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 March 31, 2022

OR

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

For the transition period from _____ to _____

Commission File Number: 001-41199

Amylyx Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**46-4600503**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
43 Thorndike St. Cambridge, Massachusetts	**02141**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 682-0917

N/A

(Former name, former address and former fiscal year, if changed since last report)

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	AMLX	Nasdaq Global Select Stock 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 May 9, 2022, the registrant had 58,533,226 shares of common stock, $0.0001 par value per share, outstanding.

AMYLYX PHARMACEUTICALS, INC.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2022

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, or Quarterly Report, contains forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical facts contained in this Quarterly Report are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “would” or the negative of these terms or other comparable terminology. These statements are not guarantees of future results or performance and involve substantial risks and uncertainties. Forward-looking statements in this Quarterly Report include, but are not limited to, express or implied statements about:

- our ability to obtain and maintain regulatory approval of AMX0035 and any future product candidates;
- our ability to successfully commercialize and market AMX0035 and any future product candidates, if approved, and the timing of any commercialization and marketing efforts;
- our ability to contract with third-party suppliers, manufacturers and other service providers and their ability to perform adequately and to produce sufficient quantities of clinical and potentially future commercial supplies;
- the potential market size, opportunity and growth potential for AMX0035 and any future product candidates, if approved;
- our ability to build our own sales and marketing capabilities, or seek collaborative partners, to commercialize AMX0035 and any future product candidates, if approved;
- our ability to obtain funding for our operations;
- the initiation, timing, progress and results of our preclinical studies and clinical trials, including our Phase 3 clinical trial of AMX0035 for the treatment of ALS, known as the PHOENIX trial, and our research and development activities;
- our ability to retain the continued service of our key professionals and to identify, hire and retain additional qualified professionals;
- our ability to advance AMX0035 and any future product candidates into, and successfully complete, clinical trials;
- our ability to successfully recruit and enroll suitable patients in our clinical trials;
- the timing or likelihood of the accomplishment of various scientific, clinical, regulatory filings and approvals and other product development objectives;
- the pricing and reimbursement of our product candidates, if approved;
- the rate and degree of market acceptance AMX0035 and any future product candidates by physicians, patients, third-party payors and others in the medical community;
- the implementation of our business model, strategic plans for our business, product candidates and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- developments relating to our competitors and our industry, including any regulatory developments;
- the accuracy of our estimates regarding expenses, capital requirements, cash runway and future and needs for additional financing;
- our financial performance; and
- other risks and uncertainties, including those listed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, or our Annual Report.

Any forward-looking statements in this Quarterly Report reflect our current views with respect to future events and with respect to our future financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those described under Part II, Item 1A, “Risk Factors” and elsewhere in this Quarterly Report, as well as in Part I, Item 1A. and elsewhere in our Annual Report. Given these uncertainties, you should not place undue reliance on these

forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

All of our forward-looking statements are as of the date of this Quarterly Report only. In each case, actual results may differ materially from such forward-looking information. We can give no assurance that such expectations or forward-looking statements will prove to be correct. An occurrence of or any material adverse change in one or more of the risk factors or risks and uncertainties referred to in this Quarterly Report or included in our other public disclosures or our other periodic reports or other documents or filings filed with or furnished to the Securities and Exchange Commission, or the SEC, could materially and adversely affect our business, prospects, financial condition and results of operations. Except as required by law, we do not undertake or plan to update or revise any such forward-looking statements to reflect actual results, changes in plans, assumptions, estimates or projections or other circumstances affecting such forward-looking statements occurring after the date of this Quarterly Report, even if such results, changes or circumstances make it clear that any forward-looking information will not be realized. Any public statements or disclosures by us following this Quarterly Report that modify or impact any of the forward-looking statements contained in this Quarterly Report will be deemed to modify or supersede such statements in this Quarterly Report.

We may from time to time provide estimates, projections and other information concerning our industry, the general business environment, and the markets for certain diseases, including estimates regarding the potential size of those markets and the estimated incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties, and actual events, circumstances or numbers, including actual disease prevalence rates and market size, may differ materially from the information reflected in this Quarterly Report. Unless otherwise expressly stated, we obtained this industry, business information, market data, prevalence information and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data, and similar sources, in some cases applying our own assumptions and analysis that may, in the future, prove not to have been accurate.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

AMYLYX PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)
(Unaudited)

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 110,403	$ 50,191
Short-term investments	144,802	45,927
Prepaid expenses and other current assets	10,283	5,392
Deferred offering costs	—	3,441
Total current assets	265,488	104,951
Property and equipment, net	1,290	474
Restricted cash	419	189
Operating lease right-of-use assets	6,785	—
Other assets	456	—
Total assets	$ 274,438	$ 105,614
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 10,045	$ 4,372
Accrued expenses and other current liabilities	16,256	13,024
Operating lease liabilities, current portion	1,405	—
Total current liabilities	27,706	17,396
Operating lease liabilities, net of current portion	5,786	—
Deferred rent	—	35
Total liabilities	33,492	17,431
Commitments and contingencies (Note 13)		
Series A redeemable convertible preferred stock, $0.0001 par value; 0 and 6,289,609 shares authorized, issued and outstanding as of March 31, 2022 and December 31, 2021, respectively	—	7,675
Series B redeemable convertible preferred stock, $0.0001 par value; 0 and 15,100,000 shares authorized as of March 31, 2022 and December 31, 2021; 0 and 14,496,835 shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively	—	64,387
Series C-1 redeemable convertible preferred stock, $0.0001 par value; 0 and 13,150,430 shares authorized, issued and outstanding as of March 31, 2022 and December 31, 2021, respectively	—	134,791
Series C-2 redeemable convertible preferred stock, $0.0001 par value; 0 and 3,170,585 shares authorized, issued and outstanding as of March 31, 2022 and December 31, 2021, respectively	—	32,498
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; 10,000,000 and 0 shares authorized as of March 31, 2022 and December 31, 2021, respectively; 0 shares issued or outstanding as of March 31, 2022 and December 31, 2021	—	—
Common stock, $0.0001 par value; 300,000,000 authorized and 57,864,186 issued and outstanding as of March 31, 2022; 56,500,000 shares authorized and 7,020,487 shares issued and outstanding as of December 31, 2021	6	1
Additional paid-in capital	444,784	4,667
Accumulated deficit	(203,693)	(155,845)
Accumulated other comprehensive (loss) income	(151)	9
Total stockholders' equity (deficit)	240,946	(151,168)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	$ 274,438	$ 105,614

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

AMYLYX PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share data)
(Unaudited)

	Three Months Ended March 31,	
	2022	2021
Operating expenses:		
Research and development	$ 21,464	$ 6,864
General and administrative	26,350	6,004
Total operating expenses	47,814	12,868
Loss from operations	(47,814)	(12,868)
Other income (expense), net:		
Interest income	131	2
Change in fair value of convertible notes	—	(1,918)
Other (expense) income, net	(19)	261
Total other income (expense), net	112	(1,655)
Loss before income taxes	(47,702)	(14,523)
Provision for income taxes	146	—
Net loss	$ (47,848)	$ (14,523)
Net loss per share attributable to common stockholders —basic and diluted	$ (0.93)	$ (2.33)
Weighted-average shares used in computing net loss per share attributable to common stockholders—basic and diluted	51,604,310	6,234,637

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

AMYLYX PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(in thousands)
(Unaudited)

	Three Months Ended March 31,	
	2022	2021
Net loss	$ (47,848)	$ (14,523)
Other comprehensive loss:		
Foreign currency translation adjustment	(68)	—
Net unrealized loss on investments held	(92)	—
Other comprehensive loss	(160)	—
Comprehensive loss	$ (48,008)	$ (14,523)

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

AMYLYX PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(in thousands, except share data)
(Unaudited)

	Series A Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Series C-1 Redeemable Convertible Preferred Stock		Series C-2 Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance as of December 31, 2020	6,289,609	$ 7,675	14,496,835	$ 64,387	—	$ —	—	$ —	6,137,206	$ 1	$ 1,188	$ —	$ (67,914)	$ (66,725)
Issuance of common stock upon exercise of stock options	—	—	—	—	—	—	—	—	290,032	—	31	—	—	31
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	586	—	—	586
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(14,523)	(14,523)
Balance as of March 31, 2021	6,289,609	$ 7,675	14,496,835	$ 64,387	—	$ —	—	$ —	6,427,238	$ 1	$ 1,805	$ —	$ (82,437)	$ (80,631)
Balance as of December 31, 2021	6,289,609	$ 7,675	14,496,835	$ 64,387	13,150,430	$ 134,791	3,170,585	$ 32,498	7,020,487	$ 1	$ 4,667	$ 9	$ (155,845)	$ (151,168)
Conversion of preferred stock into common stock upon initial public offering	(6,289,609)	(7,675)	(14,496,835)	(64,387)	(13,150,430)	(134,791)	(3,170,585)	(32,498)	39,474,330	4	239,347	—	—	239,351
Issuance of common stock upon initial public offering, net of issuance costs of $19,639	—	—	—	—	—	—	—	—	11,369,369	1	196,378	—	—	196,379
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	4,392	—	—	4,392
Other comprehensive loss	—	—	—	—	—	—	—	—	—	—	—	(160)	—	(160)
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(47,848)	(47,848)
Balance as of March 31, 2022	—	$ —	—	$ —	—	$ —	—	$ —	57,864,186	$ 6	$ 444,784	$ (151)	$ (203,693)	$ 240,946

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

AMYLYX PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)
(Unaudited)

	Three Months Ended March 31,	
	2022	2021
Cash flows used in operating activities:		
Net loss	$ (47,848)	$ (14,523)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	4,392	586
Depreciation expense	35	10
Net amortization of premiums and discounts on investments	2	—
Change in fair value of convertible notes	—	1,918
Changes in operating assets and liabilities:		
Interest receivable	(1)	(2)
Prepaid expenses and other current assets	(4,890)	(244)
Operating lease right-of-use assets	374	—
Other assets	(456)	102
Accounts payable	5,020	177
Accrued expenses and deferred rent	2,741	(667)
Operating lease liabilities	(3)	—
Net cash used in operating activities	(40,634)	(12,643)
Cash flows used in investing activities:		
Purchases of property and equipment	(342)	(14)
Purchases of investments	(123,880)	—
Proceeds from maturities of short-term investments	24,911	—
Net cash used in investing activities	(99,311)	(14)
Cash flows from financing activities:		
Forgiveness of PPP loan	—	(263)
Proceeds from initial public offering	200,897	—
Initial public offering costs paid during the quarter	(442)	—
Proceeds from issuance of convertible notes—related parties	—	14,272
Proceeds from issuance of convertible notes	—	11,887
Proceeds from exercise of stock options	—	31
Net cash provided by financing activities	200,455	25,927
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(68)	—
Net increase in cash, cash equivalents and restricted cash	60,442	13,270
Cash, cash equivalents and restricted cash, beginning of period	50,380	13,066
Cash, cash equivalents and restricted cash, end of period	$ 110,822	$ 26,336
Supplemental disclosure of cash flow information:		
Unrealized loss on short-term investments	$ 92	$ —
Purchases of property and equipment included in accounts payable	$ 509	$ —
Right-of-use assets and liabilities upon ASC842 adoption	$ 2,201	$ —
Right-of-use assets obtained in exchange for lease liabilities	$ 4,958	$ —
Movement of deferred offering costs to equity	$ 2,474	$ —
Initial public offering costs included in accounts payable and accrued expenses	$ 1,602	$ 388
Conversion of preferred stock to common stock upon initial public offering	$ 239,351	$ —

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

1. NATURE OF THE BUSINESS

Amylyx Pharmaceuticals, Inc., together with its wholly owned subsidiaries ("Amylyx" or the "Company") was incorporated under the laws of the State of Delaware on January 10, 2014 and headquartered in Cambridge, Massachusetts. The Company is a clinical stage biotechnology company with a goal to improve the quality and length of life of patients suffering from neurodegenerative disease. The Company is pursuing commercialization of its asset, AMX0035, which it believes is the first drug candidate to show both a functional and survival benefit in a large-scale clinical trial of patients with amyotrophic lateral sclerosis, or ALS. The Company believes AMX0035 has the potential to be a foundational therapy, meaning that it could be used alone or in conjunction with other therapies to change the treatment paradigm across a broad range of neurodegenerative diseases. The Company has designed AMX0035 to target two key pathways of neuron death, specifically endoplasmic reticulum, or ER, stress and mitochondrial dysfunction. The Company is focused on the development of and potential commercialization of AMX0035 for ALS globally. In addition, the Company is developing AMX0035 for other neurodegenerative diseases by leveraging its unique knowledge and relationships in the neurodegenerative space.

In January 2022, the Company completed an initial public offering (the "IPO"), in which the Company issued and sold 11,369,369 shares of its common stock at a price of $19.00 per share. After deducting underwriting discounts and commissions and estimated offering expenses, the Company received net proceeds of approximately $196.4 million. Upon the completion of the initial public offering, all of the Company's outstanding shares of preferred stock were converted into shares of its common stock.

Risks and Uncertainties

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, the outcome of clinical trials, potential difficulties with or delays in timing with respect to the regulatory approval processes of the U.S. Food and Drug Administration ("FDA"), Health Canada, the European Medicines Agency and other comparable foreign authorities, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, ability to secure additional capital to fund operations, and risks associated with the ongoing COVID-19 global pandemic, including potential delays associated with the Company's ongoing and anticipated trials. The COVID-19 pandemic may have an adverse impact on the Company's operations, supply chains and distribution systems or those of its contractors, and increase expenses, including as a result of impacts associated with preventive and precautionary measures that are being taken, such as restrictions on travel and border crossings. The Company and its contractors may experience disruptions in supply of items that are essential for its research and development activities, including, for example, raw materials and bulk drug substances that the Company imports from Europe and Canada used in the manufacturing of AMX0035, and any future product candidates. In addition, the continued spread of COVID-19 has disrupted global healthcare and healthcare regulatory systems which could divert healthcare resources away from, or materially delay, U.S. Food and Drug Administration ("FDA") approval and approval by other health authorities worldwide with respect to AMX0035 and any future product candidates. Furthermore, the Company's clinical trials may be negatively affected by the ongoing COVID-19 outbreak. Site initiation, patient enrollment and patient follow-up visits may be delayed, for example, due to prioritization of hospital resources toward the COVID-19 outbreak, travel restrictions, the inability to access sites for initiation and monitoring, and difficulties recruiting or retaining patients in the Company's ongoing and planned clinical trials.

There can be no assurance that the Company will be able to successfully complete the development of, or receive regulatory approval for, any products developed, and if approved, that any products will be commercially viable. Any products resulting from the Company's current research and development efforts will require significant additional research and development, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts will require significant amounts of additional capital, adequate personnel, infrastructure, and extensive compliance reporting capabilities. The Company has not generated any revenues from the sale of any products to date. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

Going Concern

In accordance with Accounting Standards Update ("ASU") 2014-15, *Disclosure of Uncertainties About an Entity's Ability to Continue as a Going Concern (Subtopic 205-40)*, the Company has evaluated whether there are conditions and events that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the unaudited consolidated financial statements are issued.

Since its inception, the Company has devoted substantially all of its efforts to research and development activities, including recruiting management and technical staff, raising capital, producing materials for non-clinical and clinical studies, and building infrastructure to support such activities. Expenses have primarily been for research and development and related general and administrative costs. The Company has generated revenues through five grants from ALS Association, ALS Finding a Cure Foundation, Cure Alzheimer's Fund, Alzheimer's Drug Discovery Foundation and Alzheimer's Association (collectively, the "Grantors"). In addition to money received from its grants, the Company has also financed its operations through the issuance of redeemable convertible preferred stock and convertible notes (see Notes 8 and 7, respectively). In addition, the Company has financed its operation pursuant to the loan under the Paycheck Protection Program, or the PPP, of the Coronavirus Aid, Relief, and Economic Security ("CARES") Act (the "PPP Loan") as administered by the SBA (See Note 7). In January 2022, the Company completed the initial public offering of its common stock.

The accompanying condensed consolidated financial statements have been prepared on a going-concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company has incurred recurring losses and negative cash flows from operations since inception. As of March 31, 2022, the Company had an accumulated deficit of $203.7 million. The Company expects its operating losses and negative operating cash flows to continue into the foreseeable future as it continues to build capabilities and develop AMX0035, and any future product candidates. The Company expects that its cash, cash equivalents and short-term investments as of March 31, 2022 will enable the Company to fund its ongoing operating expenses and capital expenditure requirements for at least the twelve-month period following the issuance of these condensed consolidated financial statements.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Significant Accounting Policies

The Company's significant accounting policies are disclosed in the audited consolidated financial statements for the year ended December 31, 2021 and the notes thereto, which are included in the Company's most recent Annual Report on Form 10-K. Since the date of those consolidated financial statements, there have been no material changes to its significant accounting policies, with the exception of significant accounting policies related to the adoption of FASB ASC Topic 842, *Leases*, effective January 1, 2022, as described below.

Basis of Presentation and Consolidation

The accompanying condensed consolidated financial statements are unaudited and have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP") and include the accounts of the Company and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation. Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and ASU of the Financial Accounting Standards Board ("FASB").

Use of Estimates

The preparation of the condensed consolidated financial statements in conformity with GAAP requires the Company's management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amount of expenses during the reporting period. Actual results could differ from those estimates. Management considers many factors in selecting appropriate financial accounting policies in developing the estimates and assumptions that are used in the preparation of the financial statements. Management must apply significant judgment in this process. Management's estimation process often may yield a range of potentially reasonable estimates and management must select an amount that falls within that range of reasonable estimates. Estimates are used in the following areas, among others: determining the fair value of the Company's common stock prior to the Company's initial public offering in January 2022; determining the fair value of convertible notes; accrued expenses; stock option valuations; valuation allowance for deferred tax assets and research and development expenses.

Recently Adopted Accounting Pronouncements

Effective January 1, 2022, the Company adopted the requirements under the Financial Accounting Standards Board ("FASB"), Accounting Standards Codification ("ASC") 842, *Leases* ("ASC 842") using the cumulative effect adjustment transition option. Comparative periods have not been restated. This standard requires entities that lease assets to recognize the assets and liabilities for the rights and obligations created by those leases on the balance sheet. The Company elected the available package of practical expedients which allows it to not reassess previous accounting conclusions around whether arrangements are or contain

leases, the classification of its leases, and the treatment of initial direct costs. The Company has made an accounting policy election to keep leases with an initial term of 12 months or less off of the balance sheet. ASC 842 was issued in order to increase transparency and comparability of financial reporting related to leasing arrangements. The main difference between previous U.S. GAAP ("ASC 840") and ASC 842 is the recognition of right-of-use lease assets and lease liabilities by lessees for those leases that were classified as operating leases under ASC 840. At January 1, 2022, the Company recorded right-of-use assets of $2.2 million and operating lease liabilities of $2.2 million. Adoption of the standard did not have a material impact on the consolidated statements of operations. For additional information regarding how the Company is accounting for leases under ASC 842, refer to Note 5, Leases.

New Accounting Pronouncements Not Yet Adopted

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses (Topic 326) Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"). The provisions of ASU 2016-13 modify the impairment model to utilize an expected loss methodology in place of the currently used incurred loss methodology and require a consideration of a broader range of reasonable and supportable information to inform credit loss estimates. Credit losses relating to available-for-sale debt securities will be recorded through an allowance for credit losses rather than as a direct write-down to the security. ASU 2016-13 requires a cumulative effect adjustment to the consolidated balance sheet as of the beginning of the first reporting period in which the guidance is effective. In November 2019, the FASB issued ASU 2019-10, *Financial Instruments—Credit Losses (Topic 326), Derivatives and Hedging (Topic 815) and Leases (Topic 842): Effective Dates*, which defers the effective date of ASU 2016-13 to fiscal years beginning after December 15, 2022 for all entities except Securities and Exchange Commission filers that are not smaller reporting companies. ASU 2016-13 will be effective for the Company beginning January 1, 2023. The Company intends to adopt the ASU when it becomes effective. The Company is currently evaluating the impact of this ASU and does not expect that adoption of this standard will have a material impact on its condensed consolidated financial statements and related disclosures.

3. SHORT-TERM INVESTMENTS

Short-term investments, which are classified as available-for-sale, consisted of the following:

Balance at March 31, 2022:	Amortized Cost Basis	Unrealized Loss	Fair Value
		(in thousands)	
Treasury notes	$ 12,054	$ (15)	$ 12,039
Treasury bills	47,923	(21)	47,902
Commercial paper	63,725	(1)	63,724
Corporate debt securities	21,196	(59)	21,137
Total short-term investments	$ 144,898	$ (96)	$ 144,802

Balance at December 31, 2021:	Amortized Cost Basis	Unrealized Loss	Fair Value
		(in thousands)	
Commercial paper	$ 33,979	$ (1)	$ 33,978
Corporate debt securities	11,953	(4)	11,949
Total short-term investments	$ 45,932	$ (5)	$ 45,927

As of March 31, 2022 and December 31, 2021, all investments had contractual maturities within one year.

4. FAIR VALUE MEASUREMENTS

The following table presents information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicates the level of the fair value hierarchy utilized to determine such fair values:

	March 31, 2022			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets:				
Money market funds	$ 89,694	$ —	$ —	$ 89,694
Short-term investments:				
Treasury notes	12,039	—	—	12,039
Treasury bills	47,902	—	—	47,902
Commercial paper	—	63,724	—	63,724
Corporate debt securities	—	21,137	—	21,137
Restricted cash	419	—	—	419
Total financial assets	$ 150,054	$ 84,861	$ —	$ 234,915

	December 31, 2021			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets:				
Money market funds	$ 49,271	$ —	$ —	$ 49,271
Short-term investments:				
Commercial paper	—	33,978	—	33,978
Corporate debt securities	—	11,949	—	11,949
Restricted cash	189	—	—	189
Total financial assets	$ 49,460	$ 45,927	$ —	$ 95,387

The Company classifies its money market funds, treasury bills and treasury notes as Level 1 assets under the fair value hierarchy, as these assets have been valued using quoted market prices in active markets without any valuation adjustment. The Company classifies its commercial paper and corporate debt securities as Level 2 assets under the fair value hierarchy, as these assets have been valued using information obtained through a third-party pricing service at each balance sheet date, using observable market inputs that may include trade information, broker or dealer quotes, bids, offers, or a combination of these data sources.

5. LEASES

The Company adopted ASC 842 on January 1, 2022. ASC 842 allows the Company to elect a package of practical expedients, which include: (i) an entity need not reassess whether any expired or existing contracts are or contain leases; (ii) an entity need not reassess the lease classification for any expired or existing leases; and (iii) an entity need not reassess any initial direct costs for any existing leases. Another practical expedient allows the Company to use hindsight in determining the lease term when considering lessee options to extend or terminate the lease and to purchase the underlying asset. The Company has elected to utilize this package of practical expedients and has not elected the hindsight methodology in its implementation of ASC 842.

The Company leases its office facilities under non-cancelable operating leases that expire at various dates through October 2026. The Company entered into a new office space lease at 121 First Street in Cambridge, Massachusetts on January 10, 2022, for 36 months, with an option to extend the lease for 3 years. The Company initially recognized a ROU asset of $5.0 million and a lease liability of $5.0 million upon commencement.

Components of lease expense required by ASC 842 are presented below for the three months ended March 31, 2022.

	Three Months Ended March 31, 2022
	(in thousands)
Lease cost	
Operating lease cost	$ 504
Total lease cost	$ 504

Lease liabilities are measured by calculating the present value of remaining lease payments under the lease arrangement. Since the rates implicit in our leases are not readily determinable, we use estimated incremental borrowing rates in determining the discount rate used to calculate the present value of remaining lease payments. The incremental borrowing rate is the rate of interest that we would have to pay to borrow, on a collateralized basis, an amount equal to the lease payments over a similar term equal to the lease term in a similar economic environment. The incremental borrowing rate is based on the information available at commencement date. As we have no recent external borrowings, the incremental borrowing is a hypothetical rate based on our understanding of what our credit rating would be and adjusted to reflect a collateralized borrowing.

The Company's leases contain renewal options that can extend the lease for additional years. Because the Company is not reasonably certain to exercise these renewal options, they are not considered in determining the lease terms, and associated potential additional payments are excluded from lease payments. The Company has elected to account for each lease component and its associated non-lease components as a single lease component and has allocated all of the contract consideration across lease components only. The Company has existing net leases in which the non-lease components (e.g. common area maintenance) are paid separately from rent based on actual costs incurred and therefore are not included in the operating lease right-of-use assets and lease liabilities and are reflected as an expense in the period incurred.

The following table summarizes the presentation in the Company's consolidated balance sheet of its operating leases (in thousands):

	As of March 31, 2022
Assets	
Operating lease right-of-use assets	$ 6,785
Liabilities	
Operating lease right-of-use liabilities, current	$ 1,405
Operating lease right-of-use liabilities, net of current portion	5,786
Total operating lease liabilities	$ 7,191

During the three months ended March 31, 2022, the Company made cash payments of $0.1 million for operating leases. Future minimum lease payments under non-cancelable leases as of March 31, 2022, were as detailed below (in thousands):

	As of March 31, 2022
2022 (remaining 9 months)	$ 1,284
2023	2,417
2024	2,478
2025	1,586
2026	476
Total undiscounted lease payments	8,241
Less: imputed interest	(1,050)
Total operating lease liabilities	$ 7,191

As of March 31, 2022, the weighted average remaining lease term was 3.7 years and the weighted average incremental borrowing rate used to determine the operating lease right-of-use assets was 7.3%.

ASC 840 Disclosures

Future minimum lease payments under non-cancelable leases as of December 31, 2021, were as detailed below (in thousands):

	As of December, 31, 2021
2022	$ 532
2023	541
2024	555
2025	563
2026	476
Total operating lease liabilities	$ 2,667

6. ACCRUED EXPENSES

Accrued expenses consisted of the following:

	March 31, 2022	December 31, 2021
	(in thousands)	
External research and development	$ 5,905	$ 5,666
Payroll and employee related expenses	3,581	4,280
Accrued consulting and other professional fees	6,331	2,820
Other accrued expenses	439	258
Total accrued expenses	$ 16,256	$ 13,024

7. CONVERTIBLE NOTES

Issuance of the 2021 Notes (the "2021 Notes")

In January 2021, the Company issued, in aggregate, $27.3 million in convertible notes ("2021 Notes") to certain investors, including related parties, of which proceeds of $1.2 million were received in advance of issuance of the 2021 Notes in December 2020 and the remaining proceeds of $26.1 million were received in January and February 2021. The 2021 Notes were to mature on June 30, 2022 and carried both automatic and optional conversion features. The 2021 Notes were secured and carried an interest rate of 3%. The Company recorded the $1.2 million of proceeds received in December 2020 as proceeds received in advance of issuance of 2021 Notes in the consolidated balance sheet as of December 31, 2020, as the subscription agreement and commitment to issue the 2021 Notes was not effective until January 2021.

The 2021 Notes contained the following features:

Automatic Conversion Features—The 2021 Notes were to automatically convert into conversion shares ("Conversion Shares") upon (i) an initial public offering, (ii) any transaction in which the Company merges with, consolidates with or enters into other similar transaction with a Special Purpose acquisition Corp ("SPAC"), resulting in some or all of its shares being registered for sale under applicable securities laws and listed for trading on a national or foreign exchange ("De-SPAC transaction"), (iii) the acquisition of the Company by another person or entity by means of any transaction in which holders of the outstanding voting securities of the Company immediately before such transaction held less than 50% of the voting securities of the Company or the surviving corporation after such transaction or a sale of all or substantially all of the assets of the Company but excluding De-SPAC transaction, initial public offering, and the occurrence of equity financing in which the Company sold shares of its preferred stock for new money and which was neither an initial public offering or a Qualified Financing ("Change of Control") and (iv) the closing of a sale of an equity transaction in which the Company sold shares with an aggregate gross proceeds of at least $10.0 million ("Qualified Financing").

In the event of a Change of Control, De-SPAC transaction, or an initial public offering, the Conversion Shares would be common stock of the Company. In the event of a Qualified Financing, the Conversion Shares would be shares of preferred stock issued in such transaction.

Optional Conversion Feature—The holders of the 2021 Notes had the option to elect to convert their notes into Conversion Shares at the Conversion Price upon the occurrence of an equity financing in which the Company sold shares of its preferred stock for new money and which was neither an initial public offering or a Qualified Financing ("Non-Qualified Financing" and together with the initial public offering, De-SPAC transaction, Change of Control, and the Qualified Financing, collectively, the "Conversion

Events"). In the event of a Non-Qualified Financing, the Conversion Shares would be the class of equity shares issued in such transaction. The 2021 Notes would be deemed to have converted into the Conversion Shares if no election was made by the holders of the 2021 Notes.

Conversion Price—Upon the occurrence of an initial public offering, the 2021 Notes would convert into shares of common stock at the conversion price equal to the lesser of (i) 85% of the price at which the Company offered each share of common stock in the initial public offering without deducting any amount for discounts, commissions, fees, or other costs and (ii) $600.0 million divided by the fully diluted capital.

Upon the occurrence of a De-SPAC transaction, the 2021 Notes would convert into shares of common stock at the conversion price equal to the lesser of (i) 85% of the common stock price in the De-SPAC transaction, which would be determined by dividing (x) the total consideration to be paid to common stockholders upon a De-SPAC transaction less the principal amount of the 2021 Notes including accrued and unpaid interest by (y) the common stock issued and outstanding immediately prior to the De-SPAC transaction and that would be exchanged as a result of the De-SPAC transaction including common stock that would be issued upon the exercise of stock options immediately before the Change of Control transaction but excluding the common stock issuable upon conversion of the 2021 Notes and (ii) $600.0 million divided by the fully diluted capital.

Upon the occurrence of a Change of Control, the 2021 Notes would convert into shares of common stock at the conversion price equal to the lesser of (i) 85% of the common stock price in the Change of Control, which would be determined by dividing (x) the total consideration to be paid to common stockholders upon a Change of Control less the principal amount of the 2021 Notes including accrued and unpaid interest by (y) the common stock issued and outstanding immediately prior to the Change of Control and that would be exchanged upon a Change of Control including common stock that would be issued upon the exercise of stock options before the Change of Control but excluding the common stock issuable upon conversion of the 2021 Notes and (ii) $600.0 million divided by the fully diluted capital.

Upon a Qualified Financing, the 2021 Notes would convert into shares of preferred stock issued in the Non-Qualified Financing at the conversion price equal to the lesser of (i) 85% of the lowest price at which the Company sold shares of its stock in the Qualified Financing and (ii) $600.0 million divided by the fully diluted capital.

Repayment—Each holder of the 2021 Notes had the option to elect to receive a payment in the amount equal to the principal amount plus accrued and unpaid interests upon a Change of Control. If a Change of Control occurred and no election was made by the holder, the principal amount and accrued and unpaid interest would be deemed to have automatically be converted into shares of the Company's common stock of the Company immediately prior to the close of the Change of Control.

The Company qualified for and elected to account for the 2021 Notes under the fair value option and, in doing so, bypassed the analysis of potential embedded derivative features. The Company believes that the fair value option better reflects the underlying economics of the 2021 Notes. As a result, the 2021 Notes were recorded at fair value upon issuance, which was determined to be equal to principal amounts of these notes of $27.3 million. At each financial reporting period, and immediately prior to conversion, the Company remeasured the fair value of the 2021 Notes. The change in fair value of the 2021 Notes from inception to March 31, 2021 totaled $1.9 million, which is recorded as change in fair value of convertible notes in the consolidated statement of operations for the three months ended March 31, 2021.

Conversion of the 2021 Notes

In July 2021, the Company consummated a financing transaction in which it issued shares of Series C-1 redeemable convertible preferred stock. The consummation of this financing transaction resulted in the automatic conversion of the 2021 Notes into shares of Series C-2 redeemable convertible preferred stock (together with the Series C-1 redeemable convertible preferred stock, the "Series C Preferred Stock") pursuant to their original terms. The Series C Preferred Stock was determined to have a fair value of $10.265809. Under the fair value option, the 2021 Notes were remeasured to fair value immediately prior to conversion at a price per share equal to the fair value of the Series C-1 redeemable convertible preferred stock. The Company recorded $5.2 million loss related to change in fair value of the 2021 Notes in its consolidated statement of operations for the year ended December 31, 2021. The 2021 Notes converted into 3,170,585 shares of Series C-2 redeemable convertible preferred stock at the effective conversion price of $8.725938.

There were no convertible notes outstanding as of March 31, 2022 or December 31, 2021.

Convertible Notes—Related Parties

There were no convertible notes issued to related parties that were outstanding as of March 31, 2022 or December 31, 2021. In connection with the issuance of the 2021 Notes, the Company issued, in aggregate, $14.3 million of convertible notes to certain related parties. These notes were issued under the same terms and conditions as the 2021 Notes.

Valuation of the 2021 Notes

At the issuance date of the 2021 Notes, the Company determined that the fair value of the 2021 Notes approximated the principal amounts of the 2021 Notes as the transaction was deemed to be at arm's length. Subsequent measurement of fair value of the 2021 Notes at each reporting period was estimated based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The Company used a scenario-based analysis to incorporate estimates and assumptions concerning the Company's prospects and market indications into a model to estimate the value of the 2021 Notes. The most significant estimates and assumptions used as inputs were those concerning timing, probability of possible scenarios for conversion or settlement of the 2021 Notes and discount rates. The fair value of the 2021 Notes upon settlement in July 2021 was determined based on the fair value of the Series C-1 redeemable convertible preferred stock issued. This method was selected as the Company concluded that the contemporaneous financing transaction was an arm's length transaction. The issuance of the Series C-1 redeemable convertible preferred stock was considered to be a Qualified Financing (see Note 8) pursuant to the original terms of the 2021 Notes. Accordingly, the fair value calculation for the 2021 Notes immediately before conversion considered both the fair value of the Series C-1 redeemable convertible preferred stock and the conversion price, which was 85% of the fair value of the Series C-1 redeemable convertible preferred stock. The fair value of the 2021 Notes as of June 30, 2021 was determined to be the same as that on the settlement date in July 2021 based on management's determination of no material changes to the assumptions underlying the determination of the fair value of the 2021 Notes.

8. REDEEMABLE CONVERTIBLE PREFERRED STOCK

On July 1, 2021, the Company amended its certificate of incorporation in which it authorized 13,150,430 shares of Series C-1 redeemable convertible preferred stock and 3,170,585 shares of Series C-2 redeemable convertible preferred stock.

In July 2021, the Company consummated a financing transaction in which it issued 13,150,430 shares of Series C-1 redeemable convertible preferred stock. In connection with the issuance of these shares, the principal including accrued interest of the 2021 Notes totaling $27.7 million automatically converted into 3,170,585 shares of Series C-2 redeemable convertible preferred stock.

The Company's redeemable convertible preferred stock consisted of the following:

	December 31, 2021 (dollars in thousands)				
	Preferred Shares Authorized	Preferred Shares Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A preferred stock	6,289,609	6,289,609	$ 7,675	$ 7,730	6,407,256
Series B preferred stock	15,100,000	14,496,835	$ 64,387	$ 246,070	16,746,059
Series C-1 preferred stock	13,150,430	13,150,430	$ 134,791	$ 135,000	13,150,430
Series C-2 preferred stock	3,170,585	3,170,585	$ 32,498	$ 27,666	3,170,585
	37,710,624	37,107,459	$ 239,351	$ 416,466	39,474,330

As of December 31, 2021, the holders of the Series C Preferred Stock (together with the "Series A redeemable convertible preferred stock" and "Series B redeemable convertible preferred stock", collectively, the "Preferred Stock") have the following rights and preferences:

Conversion— On June 18, 2020, in connection with the conversion of the 2017 Notes, the Company adjusted the conversion price for the Series A redeemable convertible preferred stock of $1.229073 per share to $1.2065. The adjustment was made in accordance with the anti-dilution provisions in the certificate of incorporation then in effect immediately prior to the conversion of the 2017 Notes. The adjustment to the conversion price resulted in neither modification nor extinguishment of the Series A redeemable convertible preferred stock as the terms of the Series A redeemable convertible preferred stock were not amended. The adjustment to the conversion price resulted in additional 117,650 shares of common stock to be issued to holders of the Series A redeemable convertible preferred stock upon conversion of such shares into common stock. As of December 31, 2020, these additional shares of common stock were not issued and outstanding.

In July 2021, in connection with the conversion of the 2021 Notes, the Company adjusted the conversion price for the Series B redeemable convertible preferred stock of $16.974077 per share to $14.6942. The adjustment was made in accordance with the anti-dilution provisions in the certificate of incorporation then in effect immediately prior to the conversion of the 2021 Notes. The adjustment to the conversion price resulted in additional 2,249,224 shares of common stock into which Series B redeemable convertible preferred stock would be convertible. As of December 31, 2021, these additional shares were not issued and outstanding. Each share of Preferred Stock is convertible into an equivalent number of common stock, at any time, at the option of the holder. The initial conversion price for the Series C-1 redeemable convertible preferred stock and Series C-2 redeemable convertible preferred stock is the respective original issue prices.

The conversion price for the Preferred Stock was subject to adjustments for stock splits, stock dividends, or similar recapitalization, and subject to adjustments in accordance with the anti-dilution provisions.

The shares of Preferred Stock were to automatically convert into common stock of the Company immediately upon either (a) the closing of the sale of shares of common stock to the public in a firm commitment underwritten public offering pursuant to an effective registration statement under the Securities Act, resulting in at least $75.0 million of proceeds, net of the underwriting discount and commissions, to the Company (a “Qualified IPO”) or (b) the date and time, or the occurrence of an event, specified by vote or written consent of the holders of a majority of the then outstanding shares of Preferred Stock.

Dividends—Dividends may be paid to the holders of the Series A redeemable convertible preferred stock. The holders the Series A redeemable convertible preferred stock are entitled to receive non-cumulative dividends at a rate per annum of $0.073744 per share when and if declared by the Board of Directors. The holders of the Series B redeemable convertible preferred stock were entitled to receive a non-cumulative dividend at the rate of 6% per annum of the Series B original issue price per share when and if declared by the Board of Directors. As of December 31, 2021, no cash dividends were declared or paid. From and after the date of issuance of the Series C Preferred Stock, the Company was not to set, declare, pay or set aside unless holders of the Series C Preferred Stock then outstanding shall first receive, or simultaneously receive, dividends on each outstanding share of Series C Preferred Stock in an amount equal to (i) in the case of dividends being distributed to common stock or any class or series of capital stock that is convertible into common stock, the equivalent dividend on an as-converted basis or (ii) in the case of dividends being distributed on a series or class not convertible into common stock, an additional dividend equal to a dividend rate calculated based on the respective original issue price of the Series C Preferred Stock. The original issue prices per share for the Series C-1 redeemable convertible preferred stock and Series C-2 redeemable convertible preferred stock were $10.265809 and $8.725938, respectively.

Voting Rights— The holders of the Preferred Stock were entitled to vote on any matter presented to stockholders of the Company for consideration. Each holder of the Preferred Stock was entitled to cast the number of votes equal to the number of shares of common stock into which the shares of the Preferred Stock held by such holder were convertible on such date.

Redemption—The Preferred Stock did not contain any mandatory redemption features. In accordance with FASB ASC Topic 480, Distinguishing Liabilities from Equity (ASC 480), preferred stock issued with redemption provisions that are outside of the control of the Company or that contain certain redemption rights in a deemed liquidation event is required to be presented outside of stockholders’ deficit on the face of the consolidated balance sheets. The Company classified the Preferred Stock outside of the stockholders’ deficit as mezzanine equity because in the event of certain deemed liquidation events, which included events such as a sale or merger, that were not solely within the control of the Company, the shares of the Preferred Stock would have become redeemable at the option of the holders. As of March 31, 2021, the Company did not adjust the carrying values of the Preferred Stock to the redemption values of such shares since a deemed liquidation event did not occur and the shares were not probable of becoming redeemable in the future as of the consolidated balance sheet dates.

Liquidation—In the event of a liquidation, deemed liquidation, dissolution or winding up of the Company, holders of the Preferred Stock would have been entitled to be paid out of the assets of the Company that were available for distribution before any payment is made to the holders of common stock. The amount to paid would have been the greater of (i) respective original issue prices plus any dividends declared but unpaid or (ii) the amount that would have been payable had all shares of Preferred Stock been converted into common stock immediately before such event. If upon any such liquidation, deemed liquidation, dissolution or winding up of the Company, the assets of the Company available for distribution to its stockholders would have been insufficient to pay the holders of Preferred Stock the full amount to which they would have been entitled, the holders of Preferred Stock would have shared ratably in any distribution of the assets available for distribution in proportion to the respective amounts which would otherwise be payable in respect of the shares held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full.

After the payment of all preferential amounts required to be paid to the holders of Preferred Stock, the remaining assets of the Company available for distribution to its stockholders would have been distributed among the holders of the shares of common stock on a pro rata basis based on the number of shares held by each such holder.

In January 2022, upon the completion of the initial public offering, all of the Company's outstanding shares of preferred stock were converted into shares of its common stock. There were no redeemable convertible preferred stock outstanding as of March 31, 2022.

9. STOCKHOLDERS' EQUITY (DEFICIT)

Common Stock

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders provided, however, that, except as otherwise required by law, holders of common stock shall not be entitled to vote on any amendment to the Corporation's Certificate of Incorporation that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together with the holders of one or more other such series, to vote thereon pursuant to the Certificate of Incorporation or pursuant to the Delaware General Corporation Law. Common stockholders are entitled to receive dividends, as may be declared by the Company's Board of Directors, if any, subject to the preferential dividend rights of the Preferred Stock. No dividends have been declared or paid during the three months ended March 31, 2022 and 2021.

The Company had reserved shares of common stock for issuance in connection with the following:

	March 31, 2022	December 31, 2021
Common stock authorized	300,000,000	56,500,000
Common stock issued and outstanding	57,864,186	7,020,487
Common stock authorized and reserved for future issuances:		
Series A redeemable convertible preferred stock	—	6,407,256
Series B redeemable convertible preferred stock	—	16,746,059
Series C-1 redeemable convertible preferred stock	—	13,150,430
Series C-2 redeemable convertible preferred stock	—	3,170,585
Common stock reserved for the exercise of stock options	8,992,860	5,339,011
Common stock reserved for the unvested restricted stock units	596,709	—
Common stock reserved for future issuance of share-based awards	3,395,390	1,444,492
Total common stock authorized and reserved for future issuance	12,984,959	46,257,833
Unreserved common stock available for future issuance	229,150,855	3,221,680

10. STOCK OPTION AND GRANT PLAN

Stock Incentive Plan

In January 2022, the Company's board of directors adopted, and its stockholders approved the 2022 Stock option and Incentive Plan (the "2022 Plan"), which became effective on January 5, 2022, at which point no further grants would be made under the 2015 Stock Option and Restricted Stock Plan (the "2015 Plan"). Under the 2022 Plan, the Company may grant incentive stock options ("ISOs"), non-statutory stock options, stock appreciation rights, restricted stock units, restricted stock awards and other stock-based awards. As of March 31, 2022, there were 3,395,390 shares available for future issuance under the 2022 Plan. The options issued under the 2022 Plan expire after 10 years.

Initially, subject to adjustment as provided in the 2022 Plan, the aggregate number of shares of the Company's common stock available for issuance under the 2022 Plan is 7,650,000. The number of shares of the Company's common stock reserved for issuance under the 2022 Plan will automatically increase on January 1 of each year commencing January 1, 2023, by 5% of the total number of shares of the Company's common stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares as may be determined by the Company's board of directors. The maximum number of shares that may be issued pursuant to the exercise of ISOs under the 2022 Plan is 7,650,000.

The maximum number of shares of the Company's common stock subject to awards granted under the 2022 Plan or otherwise during a single calendar year to any nonemployee directors, taken together with any cash fees paid by the Company to such nonemployee director during the calendar year for serving on the Company's board of directors, will not exceed $750,000 in total

value, or, with respect to the calendar year in which a nonemployee director is first appointed or elected to the Company's board of directors, $1,000,000.

All options and awards granted under the 2015 Plan consisted of the Company's common stock. As of January 6, 2022, no additional stock awards have been or will be granted under the 2015 Plan. Although the 2015 Plan was terminated as to future awards in January 2022, it continues to govern the terms of options that remain outstanding under the 2015 Plan.

General Option Information

A summary of option activity for the three months ended March 31, 2022, is as follows:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2021	5,339,011	$ 5.54	8.7	$ 15,627
Granted	3,657,901	$ 19.55		
Exercised	—	$ —		
Cancelled or forfeited	(4,052)	$ 6.88		
Outstanding at March 31, 2022	8,992,860	$ 11.24	8.8	$ 39,190
Options exercisable as of March 31, 2022	1,772,463	$ 2.68	6.9	$ 18,020
Options unvested as of March 31, 2022	7,220,397	$ 13.34	9.2	$ 21,170
Weighted average grant-date fair value of options granted during the period	$ 14.56			

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the options and the fair value of the Company's common stock for those options that had exercise prices lower than the fair value of the Company's common stock. The aggregate intrinsic value of options exercised during the three months ended March 31, 2022 and 2021, was zero and $2.0 million, respectively.

The total fair value of stock options vested during the three months ended March 31, 2022 and 2021 was $1.8 million and $0.2 million, respectively.

Restricted Stock Unit Activity

A summary of restricted stock unit activity for the three months ended March 31, 2022, is as follows:

	Number of shares	Weighted Average Grant Date Fair Value
Nonvested as of December 31, 2021	—	$ —
Granted	596,709	$ 19.77
Vested	—	—
Forfeited	—	—
Nonvested as of March 31, 2022	596,709	$ 19.77

Summary of Stock-Based Compensation Expense

Stock-based compensation expense recorded in the condensed consolidated statements of comprehensive income for the three months ended March 31, 2022 and 2021, is as follows:

	Three Months Ended March 31,	
	2022	2021
	(in thousands)	
Research and development	$ 1,125	$ 203
General and administrative	3,267	383
Total stock-based compensation expense	$ 4,392	$ 586

The following table summarizes stock-based compensation by type of award (in thousands):

	Three Months Ended March 31,	
	2022	2021
	(in thousands)	
Stock options	$ 3,908	$ 586
Restricted stock units	484	—
Total stock-based compensation expense	$ 4,392	$ 586

The following table summarizes unrecognized stock-based compensation expense as of March 31, 2022, by type of awards, and the weighted-average period over which that expense is expected to be recognized. The total unrecognized stock-based compensation expense will be adjusted for actual forfeitures as they occur.

	As of March 31, 2022	
	Unrecognized Expense	Weighted-average Recognition Period
	(in thousands)	(in years)
Stock options	$ 66,408	3.39
Restricted stock units	$ 11,314	3.84

11. NET LOSS PER SHARE

***Net Loss per Share Attributable to Common Stockholders*—**Because the Company reports a net loss attributable to common stockholders, basic and diluted net loss per share attributable to common stockholders are the same for both periods presented. All preferred stock, stock options and restricted stock units have been excluded from the computation of diluted weighted-average shares outstanding because such securities would have an antidilutive impact. The following common stock equivalents outstanding at each period end have been excluded from the calculation of diluted net loss per share because their inclusion would have been antidilutive:

	March 31, 2022	December 31, 2021
Options to purchase common stock	8,992,860	5,339,011
Unvested restricted stock units	596,709	—
Redeemable convertible preferred stock	—	39,474,330

12. RELATED PARTY TRANSACTIONS

Convertible Notes

In connection with the issuance of the 2021 Notes, the Company issued, in aggregate, $14.3 million of convertible promissory notes to Morningside Ventures Investments Limited, and certain members of the board of directors of the Company. Morningside Ventures Investments Limited is a 5% significant stockholder and has appointed representatives to the board of directors of the Company. These notes were issued under the same terms and conditions as the 2021 Notes (see Note 7).

Supplier Agreements

In the ordinary course of business, the Company may purchase materials or supplies or services from entities that are associated with a party that meets the criteria of a related party of the Company. These transactions are reviewed quarterly and to date have not been material to the Company's condensed consolidated financial statements.

13. COMMITMENTS AND CONTINGENCIES

Lease Commitments

The Company has two operating lease agreements for its office space. See Note 5, *Leases*, to these notes to condensed consolidated financial statements for additional information.

Letter of Credit

Restricted cash consists of cash serving of $0.2 million as collateral for a letter of credit issued for the Company's office space, and $0.2 million as collateral for a corporate credit card program. As of March 31, 2022 and December 31, 2021, the Company's restricted cash balance was $0.4 million and $0.2 million on its consolidated balance sheets, respectively.

Legal Proceedings

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

Royalty Payments

Between August 2016 and February 2019, the Company entered into agreements with the Grantors. Under the terms of the agreements, the Company was granted, in aggregate, $4.3 million. These grants were provided to the Company for the purpose of furthering the research and development of AMX0035 as a therapeutic benefit for ALS disease and Alzheimer's diseases. Under the terms of the arrangements, the Company would receive a tranche of funds as it completes certain milestones. Pursuant to the terms of the grant agreements, the Company has certain payment obligations that are contingent upon future events such as the achievement of commercialization or the receipt of proceeds from a revenue generating transaction resulting from the projects for which the grants are used for.

Pursuant to the terms of the respective grant agreements among the Company, ALS Association and ALS Finding a Cure, the Company will be required to make royalty payments to each Grantor in the total amount equal to 150% of the grant received. The royalty payments will be achieved through a combination of the following payment methods: (i) an annual installment payment of 3% of net sales of any products developed under the project for which the grant was used for and (ii) 3% of cash proceeds resulting from revenue generating transaction under the project for which the grants are used for.

Under the terms of the respective grant agreements among the Company, Alzheimer's Drug Discovery Foundation, the Alzheimer's Association, and Cure Alzheimer's Fund, the Company will make royalty payments up to the maximum amount of $15.0 million to each Grantor (or $45.0 million in aggregate). The royalty payment will be made through a combination of the following payment methods: (i) 4% of annual net sales of any product commercialized from the project for which the grant was used for and directly related to the treatment of the Alzheimer's disease and (ii) 15% of all royalties and cash proceeds resulting from revenue generating transactions associated with the projects for which the grants were used for under the grant agreements. As the achievement and timing of these future royalty payments were not probable or estimable, such amounts have not been included in the consolidated balance sheets as of March 31, 2022 and December 31, 2021.

14. SUBSEQUENT EVENTS

The Company has evaluated all subsequent events after March 31, 2022 and through the date of this filing, and there were no material subsequent events requiring disclosure.

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

The following information should be read in conjunction with the condensed consolidated financial information and the notes thereto appearing elsewhere in this Quarterly Report.

This discussion and other parts of this Quarterly Report contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions. As a result of many factors, including those factors set forth in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

Our mission is to develop therapies that change the treatment paradigm for amyotrophic lateral sclerosis, or ALS, and a broad range of other neurodegenerative diseases by keeping neurons alive. Unlike most other cells in the body that regularly die and are replaced as part of healthy function, mature neurons are normally resistant to cell death and generally cannot regenerate. We are pursuing commercialization of our product candidate, AMX0035, which we believe is the first drug candidate to show both a functional and survival benefit in a large-scale clinical trial of patients with ALS. We submitted a New Drug Submission, or NDS, in Canada in the second quarter of 2021 for AMX0035 for the treatment of ALS, which was accepted for review in the third quarter of 2021, a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA, in the fourth quarter of 2021, which was accepted for priority review in the same quarter and a Marketing Authorization Application, or MAA, in Europe in the first quarter of 2022, which was validated in the same quarter. The Prescription Drug User Fee Act date, the target date by which the FDA intends to complete its review and take action on the NDA for AMX0035 for the treatment of ALS, is June 29, 2022. On March 30, 2022, the FDA held a virtual meeting of its Peripheral and Central Nervous System Drugs Advisory Committee, or the Advisory Committee. At that meeting, on the question whether the data from our randomized, controlled Phase 2 CENTAUR trial and open-label extension, or OLE, trial established a conclusion that AMX0035 is effective in the treatment of patients with ALS, the Advisory Committee voted 4 (yes) and 6 (no). Although the FDA considers the recommendations of its advisory committees, the recommendation by the Advisory Committee is non-binding. The final decision regarding approval of a pending NDA is made by the FDA, and we remain committed to pursuing its approval given the pressing need for new treatments for ALS. The Prescription Drug User Fee Act date, the target date by which the FDA intends to complete its review and take action on the NDA for AMX0035 for the treatment of ALS, is June 29, 2022. We believe AMX0035 has the potential to be a foundational therapy, meaning that it could be used alone or in conjunction with other therapies to change the treatment paradigm across a broad range of neurodegenerative diseases.

AMX0035 is a dual UPR-Bax apoptosis inhibitor composed of sodium phenylbutyrate, or PB, and TURSO (also known as tauroursodeoxycholic acid, or TUDCA). Through the resolution of the unfolded protein response, or UPR, and by inhibiting translocation of the Bcl-2 Associated X-protein, or Bax, to the outer mitochondrial membrane, we have shown in multiple models that AMX0035 can keep neurons alive under a variety of different conditions and stresses, including in in vitro models of neurodegeneration, endoplasmic reticulum stress, mitochondrial dysfunction, oxidative stress and disease-specific models of a variety of other conditions, as well as in vivo models of Alzheimer's Disease, or AD, and multiple sclerosis. We are pursuing ALS as our first indication as it is a disease of rapid and profound neurodegeneration, and we are focused on the development and potential commercialization of AMX0035 for ALS globally.

In November 2021, we initiated a global Phase 3 clinical trial of AMX0035 for the treatment of ALS, known as the PHOENIX trial, at clinical trial sites in the United States and Europe. Enrollment in this trial has completed in the United States and remains ongoing in Europe. We anticipate topline results from the PHOENIX trial in 2024. This trial is designed to provide further data supporting the safety and efficacy of AMX0035 for the treatment of ALS and to further support our global regulatory efforts. Based on dialogue with the FDA prior to our NDA submission, including at a pre-NDA meeting recommended by the FDA and subsequent discussions, we believed that data from the PHOENIX trial would not be required for the FDA to make a determination on the approval of AMX0035 for the treatment of ALS, although we had no assurance that the FDA would not require further data before making a determination. Based on the Advisory Committee meeting held on March 30, 2022, and the FDA's feedback at that meeting, it remains uncertain whether additional clinical data will be required to make a determination on the approval of AMX0035 for the treatment of ALS. On March 18, 2022, we also announced the launch of a United States expanded access program that the FDA has authorized for people with ALS who meet eligibility criteria for participation.

Since inception in 2013, we have devoted substantially all of our efforts to research and development activities, including recruiting management and technical staff, raising capital, producing materials for non-clinical and clinical studies, planning for potential commercialization and building infrastructure to support such activities. We do not have any products approved for sale and have not generated any revenue from product sales. As of March 31, 2022, we have funded our operations primarily with net cash

proceeds of $172.7 million from the sale of our redeemable convertible preferred stock, $58.6 million from convertible notes and net cash proceeds of $196.4 million from the sale of common stock in our initial public offering. We have also generated grant revenues through five grants from ALS Association, ALS Finding a Cure Foundation, Cure Alzheimer's Fund, Alzheimer's Drug Discovery Foundation and Alzheimer's Association, or the Grantors.

We have incurred operating losses since inception, including a net loss of $47.8 million for the three months ended March 31, 2022. As of March 31, 2022, we had an accumulated deficit of $203.7 million. These losses have resulted primarily from costs incurred in connection with research and development activities and general and administrative costs associated with our operations. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future as we advance AMX0035 and any future product candidates through preclinical and clinical development, hire additional clinical, scientific, management and administrative personnel, seek regulatory approval and pursue commercialization of any approved product candidates. To date, we have primarily developed AMX0035 internally, with assistance from our network of contract research organizations, or CROs, and other advisors. This has resulted in increased research and development spending but has enabled us to manage AMX0035 efficiently through the development and manufacturing process.

We expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company. As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources, including potential collaborations with other companies, royalty financings, or other strategic transactions. Our inability to raise capital as and when needed could have a negative impact on our financial condition and ability to pursue our business strategies. There can be no assurances, however, that our current operating plan will be achieved or that additional funding will be available on terms acceptable to us, or at all.

As of March 31, 2022, we had cash, cash equivalents and short-term investments of $255.2 million. We believe that our existing cash, cash equivalents and short-term investments will be sufficient to meet our anticipated operating and capital expenditure requirements for at least one year from the date of this filing. 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—Funding Requirements" below.

Impact of COVID-19

The development of AMX0035 and any future product candidates could be disrupted and materially adversely affected in the future by a pandemic, epidemic or outbreak of an infectious disease, such as the ongoing and evolving COVID-19 pandemic. The spread of COVID-19 and identification of new variants of the virus has impacted the global economy and our operations, including requiring us to make certain alterations to our preclinical and clinical trial activities, such as scheduling certain work off-site and performing off-site assessments. In addition, we had to amend our CENTAUR trial protocol to allow for remote visits by patients, instead of patients making site visits and in certain cases we were forced to delay enrollment at certain sites in our Phase 2 clinical trial for AMX0035 in AD.

In spite of vaccination efforts, if the disruption due to the ongoing COVID-19 pandemic continues, our ongoing global Phase 3 PHOENIX clinical trial for AMX0035 for the treatment of ALS could be delayed due to government orders and site policies on account of the pandemic. Additionally, some patients may be unwilling or unable to travel to study sites, enroll in our trials or be unable to comply with clinical trial protocols, which would delay our ability to conduct preclinical studies and clinical trials or release clinical trial results, as well as delay our ability to obtain regulatory approval for and commercialize AMX0035. Furthermore, the COVID-19 pandemic could continue to affect our employees or the employees of research sites and service providers on whom we rely as well as those of companies with which we do business, including our suppliers, thereby disrupting our business operations. Existing or renewed quarantines and travel restrictions imposed by governments in the jurisdictions in which we and the companies with which we do business operate could materially impact the ability of employees to access preclinical and clinical sites, laboratories, manufacturing sites and offices. We have implemented and continue to follow work-at-home policies and may

experience limitations in employee resources. Our continued reliance on personnel working from home may negatively impact productivity, or disrupt, delay or otherwise adversely impact our business.

Components of Our Results of Operations

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with the research and development of AMX0035. We expense research and development costs as incurred. These expenses include:

- expenses incurred under agreements with CROs, contract manufacturing organizations, or CMOs, as well as investigative sites and consultants that conduct our clinical trials, preclinical studies and other scientific development services;
- manufacturing scale-up expenses and the cost of acquiring and manufacturing preclinical studies, including manufacturing registration and validation batches, as well as clinical trial materials;
- expenses to acquire technologies to be used in research and development;
- employee-related expenses, including salaries, payroll taxes, related benefits and stock-based compensation expense for employees engaged in research and development functions; and
- costs related to compliance with quality and regulatory requirements.

Advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. Such amounts are recognized as an expense as the goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered, or the services rendered.

Certain of our indirect research and development expenses are not tracked on an indication-by-indication basis for AMX0035. We do not allocate employee costs and facilities, including depreciation or other indirect costs, to specific indications because these costs are deployed across multiple indications and, as such, are not separately classified. We use internal resources to oversee the research and discovery as well as to manage our preclinical development, process development, manufacturing and clinical development activities. These employees work across multiple indications and, therefore, we do not track their costs by indication.

Research and development activities are central to our business model. Product candidates such as AMX0035 in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials and related product manufacturing expenses. We expect that our research and development expenses will continue to increase substantially in connection with our planned clinical development activities in the near term and in the future. At this time, we cannot accurately estimate or know the nature, timing and costs of the efforts that will be necessary to complete the clinical development of AMX0035 and any future product candidates. Our clinical development costs may vary significantly based on factors such as:

- per patient trial costs;
- the number of trials required for approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients that participate in the trials;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up periods;
- the cost and timing of manufacturing our current or future product candidates;

- the phase of development of our current or future product candidates;
- the efficacy and safety profile of our current or future product candidates; and
- the number of product candidates we are developing.

The successful development and commercialization of AMX0035 and any future product candidates is highly uncertain, due to the numerous risks and uncertainties associated with product development and commercialization, including the following:

- the timing and progress of nonclinical and clinical development activities;
- the number and scope of nonclinical and clinical trials for separate indications we decide to pursue;
- raising necessary additional funds;
- the progress of the development efforts of parties with whom we may enter into collaboration arrangements;
- our ability to maintain our current development activities and to establish new ones;
- our ability to establish new licensing or collaboration arrangements;
- the successful initiation and completion of clinical trials with safety, tolerability and efficacy profiles that are satisfactory to Health Canada, the U.S. Food and Drug Administration, or the FDA, the European Medicines Association, or the EMA, or any other comparable foreign regulatory authority;
- the receipt and related terms of regulatory approvals from applicable regulatory authorities;
- the availability of drug substance and drug product for use in production of AMX0035;
- establishing and maintaining agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if AMX0035 is approved;
- our ability to obtain and maintain patents, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- our ability to protect our rights in our intellectual property portfolio;
- the commercialization of AMX0035, if and when approved;
- obtaining and maintaining third-party insurance coverage and adequate reimbursement;
- the acceptance of AMX0035, if approved, by patients, the medical community and third-party payors;
- competition with other product; and
- a continued acceptable safety profile of our therapies following approval.

A change in the outcome of any of these variables with respect to the development of AMX0035 or any future product candidates. We may never succeed in obtaining regulatory approval for AMX0035 or any future product candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for personnel in executive, finance, sales, marketing, as well as administrative functions. General and administrative expenses also include legal fees relating to patent and corporate matters; professional fees for accounting, auditing, tax and administrative consulting services; insurance costs; administrative travel expenses; marketing expenses; rent expense and other operating costs. We anticipate that our general and administrative expenses will continue to increase in the future as we further increase our headcount to support our continued research activities and development of AMX0035 and as we continue to increase headcount and incur other significant costs related to our pre-commercialization activities as we prepare for potential near term regulatory approvals. We also anticipate that we will 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 being a public company. Additionally, we are pursuing regulatory approval of AMX0035 for the treatment of ALS, initially in Canada, the United States and Europe. As we prepare for a potential approval in each territory, we have incurred increased, and anticipate further increases in, payroll and expense as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of AMX0035.

Other Income (Expense), Net

Interest Income

Interest income consists of interest income earned on our cash and cash equivalents, and short-term investments.

Other (Expense) Income, Net

Other (expense) income, net consists primarily of realized and unrealized gains and losses on foreign exchange transactions.

Change in Fair Value of Convertible Notes

Change in fair value of convertible notes is comprised of adjustments to the fair value of our 2021 Notes. As permitted under ASC Topic 825, *Financial Instruments* (ASC 825), we elected the fair value option to account for our 2021 Notes, and as a result, we measured our 2021 Notes at fair value at each financial reporting period and immediately before conversion in July 2021. All changes to the fair value of our 2021 Notes for the three months ended March 31, 2021 resulted in a loss. Our 2021 Notes converted into shares of Series C-2 redeemable convertible preferred stock concurrently with the issuance of our Series C-1 redeemable convertible preferred stock. Immediately prior to the conversion, we determined the fair value of our 2021 Notes based on the fair value of the Series C-1 redeemable convertible preferred stock and the conversion price at which these notes converted, which was at 85% of the fair value of the Series C-1 redeemable convertible preferred stock.

Income Taxes

The provision for income taxes primarily consists of provisions for foreign taxes payable.

Results of Operations

Comparison of the three months ended March 31, 2022 and 2021

The following table summarizes our results of operations for the three months ended March 31, 2022 and 2021:

	Three Months Ended March 31,			
	2022	2021	$ Change	% Change
	(in thousands)			
Operating expenses:				
Research and development	$ 21,464	$ 6,864	$ 14,600	213 %
General and administrative	26,350	6,004	20,346	339 %
Total operating expenses	47,814	12,868	34,946	272 %
Loss from operations	$ (47,814)	$ (12,868)	$ (34,946)	272 %
Other income (expense), net:				
Interest income	131	2	129	6450 %
Change in fair value of convertible notes	—	(1,918)	1,918	(100)%
Other (expense) income, net	(19)	261	(280)	(107)%
Total other expense, net	112	(1,655)	1,767	(107)%
Loss before income taxes	(47,702)	(14,523)	(33,179)	228 %
Provision for income taxes	146	—	146	*NM
Net loss	$ 47,848	$ 14,523	$ 33,325	229 %

* NM - not meaningful

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended March 31, 2022 and 2021:

	Three months ended March 31,			
	2022	2021	$ Change	% Change
	(in thousands)			
AMX0035 - ALS	$ 15,236	$ 4,014	$ 11,222	280 %
Payroll and personnel-related	5,866	1,448	4,418	305 %
Other	362	1,402	(1,040)	(74)%
	$ 21,464	$ 6,864	$ 14,600	213 %

Research and development expenses were $21.5 million for three months ended March 31, 2022, compared to $6.9 million for the three months ended March 31, 2021. During these periods, all our research and development expenses were related to the development of and clinical trials of AMX0035. The increase of $14.6 million was primarily due to a $11.2 million increase in spending on AMX0035 for the treatment of ALS, a $4.4 million increase in payroll and personnel-related costs, and a $1.0 million decrease in all other costs. The increases in spending on AMX0035 were primarily related to costs associated with our Phase 3 Phoenix trial of AMX0035 in ALS that commenced in 2021 and consulting and manufacturing development expenses in anticipation of potential commercialization. The increase in payroll and personnel-related costs was primarily due to an increase in the number of employees supporting research and development efforts. Decrease in other costs is primarily due to a decrease in costs associated with research and development spend for AMX0035 in other indications.

General and Administrative Expenses

General and administrative expenses were $26.4 million for the three months ended March 31, 2022 compared to $6.0 million for the three months ended March 31, 2021. The increase of $20.3 million was primarily due to an increase of $10.9 million in payroll and personnel-related costs, $5.5 million increase in professional services and $2.4 million in consulting expenses. The increase in payroll and personnel-related costs was primarily due to hiring additional personnel in general and administrative functions to support our growth and launch preparation initiatives. The increase in professional services and consulting expenses was primarily due to an increase in spending for commercial readiness activities.

Other Income (Expense), Net

Interest Income

Interest income for the three months ended March 31, 2022 was $0.1 million compared to less than $0.1 million for the three months ended March 31, 2021. The increase is primarily attributable to higher investment balances driven by our proceeds received from our January 2022 initial public offering, resulting in higher interest earned.

Interest Expense

Interest expense was zero for the three months ended March 31, 2022 compared to less than $0.1 million for the three months ended March 31, 2021.

Change in Fair Value of Convertible Notes

The change in fair value of convertible notes was zero for the three months ended March 31, 2022 due to conversion to preferred stock in July 2021, compared to $1.9 million for the three months ended March 31, 2021. The $1.9 million recorded for the three months ended March 31, 2021 represented a loss in fair value related to our 2021 Notes.

Other Expense (Income), Net

Other expense, net was zero for the three months ended March 31, 2022, compared to other income of $0.3 million for the three months ended March 31, 2021. The $0.3 million of other income in the three months ended March 31, 2021 was primarily related to the forgiveness of the PPP loan.

Income Taxes

Provision for income taxes was $0.1 million for the three months ended March 31, 2022 compared to zero for the three months ended March 31, 2021 and consists of current income tax expense arising from activities of our foreign subsidiaries.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have incurred significant operating losses and generated revenues through five grants from the Grantors. We have not yet commercialized any products. To date, we have financed our operations primarily through the sale and issuance of common stock, convertible preferred stock, convertible notes, grant agreements with the Grantors and, to a lesser extent, a government loan. As of March 31, 2022, we had cash, cash equivalents and short-term investments of $255.2 million.

From inception through March 31, 2022, we have raised $430.8 million in aggregate proceeds, net of issuance costs, primarily from the issuance of common stock, convertible preferred stock, convertible notes and grant agreements. In July 2021, we issued and sold shares of Series C-1 preferred stock for an aggregate purchase price of approximately $135.0 million. The 2021 Notes automatically converted into shares of Series C-2 preferred stock pursuant to their original terms in July 2021 in connection with our sale of Series C-1 preferred stock. On January 11, 2022, we completed our initial public offering, pursuant to which we received aggregate net proceeds of $196.4 million, including the partial exercise by the underwriters of their option to purchase additional shares, and after deducting underwriting discounts and commissions and other offering costs. Based on our current operational plans and assumptions, we believe that our existing cash, cash equivalents and short-term investments, together with the net proceeds from our initial public offering, will be sufficient to meet our anticipated operating and capital expenditure requirements for at least twelve months after the date of the filing of this Quarterly Report.

Capital Resources

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities, manufacturing and clinical trials of AMX0035 and any future product candidates, and prepare for the commercial launch of AMX0035, if approved. In addition, we expect to incur additional costs associated with operating as a public

company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company. Our expenses will also increase as we:

- continue our research and development efforts, including our ongoing global Phase 3 PHOENIX trial of AMX0035 for the treatment of ALS;
- pursue commercialization of AMX0035 for the treatment of ALS, initially in Canada, the United States and Europe;
- submit investigational new drug applications, or INDs, of AMX0035 for the treatment of Wolfram syndrome and potentially for other indications;
- conduct preclinical studies and clinical trials for potential future product candidates;
- seek to identify and develop, acquire or in-license additional product candidates;
- experience any delays or encounter any issues with any of the above, including but not limited to failed studies, complex results, safety issues, or other regulatory challenges;
- develop the necessary processes, controls and manufacturing data to obtain marketing approval for AMX0035 or any future product candidates and to support manufacturing on a commercial scale;
- seek regulatory approvals for AMX0035 or any future product candidates that successfully complete clinical trials, if any;
- hire and retain additional personnel, such as non-clinical, clinical, quality assurance, regulatory affairs, manufacturing, distribution, legal, compliance, finance, general and administrative, commercial and scientific personnel;
- develop, maintain, expand and protect our intellectual property portfolio; and
- continue to transition our organization to being a public company.

We are now a publicly traded company and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act of 2002, as well as rules adopted by the SEC and the Nasdaq Global Select Market, require public companies to implement specified corporate governance practices that are currently not applicable to us as a private company. Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we will first be required to furnish a report by our management on our internal control over financial reporting for the year ending December 31, 2022. However, while we remain an emerging growth company and/or a smaller reporting company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. We expect these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

Based on our current operational plans and assumptions, we expect that our current cash, cash equivalents and short-term investments, combined with the net proceeds from our initial public offering will be sufficient to fund operations for at least twelve months after the date of filing of this Quarterly Report. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. As we progress with our development activities and the regulatory review process, we expect to incur significant commercialization expenses related to product manufacturing, pre-commercial activities and commercialization.

Because of the numerous risks and uncertainties associated with research, development and commercialization of product candidates and programs, 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 drug discovery, laboratory testing, preclinical and clinical development for AMX0035 and any future product candidates;
- the costs, timing and outcome of potential future commercialization activities, including manufacturing, marketing, sales and distribution for AMX0035 or any future product candidates for which we receive marketing approval;
- the costs, timing and outcome of regulatory review of AMX0035 and any future product candidates;
- our ability to establish and maintain collaborations and license agreements on favorable terms, if at all;

- our ability to enroll clinical trials in a timely manner and to quickly resolve any delays or clinical holds that may be imposed on our development activities;
- timing delays with respect to preclinical and clinical development of AMX0035 and any future product candidates, including as result of the ongoing COVID-19 pandemic or other pandemics or disruptions;
- the costs of expanding our facilities to accommodate our expected growth in personnel, and the costs of such additional personnel;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the extent to which we acquire technologies or other assets;
- the sales price and availability of adequate third-party coverage and reimbursement for AMX0035 and any future product candidates, if and when approved; and
- the costs of operating as a public company.

Until such time, if ever, that we can generate product revenue sufficient to achieve profitability, we expect to finance our cash needs through equity offerings, debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of common stock, convertible securities or other equity securities, current ownership interests will be diluted. If we raise additional funds through collaborations or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. In addition, debt financing, if available, may result in fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, creating liens, redeeming stock or declaring dividends, that could adversely impact our ability to conduct our business. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Cash Flows

Comparison of the Three Months Ended March 31, 2022 and 2021

The following table summarizes our sources and uses of cash for the three months ended March 31, 2022 and 2021:

	Three Months Ended March 31,			
	2022	2021	$ Change	% Change
	(in thousands)			
Net cash used in operating activities	$ (40,634)	$ (12,643)	$ (27,991)	221%
Net cash used in investing activities	(99,311)	(14)	(99,297)	709,264%
Net cash provided by financing activities	200,455	25,927	174,528	673%
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(68)	—	(68)	*NM
Net increase in cash, cash equivalents and restricted cash	$ 60,442	$ 13,270	$ 47,172	355%

* NM – not meaningful

Operating Activities

During the three months ended March 31, 2022, operating activities used $40.6 million of cash, primarily resulting from our net loss of $47.8 million, offset by $4.4 million of non-cash stock-based compensation expense, less than $0.1 million of depreciation expense, less than $0.1 million net amortization of premiums and discounts on investments, and $2.8 million increase in net cash used in our operating assets and liabilities.

Net cash used in our operating assets and liabilities primarily consisted of a $4.9 million increase in prepaid expenses and other current assets due to recognition of deferred offering cost related to the initial public offering, and an increase of $0.5 million in other assets, offset by a $5.0 million increase in accounts payable, a $2.7 million increase in accrued expenses and deferred rent due to

increased spending for external research and development to support our growth, and $0.4 million decrease in operating lease right-of use assets.

During the three months ended March 31, 2021, operating activities used $12.6 million of cash, primarily resulting from our net loss of $14.5 million, $0.6 million of net cash provided by changes in our operating assets and liabilities, offset by $1.9 million of change in fair value of convertible note, $0.6 million of non-cash stock compensation expense.

Net cash provided by changes in our operating assets and liabilities primarily consisted of a $0.2 million increase in accounts payable, $0.1 million decrease in other non-current assets, offset by $0.7 million decrease in accrued expenses and other current liabilities and a $0.2 million increase in prepaid expenses and other current assets.

Investing Activities

During the three months ended March 31, 2022, net cash used in investing activities was $99.3 million, resulting from $0.3 million of purchases of property and equipment and $123.9 million of purchases of short-term investments, offset by $24.9 million of investments that matured during the period.

During the three months ended March 31, 2021, net cash used in investing activities was less than $0.1 million, driven by purchases of property and equipment.

Financing Activities

During the three months ended March 31, 2022, net cash provided by financing activities was $200.5 million. This amount consisted of $216.0 million of gross proceeds from sale of common stock from our initial public offering, offset by $15.1 million of underwriters' discounts and $0.4 million of offering costs paid during the period. Offering costs remaining to be paid as of March 31, 2022 totaled $1.6 million, coupled with offering costs paid in prior periods, results in total net proceeds from the initial public offering of $196.4 million.

During the three months ended March 31, 2021, net cash provided by financing was $25.9 million, This amount consisted of $14.3 million of proceeds from the issuance of convertible notes to related parties, $11.9 million of proceeds from the issuance of the convertible notes and less than $0.1 million of proceeds from exercises of stock options, offset by a $0.3 million forgiveness of PPP loan.

In April 2020, we received the PPP Loan from First Republic Bank. Under the terms of the CARES Act and the PPP Loan, all or portion of the principal amount of the PPP Loan was subject to forgiveness so long as, over the 24-week period following our receipt of the proceeds of the PPP Loan, we used those proceeds for payroll costs, rent, utility costs or the maintenance of employee and compensation levels. The PPP Loan was forgiven in March 2021 and notwithstanding the forgiveness of the PPP Loan, we repaid it in full on October 7, 2021.

Critical Accounting Policies, Recent Accounting Pronouncements and Significant Judgments and Estimates

There have been no significant changes to our critical accounting policies from those described in “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” disclosed in our most recent Annual Report on Form 10-K with the exception of significant accounting policies related to the adoption of FASB ASC Topic 842, Leases, effective January 1, 2022. Refer to Note 5 to the consolidated financial statements contained in this Quarterly Report for a discussion of FASB ASC Topic 842, Leases.

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 and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

Emerging Growth Company and Smaller Reporting Company Status

The Jumpstart Our Business Startups Act of 2012, or the JOBS Act, permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, we will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies, and our condensed consolidated financial statements may not be comparable to other public companies that comply with new or revised accounting pronouncements as of public company effective dates. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies.

We will cease to be an emerging growth company on the date that is the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more, (ii) the last day of our fiscal year following the fifth anniversary of the date of the closing of our initial public offering, (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years or (iv) the date on which we are deemed to be a large, accelerated filer under the rules of the Securities and Exchange Commission.

We are also a "smaller reporting company", meaning that the market value of our stock held by non-affiliates plus the aggregate amount of gross proceeds to us as a result of our initial public offering is less than $700 million and our annual revenue was less than $100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company after our initial public offering if either (i) the market value of our stock held by non-affiliates is less than $250 million or (ii) our annual revenue was less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures.

We maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive officers and principal financial officer, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our management, with the participation of our Chief Executive Officers and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2022. Based upon the evaluation, our Chief Executive Officers and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control over Financial Reporting.

There were no changes in our internal control over financial reporting that occurred during the three months ended March 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

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

Item 1A. Risk Factors.

There have been no material changes in risk factors set forth in our most recent Annual Report filed on Form 10-K for the fiscal year ended December 31, 2021.

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

Use of Proceeds from Our Initial Public Offering

In January 2022, we completed our initial public offering in which we issued and sold 11,369,369 shares of common stock at a price to the public of $19.00 per share, for gross proceeds of $216.0 million and net proceeds of approximately $196.4 million after deducting underwriting discounts and commissions and other offering expenses. None of the expenses associated with the initial public offering were paid to directors, officers, persons owning 10% or more of any class of our equity securities, or to their associates, or to our affiliates. The offer and sale of our shares were registered pursuant to a Registration Statement on Form S-1 (Registration No. 333-261703) and the related Registration Statement on Form S-1 (Registration No. 333-262046) filed pursuant to Rule 462(b) under the Securities Act, which were declared effective on January 6, 2022 (together, the "Registration Statement"). Goldman Sachs & Co. LLC, SVB Leerink LLC and Evercore Group L.L.C. acted as lead book-running managers. H.C. Wainwright & Co., LLC acted as co-manager for the initial public offering. Shares of our common stock began trading on The Nasdaq Global Market on January 7, 2022.

There has been no material change in the planned use of proceeds from our initial public offering as described in our Prospectus that forms a part of our Registration Statement, which was filed with the SEC pursuant to Rule 424 on January 10, 2022. As of March 31, 2022, we consumed approximately $40.5 million of net proceeds from the initial public offering, primarily to advance AMX0035 through clinical trials, manufacture drug supply, prepare for potential commercialization and for working capital and general corporate purposes. We invested the remaining funds received in cash equivalents and other marketable securities in accordance with our investment policy.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description
3.1	Fourth Amended and Restated Certificate of Incorporation of Amylyx Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 11, 2022).
3.2	Second Amended and Restated Bylaws of Amylyx Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 11, 2022).
4.1	Specimen Common Stock Certificate (Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1/A (File No. 333-261703) filed with the Securities and Exchange Commission on January 3, 2022).
10.1#	2022 Stock Option and Incentive Plan, and form of award agreements thereunder (Incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1/A (File No. 333-261703) filed with the Securities and Exchange Commission on January 3, 2022).
10.2#	2022 Employee Stock Purchase Plan (Incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1/A (File No. 333-261703) filed with the Securities and Exchange Commission on January 3, 2022).
10.3#	Executive Cash Incentive Bonus Plan (Incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1/A (File No. 333-261703) filed with the Securities and Exchange Commission on January 3, 2022).
10.4#	Non-Employee Director Compensation Policy (Incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1/A (File No. 333-261703) filed with the Securities and Exchange Commission on January 3, 2022).
10.5#	Form of Employment Agreement, between the Registrant and Joshua Cohen (Incorporated by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1/A (File No. 333-261703) filed with the Securities and Exchange Commission on January 3, 2022).
10.6#	Form of Employment Agreement, between the Registrant and Justin Klee (Incorporated by reference to Exhibit 10.13 to the Registrant's Registration Statement on Form S-1/A (File No. 333-261703) filed with the Securities and Exchange Commission on January 3, 2022).
10.7#	Form of Employment Agreement, between the Registrant and James Frates (Incorporated by reference to Exhibit 10.14 to the Registrant's Registration Statement on Form S-1/A (File No. 333-261703) filed with the Securities and Exchange Commission on January 3, 2022).
10.8#	Form of Employment Agreement, between the Registrant and Margaret Olinger (Incorporated by reference to Exhibit 10.15 to the Registrant's Registration Statement on Form S-1/A (File No. 333-261703) filed with the Securities and Exchange Commission on January 3, 2022).
10.9#	Form of Employment Agreement, between the Registrant and Patrick D. Yeramian, M.D. (Incorporated by reference to Exhibit 10.16 to the Registrant's Registration Statement on Form S-1/A (File No. 333-261703) filed with the Securities and Exchange Commission on January 3, 2022).
10.10#	Form of Director Indemnification Agreement (Incorporated by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1 (File No. 333-261703) filed with the Securities and Exchange Commission on December 16, 2021).
10.11#	Form of Officer Indemnification Agreement (Incorporated by reference to Exhibit 10.13 to the Registrant's Registration Statement on Form S-1 (File No. 333-261703) filed with the Securities and Exchange Commission on December 16, 2021).
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 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.
31.3*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1+	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2+	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.3+	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.

101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.
+ This certification will not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, except to the extent specifically incorporated by reference into such filing.
# Indicates a management contract or any compensatory plan, contract or arrangement.

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.

AMYLYX PHARMCEUTICALS, INC.

Date: May 12, 2022

By: /s/ Joshua B. Cohen
Co-Chief Executive Officer

By: /s/ James M. Frates
Chief Financial Officer

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Joshua B. Cohen, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Amylyx Pharmaceuticals, 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:

    i. 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;

    ii. 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;

    iii. 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

    iv. 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):

    i. 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

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

Date: May 12, 2022

By: /s/ **Joshua B. Cohen**
Joshua B. Cohen
Co-Chief Executive Officer

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Justin B. Klee, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Amylyx Pharmaceuticals, 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:

    i. 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;

    ii. 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;

    iii. 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

    iv. 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):

    i. 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

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

Date: May 12, 2022

By: /s/ **Justin B. Klee**
Justin B. Klee
Co-Chief Executive Officer

Exhibit 31.3

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, James M. Frates, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Amylyx Pharmaceuticals, 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:

    i. 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;

    ii. 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;

    iii. 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

    iv. 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):

    i. 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

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

Date: May 12, 2022

By: /s/ **James M. Frates**
James M. Frates
Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Amylyx Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ending March 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: May 12, 2022

By: /s/ **Joshua B. Cohen**
Joshua B. Cohen
Co-Chief Executive Officer

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Amylyx Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ending March 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: May 12, 2022

By: /s/ **Justin B. Klee**
Justin B. Klee
Co-Chief Executive Officer

Exhibit 32.3

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Amylyx Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the period ending March 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: May 12, 2022

By: /s/ **James M. Frates**
James M. Frates
Chief Financial Officer