy. Our investments are subject to interest rate risk and could fall in value if market interest rates increase. We intend and have the ability to hold those investments to maturity and, should interest rates rise, there would be no recognition of impairment required. Declines in interest rates, however, could reduce future investment income. A hypothetical 10% relative change in interest rates during any of the periods presented would not have had a material impact on our consolidated financial statements.

We are not currently exposed to significant market risk related to changes in foreign currency exchange rates; however, we have contracted with and may continue to contract with vendors that are located outside of the United States. As a result, our operations may be subject to fluctuations in foreign currency exchange rates in the future.

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, 2023 and 2022. However, inflation has had, and may continue to have, an impact on the labor costs we incur to attract and retain qualified personnel.

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, 2023.

Changes in Internal Control Over Financial Reporting

During the three months ended June 30, 2023, we completed the implementation of an enterprise resource planning (“ERP”) system, with which we expect to improve the efficiency of certain financial and transactional processes. As a result, we have updated the design and documentation of internal controls related to processes and procedures which were impacted following the ERP implementation to ensure we continue to maintain effective internal control over financial reporting.

Except as described in the previous paragraph, there was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) which occurred during the three and six months ended June 30, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

We are not currently subject to any material legal proceedings.

Item 1A. Risk Factors.

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

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

(c) Trading Arrangements

On April 14, 2023, Stephen Brannan, M.D., the Company's Chief Medical Officer, adopted a trading arrangement, or a Rule 10b5-1 Trading Plan, providing for (i) the potential exercise of vested stock options to purchase up to a total of 105,000 shares of the Company's common stock, and (ii) the potential sale of up to 75,000 shares of the Company's common stock received upon such exercises. This Rule 10b5-1 Trading Plan is scheduled to expire on August 7, 2024, or such earlier date upon which all transactions are completed or expire without execution. This Rule 10b5-1 Trading Plan is intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act.

Other than as disclosed above, during the three months ended June 30, 2023, none of our directors or officers (as defined in Rule 16a-1(f) under the Exchange Act) adopted or terminated (1) a contract, instruction or written plan for the purchase or sale of Company securities intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or (2) a "non-Rule 10b5-1 trading arrangement" (as defined in Item 408(c) of Regulation S-K).

Item 6. Exhibits.

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

Exhibit Number	Description
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1+	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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

SIGNATURES

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

KARUNA THERAPEUTICS, INC.

Date: August 3, 2023

By: /s/ William Meury

William Meury
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 3, 2023

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, William Meury, certify that:

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

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

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

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

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

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

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

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

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

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

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

Dated: August 3, 2023

/s/ William Meury

William Meury
Chief Executive Officer and President
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO RULES 13A-14(A) AND 15D-14(A) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF SARBANES-OXLEY ACT OF 2002

I, Troy Ignelzi, certify that:

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

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

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

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

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

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

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

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

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

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

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

Dated: August 3, 2023

/s/ Troy Ignelzi

Troy Ignelzi
Chief Financial Officer
(Principal Financial and Accounting 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, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, William Meury 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 3, 2023

/s/ William Meury

William Meury
Chief Executive Officer and President
(Principal Executive Officer)

Dated: August 3, 2023

/s/ Troy Ignelzi

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