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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED March 31, 2023
OR

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

FOR THE TRANSITION PERIOD FROM _ TO _
COMMISSION FILE NUMBER 001-38501

AXCELLA HEALTH INC.
(Exact name of registrant as specified in its charter)

Delaware	26-3321056
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
P.O. Box 1270 Littleton, Massachusetts **(Address of principal executive offices)**	01460 **(Zip Code)**

(857) 320-2200
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, $0.001 par value per share	AXLA	The Nasdaq Global Market

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Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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, a 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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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 April 28, 2023, the registrant had 73,686,948 shares of common stock, $0.001 par value per share, outstanding.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

In this Quarterly Report on Form 10-Q, or Quarterly Report, we use the following defined terms:

"product candidate" to refer to one of our investigational product candidates.

"development platform" to refer to our proprietary human-focused development platform.

"dose" to refer to the exposure amount of a product candidate in Clinical Studies or Clinical Trials.

"non-drug" to refer to a non-therapeutic use of a product candidate. Such use may be as a medical food, food product or dietary supplement.

"Clinical Trial" to refer to a human clinical study of a drug product candidate subject to the requirements for an effective Investigational New Drug application, or an IND.

"Clinical Study" to refer to Institutional Review Board-Approved, or IRB-Approved, clinical studies conducted in humans with our product candidates under U.S. Food and Drug Administration, or the FDA, regulations and guidance supporting research with food outside of an IND (prior to any decision to develop a product candidate as a drug product candidate under an IND or a non-drug product candidate). In these food studies, based on our understanding of FDA regulations and guidance, we evaluate in humans, including individuals with disease, a product candidate for safety, tolerability and effects on the normal structures and functions of the body. These studies are not designed or intended to evaluate a product candidate’s ability to diagnose, cure, mitigate, treat or prevent a disease as these would be evaluated in Clinical Trials if we decide to develop a product candidate as a drug or therapeutic.

This Quarterly Report contains forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical facts contained in this Annual Report are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “may”, “will”, “should”, “expects”, “intends”, “plans”, “anticipates”, “believes”, “estimates”, “predicts”, “potential”, “continue” or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- our plans and expectations regarding our strategic alternative review process and the timing and success of such process regarding a potential transaction;
- success in retaining our officers, key employees or directors;
- our ability to fund our planned operations for the next twelve months and our ability to continue to operate as a going concern;
- expectations that our cash will be sufficient to fund our operating expenses and capital expenditure requirements into the second quarter of 2023;
- expectations that we will be able to obtain funding for our operations, including funding necessary to complete further development, any future clinical trials we may conduct and, if approved, commercialization of any product candidates we may develop;
- the benefits of our product candidates to health and/or disease and their commercial potential;
- the success, cost and timing of our product development activities, including statements regarding the timing of initiation and completion of preclinical studies, Clinical Studies or Clinical Trials and related preparatory

work, and the timing of the availability of the results of these preclinical studies, Clinical Studies and Clinical Trials;

- our ability to use our research platform to design new product candidates with desirable biological activity;
- our ability to obtain and maintain regulatory approval or find alternate regulatory commercialization pathways from the FDA, the Medicines and Healthcare products Regulatory Agency (MHRA), the European Medicines Agency, or the EMA, and other comparable regulatory authorities for our product candidates, and any related restrictions, limitations or warnings in the label of an approved product candidate;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates, development platform and the type of such protection;
- our ability and the potential to successfully manufacture our product candidates for preclinical studies, Clinical Studies and Clinical Trials and for commercial use, if approved;
- the size and growth potential of the markets for our product candidates and our ability to serve those markets, either alone or in combination with others;
- the rate and degree of market acceptance of our product candidates, if approved;
- regulatory developments in the United States and foreign countries;
- our ability to enter into a collaboration, partnership, or other agreement with a third party on reasonable terms or at all to develop one or more product candidates or commercialize any of our product candidates, if approved;
- our ability to secure sufficient manufacturing and supply chain capacity;
- the success of competing products or therapies that are or may become available;
- our ability to attract and retain key scientific, management or other necessary personnel;
- impairment charges for long-lived assets;
- our estimates regarding expenses for both product development and as a public company, future revenue, capital requirements and needs for additional financing;
- the potential for faults in our internal controls;
- the effect of the COVID-19 pandemic or any future public health emergency on any of the foregoing; and
- other risks and uncertainties, including those discussed in "Risk Factors" and "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2022, which is incorporated by reference into this Quarterly Report.

Any forward-looking statements in this Quarterly Report and the documents incorporated by reference 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 "Risk Factors" and "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2022, which is incorporated by reference into this Quarterly 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.

SUMMARY OF MATERIAL RISKS ASSOCIATED WITH OUR BUSINESS

Our business is subject to numerous risks and uncertainties that you should be aware of in evaluating our business. These risks include, but are not limited to, the following:

- We have incurred net losses in every year since our inception and anticipate that we will continue to incur net losses in the future.
- We will require additional capital to fund our operations and if we fail to obtain necessary financing, we will not be able to complete development and commercialization of our product candidates.
- Substantial doubt exists as to our ability to continue as a going concern.
- Clinical development is a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of any product candidates, which could impair our ability to fund our operations or obtain financing on acceptable terms, or at all.
- Any use of our product candidates to support and maintain homeostasis, which helps support normal structures and functions of the body, or to modulate dysregulated metabolism is a novel approach and negative perception of any product candidates that we develop could adversely affect our ability to conduct our business, obtain regulatory approvals or identify alternate regulatory pathways, to the extent required by applicable laws, to market such product candidates.
- We face significant competition from other healthcare companies, and our operating results will suffer if we fail to compete effectively.
- If we lose key management personnel, or if we are unable to recruit additional highly skilled personnel, our ability to identify and develop new or next generation product candidates will be impaired, could result in loss of markets or market share and could make us less competitive.
- COVID-19 or any future public health emergency may materially and adversely affect our business and our financial results.
- Regulatory requirements for development of our product candidates as drugs or as non-drug products are uncertain and evolving. Should we choose to develop any product candidate in parallel for more than one indication, the results from a Clinical Study or Clinical Trial in one indication, particularly any observation of a serious adverse event, may impact the Clinical Study or Clinical Studies or Clinical Trial or Clinical Trials in another indication. Changes in these laws, including our ability to conduct Clinical Studies or Clinical Trials, or the current interpretation or application of these laws, or conflicts between us and the FDA on the applicability or interpretation of applicable laws, would have a significant adverse impact on our ability to develop and commercialize our products.
- If we are unable to obtain and maintain patent protection for any product candidates we develop or for our development platform or other technologies, our competitors could develop and commercialize products or technology similar or identical to ours, and our ability to successfully commercialize any product candidates we may develop, and our technology may be adversely affected.
- We rely on third parties to conduct our Clinical Studies and Clinical Trials, and to assist us in meeting the regulatory requirements applicable to the development and marketing of our products. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize any potential product candidates.

- Our product candidates require precise, high-quality manufacturing capabilities. If any of our third-party manufacturers encounter difficulties in manufacturing our product candidates, our ability to provide supply of our product candidates for Clinical Studies or Clinical Trials, or for future commercial supply of products we bring to market under applicable regulatory requirements and approvals, could be delayed or terminated, or we may be unable to maintain a commercially viable cost structure.
- The trading price of our stock is highly volatile.

The summary risk factors described above should be read together with the text of the full risk factors below and in the other information set forth in this Quarterly Report on Form 10-Q, including our condensed consolidated financial statements and the related notes, as well as in other documents that we file with the SEC. If any such risks and uncertainties actually occur, our business, prospects, financial condition and results of operations could be materially and adversely affected. The risks summarized above or described in full in our Annual Report on Form 10-K for the year ended December 31, 2022, which is incorporated by reference into this Quarterly Report are not the only risks that we face. Additional risks and uncertainties not currently known to us, or that we currently deem to be immaterial may also materially adversely affect our business, prospects, financial condition and results of operations.

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PART I - FINANCIAL INFORMATION

Item I. Condensed Consolidated Financial Statements (Unaudited)

AXCELLA HEALTH INC.
Condensed Consolidated Balance Sheets (Unaudited)
(in thousands, except share data)

	As of	
	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 12,540	$ 17,147
Prepaid expenses and other current assets	200	876
Total current assets	12,740	18,023
Property and equipment, net	25	693
Other assets	—	211
Total assets	$ 12,765	$ 18,927
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 8,150	$ 4,707
Accrued expenses and other current liabilities	2,103	7,849
Current portion of operating lease liability	1,641	1,592
Total current liabilities	11,894	14,148
Operating lease liability	144	569
Other non-current liabilities	—	46
Total liabilities	12,038	14,763
Commitments and contingencies (Note 8)	—	—
Stockholders' equity:		
Common stock, $0.001 par value; 150,000,000 shares authorized, 74,102,008 and 74,074,201 shares issued and 73,683,027 and 73,655,220 shares outstanding at March 31, 2023 and December 31, 2022, respectively	74	74
Additional paid-in capital	423,056	422,517
Treasury stock, 418,981 shares at cost	—	—
Accumulated deficit	(422,403)	(418,427)
Total stockholders' equity	727	4,164
Total liabilities and stockholders' equity	$ 12,765	$ 18,927

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

AXCELLA HEALTH INC.
Condensed Consolidated Statements of Operations and Comprehensive Loss (Unaudited)
(in thousands, except share and per share data)

	Three Months Ended March 31,	
	2023	**2022**
Operating expenses:		
Research and development	$ 1,433	$ 13,544
General and administrative	2,750	4,786
Total operating expenses	4,183	18,330
Loss from operations	(4,183)	(18,330)
Other (expense) income:		
Interest income	140	22
Interest expense	—	(704)
Other income (expense), net	67	(27)
Total other income (expense), net	207	(709)
Net loss	$ (3,976)	$ (19,039)
Net loss per share, basic and diluted	$ (0.05)	$ (0.46)
Weighted average common shares outstanding, basic and diluted	73,669,096	41,426,107
Comprehensive loss:		
Net loss	$ (3,976)	$ (19,039)
Other comprehensive income (loss):		
Unrealized losses on marketable securities	—	(18)
Comprehensive loss	$ (3,976)	$ (19,057)

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

AXCELLA HEALTH INC.
Condensed Consolidated Statements of Cash Flows (Unaudited)
(in thousands)

	Three Months Ended March 31,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (3,976)	$ (19,039)
Adjustment to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	11	77
Share-based compensation	539	1,509
Non-cash interest expense	—	130
Gain on the sale of property and equipment	(68)	—
Non-cash lease expense	(376)	(9)
Other non-cash items	—	103
Changes in current assets and liabilities:		
Prepaid expenses and other current assets	887	635
Accounts payable	3,443	596
Accrued expenses and other current liabilities	(5,565)	(864)
Net cash used in operating activities	(5,105)	(16,862)
Cash flows from investing activities:		
Purchases of property and equipment	—	(164)
Proceeds from the sale of property and equipment	525	—
Proceeds from sales and maturities of marketable securities	—	13,324
Net cash provided by investing activities	525	13,160
Cash flows from financing activities:		
Proceeds from issuance of common stock, net of issuance costs	—	25,426
Offering costs paid	—	(71)
Proceeds from exercise of common stock options and ESPP	—	6
Repayments of the principal portion of finance lease	(27)	(43)
Net cash (used in) provided by financing activities	(27)	25,318
Net (decrease) increase in cash and cash equivalents	(4,607)	21,616
Cash and cash equivalents, beginning of period	17,147	23,574
Cash and cash equivalents, end of period	$ 12,540	$ 45,190
Supplemental cash flow information:		
Cash paid for interest	$ —	$ 573
Supplemental disclosure of non-cash activities:		
Obtaining a right-of-use asset in exchange for an operating lease liability	$ —	$ 3,340
Purchases of property and equipment included in accounts payable	$ —	$ 15
Issuance costs incurred but unpaid at period end	$ —	$ 30

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

AXCELLA HEALTH INC.
Condensed Consolidated Statements of Stockholders' Equity (Unaudited)
(in thousands, except share data)

	Three Months Ended March 31, 2022					
	Common stock		Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders' equity
	Shares	Par value				
BALANCE - January 1, 2022	39,605,701	$ 40	$ 359,261	$ (52)	$ (337,241)	$ 22,008
Issuance of common stock, net of issuance costs of $223	13,321,602	13	25,413			25,426
Exercise of common stock options	8,499		6			6
Vesting of restricted stock units	59,019					—
Share-based compensation			1,509			1,509
Unrealized loss on marketable securities				(18)		(18)
Net loss					(19,039)	(19,039)
BALANCE - March 31, 2022	52,994,821	$ 53	$ 386,189	$ (70)	$ (356,280)	$ 29,892

	Three Months Ended March 31, 2023				
	Common stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Shares	Par value			
BALANCE - January 1, 2023	74,074,201	$ 74	$ 422,517	$ (418,427)	$ 4,164
Vesting of restricted stock units	27,807				—
Share-based compensation			539		539
Net loss				(3,976)	(3,976)
BALANCE - March 31, 2023	74,102,008	$ 74	$ 423,056	$ (422,403)	$ 727

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

AXCELLA HEALTH INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

1. NATURE OF BUSINESS

Company Overview

Axcella Health Inc., doing business as “Axcella Therapeutics,” and subsidiaries ("Axcella," the "Company," "we" or "us") is a clinical-stage biotechnology company that was incorporated in Delaware on August 27, 2008 and has a principal place of business in Cambridge, Massachusetts. The Company is focused on pioneering a new approach to treat complex diseases using compositions of endogenous metabolic modulators, or EMMs. The Company's product candidates are comprised of multiple EMMs that are engineered in distinct combinations and ratios with the goal of simultaneously impacting multiple biological pathways. The Company's pipeline includes lead therapeutic candidates for the treatment of Long COVID (also known as Post COVID-19 Condition and Post-Acute Sequelae of COVID-19, or “PASC”) associated fatigue, and for the treatment of non-alcoholic steatohepatitis, or NASH.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, successful development of technology, obtaining additional funding, protection of proprietary technology, compliance with government regulations, risks of failure of preclinical studies, Clinical Studies and Clinical Trials, the need to obtain marketing approval for its product candidates, if required, and successfully market products, fluctuations in operating results, economic pressure impacting therapeutic pricing, dependence on key personnel, risks associated with changes in technologies, development by competitors of technological innovations and the ability to scale manufacturing to large scale production. Product candidates currently under development will require significant additional research and development efforts, including preclinical and clinical testing and any necessary regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities. Even if development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

In December 2022, the Board of Directors approved a reprioritization of the Company's programs and a restructuring of operations to support its streamlined set of priorities. As part of this restructuring, the Board approved a reduction in force of approximately 85% of the Company’s workforce. Since the reorganization, the Company terminated its EMMPACT Phase 2b clinical trial of AXA1125 for the treatment of NASH to focus on AXA1125 for the treatment of Long COVID associated fatigue, vacating its facility and sold its non-leased laboratory equipment.

Under Accounting Standards Update (“ASU”) 2014-15, *Presentation of Financial Statements—Going Concern (Subtopic 205-40)* (“ASC 205-40”), the Company has the responsibility to evaluate whether conditions and/or events raise substantial doubt about its ability to meet its future financial obligations as they become due within one year after the date that the financial statements are issued.

As of March 31, 2023, the Company had an accumulated deficit of $422.4 million, and cash and cash equivalents of $12.5 million. During the three months ended March 31, 2023, the Company incurred a loss of $4.0 million and used $5.1 million of cash in operations. The Company expects its reorganization will reduce its operating expenses, however the Company will need to raise additional funding to operate. Management has assessed the Company's ability to continue as a going concern in accordance with the requirements of ASC 205-40 based on the need to raise additional capital to finance its future operations, its recurring losses from operations incurred since inception, expectation of continuing operating losses for the foreseeable future, and uncertainty around the changes to the business plan. As of May 4, 2023, the issuance date of the condensed consolidated financial statements for the quarter ended March 31, 2023, the Company has concluded that there is substantial doubt about its ability to continue as a going concern for a period of one year from the date that these condensed consolidated financial statements are issued. The accompanying condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty. Accordingly, the condensed consolidated financial statements have been prepared on a basis that assumes the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

The Company's plans to alleviate its financing requirements include, among other things, pursuing the sale of its common stock, a transaction of the Company or its AXA1125 product candidate for Long COVID or other product candidates, and funding through the establishment of a collaboration(s) with a potential partner(s) to further advance its product pipeline, none of which can be guaranteed or are entirely within the Company's control. As of December 15, 2022, the Company was forced to discontinue some of its operations and develop and implement a plan to further extend payables, reduce overhead and scale back its current operating plan until sufficient additional capital is raised to support further operations. These factors individually and collectively raise substantial doubt about the Company's ability to continue as a going concern, and; therefore, it may be more difficult for the Company to attract investors. Unless the Company is able to raise additional capital to finance its operations, its long-term business plan may not be accomplished, and the Company may be forced to cease, further reduce, or further delay operations. However, the Company does not believe it is probable that those plans can be effectively implemented to mitigate the conditions or events that raise substantial doubt.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

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

Furthermore, the accompanying condensed consolidated financial statements are unaudited and certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted from this report, as is permitted by such rules and regulations. The unaudited interim financial statements have been prepared on the same basis as the audited annual financial statements as of and for the year ended December 31, 2022. The accompanying interim condensed consolidated financial statements reflect all adjustments, consisting of normal recurring adjustments, necessary for the fair presentation of the Company's financial position as of March 31, 2023, the results of its operations for the three months ended March 31, 2023 and 2022, its cash flows for the three months ended March 31, 2023 and 2022, and its statements of stockholders' equity for the three months ended March 31, 2023 and 2022.

The results for the three months ended March 31, 2023 are not necessarily indicative of the results to be expected for the year ending December 31, 2023, any other interim periods, or any future year or period. These interim financial statements should be read in conjunction with the audited financial statements as of and for the year ended December 31, 2022, and the notes thereto, together with Management's Discussion and Analysis of Financial

Condition and Results of Operations, contained in the Company's Annual Report on Form 10-K for the year ended December 31, 2022. There were no material changes to the Company's significant accounting policies and estimates as reported in its Annual Report on Form 10-K for the year ended December 31, 2022, which was filed with the SEC on March 30, 2023.

Principles of Consolidation

The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiary. All intercompany accounts and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of the condensed consolidated financial statements in accordance with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, equity, expenses and disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements and the Company's ability to continue as a going concern. The Company bases its estimates on historical experience, known trends and other market-specific or relevant factors that it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates as there are changes in circumstances, facts and experience. Actual results may differ from those estimates or assumptions.

Cash and Cash Equivalents

Cash and cash equivalents include cash held in banks and amounts held in interest-bearing money market accounts. Cash equivalents are carried at cost, which approximates their fair market value. The Company considers all highly liquid investments with a remaining maturity when purchased of three months or less to be cash equivalents.

Concentrations of Credit Risk

The Company has no off-balance sheet risk, such as foreign exchange contracts, option contracts, or other foreign hedging arrangements. Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash equivalents. The Company's cash equivalents as of March 31, 2023 consisted of bank deposits and money market funds that invest in U.S. treasury securities.

The Company's investment policy includes guidelines on the quality of the institutions and financial instruments and defines the allowable investments that the Company believes minimizes the exposure to concentrations of credit risk. The Company has not experienced any credit losses and does not believe that it is subject to significant credit risk.

Fair Value Measurements

Certain assets and liabilities of the Company are carried at fair value. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs.

Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1 — Quoted prices in active markets for identical assets or liabilities.
- Level 2 — Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

- Level 3 — Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's cash equivalents are carried at fair value, determined according to the fair value hierarchy described above. The carrying values of the Company's accounts payable and accrued expenses approximate their fair values due to the short-term nature of these liabilities.

Property and Equipment

Property and equipment are recorded at cost. Depreciation and amortization is calculated using the straight-line method over the estimated useful lives of the assets. Upon disposal, retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in the results of operations. Expenditures for repairs and maintenance that do not improve or extend the lives of the respective assets are charged to expense as incurred.

Long-Lived Assets Impairment

Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset group for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset group to its carrying value. An impairment loss would be recognized in loss from operations when estimated undiscounted future cash flows expected to result from the use and eventual disposition of an asset group are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset group over its fair value, determined based on discounted cash flows.

Leases

The Company determines whether a contract is, or contains, a lease at inception and classifies leases as operating or financing considering factors such as the length of the lease term, the present value of the lease payments, the nature of the asset being leased, and the potential for ownership of the asset to transfer during the lease term. Leases with terms greater than one-year are recognized on the consolidated balance sheets as right-of-use assets and lease liabilities and are measured at the present value of the fixed payments due over the expected lease term less the present value of any incentives, rebates or abatements received from the lessor. Options to extend a lease are included in the expected lease term if exercise of the option is deemed reasonably certain. Costs determined to be variable and not based on an index or rate are not included in the measurement of the lease liability and are expensed as incurred. The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company utilizes the appropriate incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis an amount equal to the lease payments in the same currency, for a similar term, and in a similar economic environment. The Company records expense to recognize fixed lease payments on a straight-line basis over the expected lease term. The Company has elected the practical expedient not to separate lease and non-lease components for real estate leases.

Segment Information

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the Chief Executive Officer, who is the chief operating decision maker, in making decisions on how to allocate resources and assess performance. The Company operates in one reportable business segment.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity (deficit) that result from transactions and economic events other than those with stockholders. For the three months ended March 31, 2022, the Company's only element of other comprehensive loss was unrealized gains (losses) on marketable securities. For the three months ended March 31, 2023, there were no elements of other comprehensive loss.

Net Loss Per Share

Basic net loss per share attributable to common stockholders is calculated by dividing net loss by the weighted average shares outstanding during the period. Diluted net income (loss) per share is calculated by adjusting weighted average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period. All common stock equivalents have been excluded from the calculation of diluted net loss per share, as their effect would be anti-dilutive for all periods presented.

Newly Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses (Topic 326)*. The new standard adjusts the accounting for assets held at amortized cost basis, including marketable securities accounted for as available-for-sale. The standard eliminates the probable initial recognition threshold and requires an entity to reflect its current estimate of all expected credit losses. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis of the financial assets to present the net amount expected to be collected. The adoption of this standard on January 1, 2023 did not have a material impact on its condensed consolidated financial statements.

3. FAIR VALUE MEASUREMENTS

The following tables present the Company's assets that are measured at fair value on a recurring basis and indicate the level within the fair value hierarchy (in thousands):

	Fair Value Measurements at March 31, 2023 using:			
	Level 1	**Level 2**	**Level 3**	**Total**
Assets:				
Cash equivalents:				
Money market funds	$ 12,290	$ —	$ —	$ 12,290
Total	$ 12,290	$ —	$ —	$ 12,290

	Fair Value Measurements at December 31, 2022 using:			
	Level 1	**Level 2**	**Level 3**	**Total**
Assets:				
Cash equivalents:				
Money market funds	$ 14,649	$ —	$ —	$ 14,649
Total	$ 14,649	$ —	$ —	$ 14,649

As of March 31, 2023 and December 31, 2022, the Company's cash equivalents were invested in money market funds and were valued based on Level 1 inputs. During the three months ended March 31, 2023 and 2022, there were no transfers between Level 1, Level 2 and Level 3.

4. PROPERTY AND EQUIPMENT

Property and equipment consist of the following (in thousands):

	March 31, 2023	December 31, 2022
Laboratory equipment	$ —	$ 3,506
Leasehold improvements	—	564
Office and computer equipment	86	303
Furniture and fixtures	—	122
Property and equipment	86	4,495
Less: accumulated depreciation and amortization	(61)	(3,802)
Property and equipment, net	$ 25	$ 693

Depreciation and amortization expense was nominal for the three months ended March 31, 2023, and $0.1 million for the three months ended March 31, 2022.

During the three months ended March 31, 2023, the Company sold or retired its property and equipment for proceeds of $0.5 million and recorded a gain of $0.1 million. There were no disposals for the three months ended March 31, 2022.

5. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

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

	March 31, 2023	December 31, 2022
Accrued employee compensation and benefits	$ 612	$ 808
Accrued external research and development expenses	913	4,791
Accrued professional fees	578	824
Accrued employee termination benefits	—	1,221
Other	—	205
Total accrued expenses and other current liabilities	$ 2,103	$ 7,849

During the three months ended March 31, 2023, the Company paid $1.2 million in employee termination benefits related to the December 2022 reduction-in-force.

6. STOCKHOLDERS' EQUITY

2019 Stock Option and Incentive Plan

The 2019 Stock Option and Incentive Plan (the "2019 Plan") was approved by the Company's board of directors on April 29, 2019. The 2019 Plan provides for the grant of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock units, restricted stock awards, unrestricted stock awards and cash-based awards to the Company's officers, employees, directors and consultants. Awards under the 2019 plan generally vest ratably over the vesting period (3-4 years) and have a maximum term of 10 years. The number of shares initially reserved for issuance under the 2019 Plan is 905,000, which was increased on January 1, 2020 and will be increased each January 1 thereafter by 4% of the number of shares of the Company's common stock outstanding on the immediately preceding December 31, or such lesser number of shares determined by the Company's board of directors or compensation committee of the board of directors. The number of options available for future grant under the 2019 Plan was 5,700,933 as of March 31, 2023.

2019 Employee Stock Purchase Plan

The 2019 Employee Stock Purchase Plan (the "2019 ESPP") was approved by the Company's board of directors on April 29, 2019. A total of 237,181 shares of common stock were initially reserved for issuance under this plan, which was cumulatively increased on January 1, 2020 and will be increased each January 1 thereafter by 1% of the number of shares of the Company's common stock outstanding on the immediately preceding December 31, or such lesser number of shares determined by the Company's board of directors or compensation committee of the board of directors.

The number of shares available for future issuance under the 2019 ESPP was 935,186 shares as of March 31, 2023.

Stock-Based Compensation Expense

In connection with all share-based payment awards, total stock-based compensation expense recognized was as follows (in thousands):

	Three Months Ended March 31,	
	2023	**2022**
Research and development	$ 169	$ 566
General and administrative	370	943
Total stock-based compensation expense	$ 539	$ 1,509

Fair Value of Stock Options

The fair value of stock option awards was estimated using the Black-Scholes option-pricing model. The expected term of these awards was determined using the simplified method, which uses the midpoint between the vesting date and the contractual term. The risk-free interest rate was determined by reference to the U.S. Treasury yield curve for time periods approximately equal to the remaining contractual term of the stock awards. The expected dividend was zero as the Company had not paid any dividends on its common stock. Finally, as the Company does not have long-term trading history of its common stock, the expected volatility was derived from the average historical stock volatilities of several public companies within the industry that the Company considers to be comparable to the Company's business over a period equivalent to the expected term of the stock-based awards.

The Black-Scholes option pricing model assumptions are included in the table below.

	Three Months Ended March 31,	
	2023	**2022**
Risk-free interest rate	3.95 %	1.87 %
Expected option life (in years)	6.11	6.13
Expected dividend yield	— %	— %
Expected volatility	90.1 %	91.4 %

Stock Option Activity

The following table summarizes the Company's stock option activity for the three months ended March 31, 2023:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Life (in Years)	Intrinsic Value (in thousands)
Outstanding as of January 1, 2023	6,536,977	$ 5.05		
Granted	611,500	0.68		
Exercised	—	—		
Canceled	(1,048,753)	5.11		
Outstanding as of March 31, 2023	6,099,724	$ 4.60	6.64	$ —
Exercisable as of March 31, 2023	4,081,667	$ 5.66	5.48	$ —
Vested or expected to vest as of March 31, 2023	6,099,724	$ 4.60	6.64	$ —

The intrinsic value of options exercised during the three months ended March 31, 2023 and 2022 was nominal.

The weighted-average grant date fair value of the options granted during the three months ended March 31, 2023 and 2022 was $0.52 and $1.03 per share, respectively.

As of March 31, 2023, there was $3.1 million of unrecognized compensation expense that is expected to be recognized over a weighted-average period of approximately 2.0 years.

Restricted Stock Units

The fair values of restricted stock units are based on the market value of the Company's common stock on the date of grant. The following table summarizes the Company's restricted stock unit activity for the three months ended March 31, 2023:

	Number of Shares	Weighted Average Grant Date Fair Value per Share
Outstanding as of January 1, 2023	75,233	$ 5.04
Granted	—	—
Vested	(27,807)	4.41
Forfeited	—	—
Outstanding as of March 31, 2023	47,426	$ 5.40

As of March 31, 2023, there was $0.1 million of unrecognized compensation expense that is expected to be recognized over a weighted-average period of approximately 1.0 year.

7. NET LOSS PER SHARE

Basic and diluted net loss per share attributable to common stockholders was calculated as follows (in thousands, except share and per share amounts):

	Three Months Ended March 31,	
	2023	2022
Numerator:		
Net loss	$ (3,976)	$ (19,039)
Denominator:		
Weighted average common shares outstanding, basic and diluted	73,669,096	41,426,107
Net loss per share, basic and diluted	$ (0.05)	$ (0.46)

The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	Three Months Ended March 31,	
	2023	2022
Options to purchase common stock	6,099,724	8,026,924
Unvested restricted stock units	47,426	216,331
Shares issuable under employee stock purchase plan	—	37,820
	6,147,150	8,281,075

8. COMMITMENTS AND CONTINGENCIES

Leases

The Company leases a facility containing 19,200 square feet of laboratory and office space, which is located at 840 Memorial Drive, Cambridge, Massachusetts. The lease expires in April 2024, subject to an option to extend the lease for an additional three years. The lease agreement and most recent amendment contained escalating rent payments.

In December 2022, the Company initiated activities to vacate its corporate offices in Cambridge, Massachusetts, and the activities were completed in January 2023. As a result, the Company performed a recoverability test by comparing the future cash flows attributable to the asset group to the carrying value of the corresponding long-lived, right-of-use asset for its facility lease. Based on this evaluation, the Company determined that the long-lived asset with a carrying value of $2.1 million was no longer recoverable and recorded a right-of-use asset impairment of $2.1 million in December 2022. The impairment was determined by comparing the fair value of the impacted asset group to their carrying value as of the impairment measurement date, as required under ASC 360, Property, Plant, and Equipment. The Company continues to amortize the lease liability over the lease term while its lease agreement remains in place.

The following table contains a summary of the lease costs recognized under ASC 842 and other information pertaining to the Company’s operating leases for the three months ended March 31, 2023 and 2022 (in thousands, except weighted average figures):

Operating leases	Three Months Ended March 31, 2023	2022
Lease cost		
Operating lease cost	$ 46	$ 401
Variable lease cost	196	193
Total lease cost	$ 242	$ 594
Other information		
Operating cash flows used for operating leases	$ 192	$ 603
Weighted average remaining lease term (years)	1.10	2.10
Weighted average discount rate (percentage)	9.0 %	9.0 %

For the three months ended March 31, 2023 and 2022, the Company recorded $0.2 million and $0.6 million in operating lease expense, respectively, and made lease payments of $0.2 million and $0.6 million, respectively, with such amounts reflected in the condensed consolidated statements of cash flows in operating activities.

Future minimum lease payments and lease liabilities as of March 31, 2023 and December 31, 2022 were as follows (in thousands):

Maturity of lease liabilities	As of March 31, 2023	December 31, 2022
2023	$ 1,300	$ 1,722
2024	580	580
Total future minimum lease payments	$ 1,880	$ 2,302
Less: imputed interest	(95)	(141)
Total lease liability	$ 1,785	$ 2,161
Reported as:		
Current portion of operating lease liability	$ 1,641	$ 1,592
Operating lease liability	144	569
Total lease liability	$ 1,785	$ 2,161

Other Commitments

From time to time, the Company enters into contracts in the normal course of business with contract research organizations ("CROs"), contract manufacturing organizations ("CMOs") and other third parties for preclinical research studies, Clinical Studies, Clinical Trials and testing and manufacturing services. These contracts do not contain minimum purchase commitments and are cancelable upon prior written notice. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including non-cancelable obligations of service providers, up to the date of cancellation.

Legal Proceedings

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

9. RELATED-PARTY TRANSACTIONS

There were no material related-party transactions in the periods reported.

10. SUBSEQUENT EVENTS

The Company has evaluated subsequent events for financial statement purposes occurring through the date these condensed consolidated financial statements were issued.

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

The following discussion of the financial condition and results of operations should be read in conjunction with the condensed consolidated financial statements and the related notes thereto included elsewhere in this Quarterly Report and the audited financial statements and notes included in our Annual Report on Form 10-K, filed with the SEC on March 30, 2023. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. We caution you that forward-looking statements are not guarantees of future performance, and that our actual results of operations, financial condition and liquidity, and the developments in our business and the industry in which we operate, may differ materially from the results discussed or projected in the forward-looking statements contained in this Quarterly Report. We discuss risks and other factors that we believe could cause or contribute to these potential differences elsewhere in this Quarterly Report, including under Part I, Item 1A. "Risk Factors" and under "Special Note Regarding Forward-Looking Statements." In addition, even if our results of operations, financial condition and liquidity, and the developments in our business and the industry in which we operate are consistent with the forward-looking statements contained in this Quarterly Report, they may not be predictive of results or developments in future periods. We caution readers not to place undue reliance on any forward-looking statements made by us, which speak only as of the date they are made. We disclaim any obligation, except as specifically required by law and the rules of the SEC to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

Overview

We are a clinical-stage biotechnology company focused on pioneering a new approach to treat complex diseases using compositions of endogenous metabolic modulators, or EMMs. Our product candidates are comprised of multiple EMMs that are engineered in distinct combinations and ratios with the goal of simultaneously impacting multiple biological pathways. Our pipeline includes lead therapeutic candidates for the treatment of non-alcoholic steatohepatitis, or NASH, and for the treatment of Long COVID (also known as Post COVID-19 Condition and Post-Acute Sequelae of COVID-19, or "PASC") associated fatigue.

In December 2022, we announced that we discontinued our EMMPACT Phase 2b clinical trial of AXA1125 for the treatment of NASH to focus on AXA1125 for the treatment of Long COVID associated fatigue. We also announced a corporate restructuring, whereby we reduced our workforce by approximately 85%, and that we have initiated a process to explore a range of strategic alternatives to maximize stakeholder value and we have engaged an investment bank to act as a strategic advisor for this process. Since the discontinuation of the NASH program and reduction-in-force, we have devoted and expect to continue to devote substantial time and resources to exploring strategic alternatives that our board of directors believes will maximize enterprise value. Despite devoting significant efforts to identify and evaluate potential strategic alternatives, there can be no assurance that this strategic review process will result in us pursuing any transaction or that any transaction, if pursued, will be completed on attractive terms or at all. We have not set a timetable for completion of this strategic review process, and our board of directors has not approved a definitive course of action. Additionally, there can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated or lead to increased stakeholder value or that we will make any additional cash distributions to our stakeholders.

Funding Overview

To date, we have funded our operations with proceeds from the sale of preferred stock and issuance of debt and with proceeds from our public offerings. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur expenses related to our ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception in 2008. For the three months ended March 31, 2023 and 2022, we reported net losses of $4.0 million and $19.0 million, respectively. As of March 31, 2023, we had an accumulated deficit of $422.4 million. As noted elsewhere in this report, based on our current cash and cash equivalents, we continue to operate as a going concern as we believe we do not have sufficient cash and cash

equivalents available to fund our planned operations for the next twelve months from the issuance date of this Quarterly Report on Form 10-Q.

COVID-19 Pandemic

The extent to which COVID-19 impacts our business, operations or financial results will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, new information that may emerge concerning the severity of COVID-19 or the nature or effectiveness of actions to contain COVID-19 or treat its impact, among others. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions. However, if we or any of the third parties with whom we engage were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on our business, results of operations and financial condition.

Components of our Condensed Consolidated Results of Operations

Revenue

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products in the near future. If our development efforts for our product candidates are successful and result in regulatory approval or we execute license or collaboration agreements with third parties, we may generate revenue in the future from product sales, payments from collaborations or license agreements that we may enter into with third parties, or any combination thereof.

Research and Development Expenses

Our research and development expenses consist primarily of costs incurred in connection with our research activities, including our drug discovery efforts, and the development of our product candidates, which include:

- direct external research and development expenses, including fees, reimbursed materials and other costs paid to consultants, contractors, contract manufacturing organizations, or CMOs, and clinical research organizations, or CROs, in connection with our clinical and preclinical development and manufacturing activities;
- employee-related expenses, including salaries, related benefits and stock-based compensation expense for employees engaged in research and development functions;
- expenses incurred in connection with the preclinical and clinical development of our product candidates, including any Clinical Studies, Clinical Trials and other research programs, including under agreements with third parties, such as consultants, contractors and CROs;
- the cost of developing and scaling our manufacturing process and manufacturing products for use in our preclinical studies, Clinical Studies and Clinical Trials, including under agreements with third parties, such as consultants, contractors and CMOs;
- patent-related costs incurred in connection with filing and prosecuting patent applications; and
- facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities and insurance.

We expense research and development costs as incurred. We often contract with CROs and CMOs to facilitate, coordinate and perform agreed-upon research, design, development, and manufacturing of our product candidates. To ensure that research and development costs are expensed as incurred, we record monthly accruals for Clinical Studies, Clinical Trials and manufacturing costs based on the work performed under the contract.

These CRO and CMO contracts typically call for the payment of fees for services at the initiation of the contract and/or upon the achievement of certain clinical or manufacturing milestones. In the event that we prepay CRO or CMO fees, we record the prepayment as a prepaid asset and amortize the asset into research and development expense over the period of time the contracted research and development or manufacturing services are performed. Most professional fees, including project and clinical management, data management, monitoring and manufacturing fees are incurred throughout the contract period. These professional fees are expensed based on their estimated percentage of completion at a particular date. Our CRO and CMO contracts generally include pass through fees. Pass through fees include, but are not limited to, regulatory expenses, investigator fees, travel costs and other miscellaneous costs and raw materials. We expense the costs of pass through fees under our CRO and CMO contracts as they are incurred, based on the best information available to us at the time.

A significant portion of our research and development costs are not tracked by project as they benefit multiple projects or our technology platform, and, as such, are not separately classified.

We anticipate that our future research and development expenses will decrease compared to 2022 levels due to the discontinuation of the NASH clinical trial and reduction-in-workforce. Many factors can affect the cost and timing of our Clinical Studies and Clinical Trials, including, without limitation, slow patient enrollment and the availability of supplies, including as a result of the COVID-19 pandemic, and real or perceived lack of effect on biology or safety of our product candidates. In addition, the development of all of our product candidates may be subject to extensive governmental regulation. These factors make it difficult for us to predict the timing and costs of the further development of our product candidates.

See “Risk Factors” in "Item 9A." of our Annual Report on Form 10-K for further discussion of these and additional risks and uncertainties associated with product development and commercialization that may significantly affect the timing and cost of our research and development expenses and our ability to obtain regulatory approval for and successfully commercialize our product candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, benefits, travel and stock-based compensation expense for personnel in executive, finance and administrative functions. General and administrative expenses also include professional fees for legal, consulting, accounting and audit services.

We anticipate that our future general and administrative expenses will decrease from 2022 levels due to our corporate restructuring.

Other Income (Expense), Net

Other income (expense), net primarily consists of interest income and interest expense. Interest income consists of interest earned on our investments in cash equivalents, money market funds, and high-quality fixed income securities. Interest expense primarily consists of interest on outstanding borrowings under a loan and security agreement and the amortization expense of the debt discount and debt issuance costs.

Income Taxes

Since our inception, we have not recorded any income tax benefits for the net losses we have incurred in each year or for our research and development tax credits, as we believe, based upon the weight of available evidence, that it is more likely than not that all of our net operating loss, or NOLs, carryforwards and tax credits will not be realized.

Results of Operations

Comparison of the Three Months Ended March 31, 2023 and 2022

The following table summarizes our results of operations for the three months ended March 31, 2023 and 2022 (in thousands):

	Three Months Ended March 31,		
	2023	2022	Change
Operating expenses:			
Research and development	$ 1,433	$ 13,544	$ (12,111)
General and administrative	2,750	4,786	(2,036)
Total operating expenses	4,183	18,330	(14,147)
Loss from operations	(4,183)	(18,330)	14,147
Other income (expense):			
Other income (expense), net	207	(709)	916
Total other income (expense), net	207	(709)	916
Net loss	$ (3,976)	$ (19,039)	$ 15,063

Research and Development Expenses

The following table summarizes our research and development expenses incurred during the three months ended March 31, 2023 and 2022 (in thousands):

	Three Months Ended March 31,		
	2023	2022	Change
Salary and benefits-related	$ 962	$ 4,182	$ (3,220)
Clinical research, outside services and other expenses	471	9,362	(8,891)
Total research and development expenses	$ 1,433	$ 13,544	$ (12,111)

Research and development expenses were $1.4 million for the three months ended March 31, 2023, compared to $13.5 million for the same period in 2022. The decrease in research and development expenses of $12.1 million, of which $8.9 million is attributed to the completion of the Phase 2a Long COVID Clinical Trial, the discontinuation of the Phase 2b Clinical Trial of AXA1125 for NASH and the Phase 2 Clinical Trial of AXA1665 for reduction in risk of recurrent OHE. During the first quarter of 2022, we had three ongoing Phase 2 clinical trials. Personnel-related expenses decreased by $3.2 million resulting from our headcount reductions as part of the December 2022 corporate restructuring.

General and Administrative Expenses

The following table summarizes our general and administrative expenses incurred during the three months ended March 31, 2023 and 2022 (in thousands):

	Three Months Ended March 31,		
	2023	2022	Change
Salary and benefits-related	$ 1,333	$ 3,004	$ (1,671)
Other contract services, outside costs and other expenses	1,417	1,782	(365)
Total general and administrative expenses	$ 2,750	$ 4,786	$ (2,036)

General and administrative expenses were $2.8 million for the three months ended March 31, 2023, compared to $4.8 million for the same period in 2022. The decrease in general and administrative expenses of $2.0 million primarily resulted from our headcount reductions.

Other Income (Expense), Net

For the three months ended March 31, 2023, we recorded $0.1 million of interest income on our cash balances and a gain on the sale of property and equipment of $0.1 million.

For the three months ended March 31, 2022, we recorded $0.7 million interest expense on the loan and security agreement with SLR Investment Corp. and amortization of the loan discount. We repaid the loan in full in December 2022.

Liquidity and Capital Resources

Exploring Strategic Alternatives

We require substantial additional capital to sustain our operations and pursue our strategy, including the development of our Long COVID product candidate. We have engaged an investment bank to assist with the exploration of strategic alternatives that may include, but are not limited to, the sale of all or substantially all of our assets; a strategic merger or other business combination transaction; or another change of control transaction between us and a third party. If a strategic process is unsuccessful, we may be unable to continue our operations at planned levels and be forced to further reduce or terminate our operations. These factors raise substantial doubt about our ability to continue as a going concern.

Cash Flows

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

	Three Months Ended March 31,	
	2023	2022
Cash used in operating activities	$ (5,105)	$ (16,862)
Cash provided by investing activities	525	13,160
Cash (used in) provided by financing activities	(27)	25,318
Net (decrease) increase in cash and cash equivalents	$ (4,607)	$ 21,616

Operating Activities

During the three months ended March 31, 2023, operating activities used $5.1 million of cash, primarily resulting from a net loss of $4.0 million and changes in our operating assets and liabilities of $1.2 million, partially offset by non-cash charges of $0.1 million.

During the three months ended March 31, 2022, operating activities used $16.9 million of cash, primarily resulting from a net loss of $19.0 million, partially offset by non-cash charges of $1.8 million, including $1.5 million of stock-based compensation, and changes in our operating assets and liabilities of $0.4 million.

Investing Activities

During the three months ended March 31, 2023, net cash provided by investing activities includes proceeds from the sale of property and equipment of $0.5 million.

During the three months ended March 31, 2022, net cash provided by investing activities consisted primarily of sales and maturities of marketable securities.

Financing Activities

During the three months ended March 31, 2023, net cash used in financing activities consisted of cash paid to terminate a finance lease.

During the three months ended March 31, 2022, net cash provided by financing activities consisted of net proceeds from the issuance of common stock, which were partially offset by payments of the principal portion of a finance lease and a terminal fee obligation and debt issuance costs.

Loan and Security Agreement

On September 2, 2021, we entered into a loan and security agreement with SLR Investment Corp., or SLR, (formerly known as Solar Capital Ltd.), for term loans in an aggregate principal amount of $26.0 million. The loan and security agreement replaced the loan and security agreement between us and SLR, dated as of January 9, 2018 and further amended on October 5, 2018, November 30, 2018 and August 28, 2020 (as amended, the "Prior Loan and Security Agreement").

In September 2022, we paid SLR approximately $6.4 million, including principal, accrued interest, fees and costs. In October 2022, we satisfied an equity related condition under the loan and security agreement that extended the date on which repayment of principal commences from January 2023 to July 2023. On December 15, 2022, we entered into a payoff letter with SLR, under which we voluntarily accelerated the debt and paid SLR approximately $21.0 million, in full satisfaction of all obligations, including all outstanding principal, accrued interest, fees, costs, expenses and other amounts chargeable, under the loan and security agreement. The payoff letter also provided for the termination of all commitments and obligations under the loan and security agreement and release of all liens held by SLR on our assets.

Funding Requirements

Since our inception, we have incurred significant operating losses. We have not yet commercialized any product candidates and we do not expect to generate revenue from sales of any product candidates we may develop for several years, if at all. To date, we have funded our operations with proceeds from the sale of preferred and common stock and borrowing of debt.

As of March 31, 2023, we had cash and cash equivalents of $12.5 million. Based on our current financial resources and forecasted operating plan, we believe that we will be able to operate into the second quarter of 2023. Our operating expenses have been reduced as a result of the termination of the NASH clinical trial and corporate restructuring, allowing us to pursue any viable strategic alternatives. There is no guarantee that this plan will be successful. We may not be able to successfully pursue any strategic alternatives and, even if certain strategic alternatives may be available, we cannot provide any assurance that the strategic alternatives review process will result in any particular alternative, transaction or value. We need to raise additional capital to support continuing operations. Until such time as we can generate significant revenue to fund operations, we expect to seek additional capital from the issuance of equity, debt, or other capital transactions or a strategic transaction. If we fail to raise capital or enter into such agreements as, and when, needed, we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations. See “Risk Factors” in "Item 1A." in our Annual Report on Form 10-K for further discussion of these and additional risks and uncertainties that may significantly affect the timing and amount of expenditures of our capital resources.

Based on our current operating plan, we believe we do not have sufficient cash and cash equivalents to support current operations through a full 12 months from the issuance date of this Quarterly Report on Form 10-Q and we continue to operate as a going concern.

Nasdaq Notice of Delisting or Failure to Satisfy a Continued Listing Rule or Standard; Transfer of Listing

On December 30, 2022, we received a deficiency letter from the Listing Qualifications Department, or the Staff, of The Nasdaq Stock Market LLC, or Nasdaq, notifying us that, for the last 30 consecutive business days, the bid price for our common stock had closed below the $1.00 per share minimum bid price requirement for continued inclusion on the Nasdaq Global Market pursuant to Nasdaq Listing Rule 5450(a)(1) (which we refer to as the “Minimum Bid Price Requirement”). The Nasdaq deficiency letter has no immediate effect on the listing of our common stock, and our common stock will continue to trade on the Nasdaq Global Market under the symbol “AXLA” at this time. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), or the Compliance Period Rule, we have been provided a period of 180 calendar days, or until June 28, 2023 (which we refer to as the “Compliance Date”), to regain compliance with the Minimum Bid Price Requirement. If, at any time ending June 28, 2023, the bid price for our common stock closes at $1.00 or more for a minimum of ten consecutive business days, as required under the Compliance Period Rule, the Staff will provide written notification to us that we have regained compliance with the Minimum Bid Price Requirement and our common stock will continue to be eligible for listing on the Nasdaq Global Market, unless the Staff exercises its discretion to extend this ten-day period pursuant to Nasdaq Listing Rule 5810(c)(3)(H).

If we do not regain compliance with the Minimum Bid Price Requirement by the Compliance Date, we may be eligible for an additional 180 calendar day compliance period. To qualify, we would need to transfer the listing of our common stock to The Nasdaq Capital Market, provided that we meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, with the exception of the Minimum Bid Price Requirement, and would need to provide written notice to Nasdaq of our intention to cure the deficiency during the additional compliance period. To effect such a transfer, we would also need to pay an application fee to Nasdaq and provide written notice to the Staff of our intention to cure the deficiency during the second compliance period by effecting a reverse stock split if necessary. As part of its review process, the Staff will make a determination of whether it believes we will be able to cure the deficiency. Should the Staff conclude that we will not be able to cure the deficiency, the Staff will provide written notification to us that our common stock will be subject to delisting. At that time, we may appeal the Staff’s delisting determination to a Nasdaq Listing and Hearing Review Panel. However, there can be no assurance that, if we receive a delisting notice and appeal the delisting determination by the Staff to the panel, such appeal would be successful.

We intend to monitor the closing bid price of our common stock and may, if appropriate, consider available options to regain compliance with the Minimum Bid Price Requirement, which could include seeking to effect a reverse stock split. However, there can be no assurance that we will be able to regain, or even pursue, compliance with the Minimum Bid Price Requirement, secure a second period of 180 days to regain compliance, or maintain compliance with any of the other Nasdaq continued listing requirements.

On April 3, 2023, we received written notice from the Staff of Nasdaq that (i) we are not in compliance with the requirement of a minimum Market Value of Publicly Held Shares ("MVPHS") of $15,000,000 for continued listing on the Nasdaq Global Market, as set forth in Nasdaq Listing Rule 5450(b)(2)(C); and (ii) we are not in compliance with the requirement of a minimum Market Value of Listed Securities ("MVLS") of $50,000,000, as set forth in Nasdaq Listing Rule 5450(b)(2)(A). In accordance with Nasdaq Listing Rule 5810(c)(3)(D), we have a period of 180 calendar days, or until October 2, 2023, to regain compliance with the minimum MVPHS and MVLS requirements. To regain compliance, the minimum MVPHS of our common stock is required to meet or exceed $15,000,000 for at least ten consecutive business days during this 180-calendar day compliance period; and to regain compliance, the minimum MVLS of our common stock is required to meet or exceed $50,000,000 for at least ten consecutive business days during this 180 calendar day compliance period. There can be no assurance that we will be able to regain compliance the MVPHS or MVLS requirements or maintain compliance with the other Nasdaq listing requirements.

In the event that we do not regain compliance within the 180 calendar day compliance period, we may be eligible to transfer to the Nasdaq Capital Market prior to the expiry of this period. However, if it appears to Nasdaq that we will not be able to cure the deficiencies, or if we are not otherwise eligible, Nasdaq will provide notice to us that our listed securities will be subject to delisting. In the event of such notification, we may appeal Nasdaq's determination to delist our securities, but there can be no assurance Nasdaq would grant our request for continued listing.

The MVPHS and MVLS notices are only a notification of deficiency, not of imminent delisting, and have no immediate effect on the listing of our securities on Nasdaq. If it appears to the Staff that we will not be able to cure the deficiencies, the Staff will provide written notice to us that our common stock will be subject to delisting. At that time, we may appeal the Staff's delisting determination to a Nasdaq Hearing Panel (the "Panel"). We expect that our stock would remain listed pending the Panel's decision. There can be no assurance that, if we do appeal the Staff's delisting determination to the Panel, such appeal would be successful.

Critical Accounting Policies and Use of Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make judgments and estimates that affect the reported amounts of assets, liabilities, revenues, and expenses and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions. On an ongoing basis, we evaluate our judgments and estimates in light of changes in circumstances, facts and experience. The effects of material revisions in estimates, if any, will be reflected in the financial statements prospectively from the date of change in estimates. There were no material changes to our critical accounting policies as reported in our Annual Report on Form 10-K for the year ended December 31, 2022, which was filed with the SEC on March 30, 2023.

Recently Issued Accounting Pronouncements

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

Emerging Growth Company Status

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. We may take advantage of these exemptions until we are no longer an emerging growth company. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards. We have elected to use the extended transition period for complying with new or revised accounting standards and, as a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates. We may take advantage of these exemptions up until the last day of the fiscal year following the fifth anniversary of our IPO or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company if we have more than $1.235 billion in annual revenue, we have more than $700.0 million in market value of our stock held by non-affiliates (and we have been a public company for at least 12 months and have filed one annual report on Form 10-K) or we issue more than $1.0 billion of non-convertible debt securities over a three-year period.

Item 3. Quantitative and Qualitative Disclosure About Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934 and are not required to provide the information under this item.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer ("CEO") and Principal Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2023. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act means controls and other procedures of an issuer that are designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

We had previously identified material weaknesses in our internal controls over financial reporting as of December 31, 2022. The material weaknesses we identified were (i) we did not maintain an effective control environment as we did not maintain a sufficient complement of accounting and financial reporting resources commensurate with our financial reporting requirements, (ii) we did not maintain an effective risk assessment process, whereby our risk assessment was not updated for the changes resulting from the restructuring in December 2022, (iii) we did not maintain appropriate control activities to support the appropriate segregation of duties over the review of account reconciliations and manual journal entries, and (iv) we did not document, thoroughly communicate and monitor controls processes. Due to the material weaknesses identified, the CEO and Principal Financial Officer concluded that the disclosure controls were not effective, to provide reasonable assurance that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is accumulated and communicated to management, including the CEO and Principal Financial Officer, as appropriate, to allow timely decisions regarding required disclosure and were not effective to provide reasonable assurance that such information is recorded, processed, summarized and reported within the time periods specified by the SEC's rules and forms. These material weaknesses could result in a misstatement of account balances or disclosures that would result in a material misstatement to the annual or interim financial statements that would not be prevented or detected. Had we performed an evaluation of our internal control over financial reporting in accordance with Section 404, additional control deficiencies may have been identified by management, and those control deficiencies could have also represented one or more material weaknesses.

Remediation Plan

Material weaknesses (as defined under the Exchange Act and by the auditing standards of the U.S. Public Company Accounting Oversight Board, or "PCAOB"), were identified in our internal control over financial reporting as of December 31, 2022. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual financial statements will not be prevented or detected on a timely basis.

We are in the process of remediating the control deficiencies that constituted the above material weaknesses by making enhancements to our control environment in 2023, including the following:

- Defining user roles within our systems and processes to ensure proper segregation of duties within our financial reporting procedures; and
- Engaging internal control consultants to assist us in performing a financial reporting risk assessment as well as identifying and designing our system of internal controls necessary to mitigate the risks identified.

Changes in Internal Control over Financial Reporting

Other than the ongoing remediation efforts discussed above, there were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) and 15(d)-15(f) of the Exchange Act) that occurred during the quarter ended March 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls and Procedures

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

Part II. Other Information

Item 1. Legal Proceedings

From time to time, we may be involved in various claims, threatened or actual, and legal proceedings relating to claims arising out of our operations or products, if any. We are not currently a party to any material legal proceedings. The outcome of claims or litigation cannot be predicted with certainty and some lawsuits, claims or proceedings may be disposed of unfavorably to us, which could materially affect our financial condition or results of operations.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the risks identified under "Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2022, before deciding whether to invest in our common stock. The occurrence of any of the events or developments described therein and below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

Risks Related to Our Business, Technology and Industry

We are in non-compliance with Nasdaq's continued listing standards, and if we do not regain compliance we will be delisted from Nasdaq.

On December 30, 2022, we received a deficiency letter from the Listing Qualifications Department, or the Staff, of The Nasdaq Stock Market LLC, or Nasdaq, notifying us that, for the last 30 consecutive business days, the bid price for our common stock had closed below the $1.00 per share minimum bid price requirement for continued inclusion on the Nasdaq Global Market pursuant to Nasdaq Listing Rule 5450(a)(1) (which we refer to as the "Minimum Bid Price Requirement"). The Nasdaq deficiency letter has no immediate effect on the listing of our common stock, and our common stock will continue to trade on the Nasdaq Global Market under the symbol "AXLA" at this time. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), or the Compliance Period Rule, we have been provided a period of 180 calendar days, or until June 28, 2023 (which we refer to as the "Compliance Date"), to regain compliance with the Minimum Bid Price Requirement. If, at any time ending June 28, 2023, the bid price for our common stock closes at $1.00 or more for a minimum of ten consecutive business days, as required under the Compliance Period Rule, the Staff will provide written notification to us that we have regained compliance with the Minimum Bid Price Requirement and our common stock will continue to be eligible for listing on the Nasdaq Global Market, unless the Staff exercises its discretion to extend this ten-day period pursuant to Nasdaq Listing Rule 5810(c)(3)(H). If we do not regain compliance with the Minimum Bid Price Requirement by the Compliance Date, we may be eligible for an additional 180 calendar day compliance period. To qualify, we would need to transfer the listing of our common stock to The Nasdaq Capital Market, provided that we meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, with the exception of the Minimum Bid Price Requirement, and would need to provide written notice to Nasdaq of our intention to cure the deficiency during the additional compliance period. To effect such a transfer, we would also need to pay an application fee to Nasdaq and provide written notice to the Staff of our intention to cure the deficiency during the second compliance period by effecting a reverse stock split if necessary. As part of its review process, the Staff will make a determination of whether it believes we will be able to cure the deficiency. Should the Staff conclude that we will not be able to cure the deficiency, the Staff will provide written notification to us that our common stock will be subject to delisting. At that time, we may appeal the Staff's delisting determination to a Nasdaq Listing and Hearing Review Panel. However, there can be no assurance that, if we receive a delisting notice and appeal the delisting determination by the Staff to the panel, such appeal would be successful. We intend to monitor the closing bid price of our common stock and may, if appropriate, consider available options to regain compliance with the Minimum Bid Price Requirement, which could include seeking to effect a reverse stock split. However, there can be no assurance that we will be able to regain,

or even pursue, compliance with the Minimum Bid Price Requirement, secure a second period of 180 days to regain compliance, or maintain compliance with any of the other Nasdaq continued listing requirements.

On April 3, 2023, we received written notice from the Staff of Nasdaq that (i) we are not in compliance with the requirement of a minimum Market Value of Publicly Held Shares ("MVPHS") of $15,000,000 for continued listing on the Nasdaq Global Market, as set forth in Nasdaq Listing Rule 5450(b)(2)(C); and (ii) we are not in compliance with the requirement of a minimum Market Value of Listed Securities ("MVLS") of $50,000,000, as set forth in Nasdaq Listing Rule 5450(b)(2)(A). In accordance with Nasdaq Listing Rule 5810(c)(3)(D), we have a period of 180 calendar days, or until October 2, 2023, to regain compliance with the minimum MVPHS and MVLS requirements. To regain compliance, the minimum MVPHS of our common stock is required to meet or exceed $15,000,000 for at least ten consecutive business days during this 180-calendar day compliance period; and to regain compliance, the minimum MVLS of our common stock is required to meet or exceed $50,000,000 for at least ten consecutive business days during this 180 calendar day compliance period. There can be no assurance that we will be able to regain compliance the MVPHS or MVLS requirements or maintain compliance with the other Nasdaq listing requirements.

In the event that we do not regain compliance within the 180 calendar day compliance period, we may be eligible to transfer to the Nasdaq Capital Market prior to the expiry of this period. However, if it appears to Nasdaq that we will not be able to cure the deficiencies, or if we are not otherwise eligible, Nasdaq will provide notice to us that our listed securities will be subject to delisting. In the event of such notification, we may appeal Nasdaq's determination to delist our securities, but there can be no assurance Nasdaq would grant our request for continued listing.

The MVPHS and MVLS notices are only a notification of deficiency, not of imminent delisting, and have no immediate effect on the listing of our securities on Nasdaq. If it appears to the Staff that we will not be able to cure the deficiencies, the Staff will provide written notice to us that our common stock will be subject to delisting. At that time, we may appeal the Staff's delisting determination to a Nasdaq Hearing Panel (the "Panel"). We expect that our stock would remain listed pending the Panel's decision. There can be no assurance that, if we do appeal the Staff's delisting determination to the Panel, such appeal would be successful.

Risks Related to our Organization and Structure

Our employee retention agreements may prevent changes in control.

On February 14, 2023, we entered into retention agreements, or the Retention Agreements, with each of (i) Mr. Hinshaw, (ii) Dr. Koziel, and (iii) Dr. Fehlner to provide an incentive for their continued service with us subsequent to the restructuring event on December 14, 2022. The Retention Agreements provide for retention bonuses of cash and equity in the event of certain actions by us as further described below. In connection with the retention bonuses provided under the Retention Agreements, each of Mr. Hinshaw, Dr. Koziel and Dr. Fehlner agreed to waive their rights to severance payments provided under their respective employment agreements in the event of a Terminations Without Cause or for Good Reason (as such terms are currently defined in their respective employment agreements). The costs associated with the Retention Agreements may have the effect of discouraging a third party from making an acquisition proposal for us and may thereby inhibit a change in control under circumstances that could otherwise give the holders of our common stock the opportunity to realize a greater premium over the then-prevailing market prices.

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

(a) **Recent Sales of Unregistered Equity Securities**

None.

(b) Not Applicable.

(c) **Issuer Purchases of Equity Securities**

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

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

Exhibit No.	Exhibit Index
3.1	Restated Certificate of Incorporation of the Registrant (Incorporated by reference to Exhibit 3.3 to the Registrant's Current Report on Form 8-K (File No. 001-38901) filed with the Securities and Exchange Commission on May 13, 2019).
3.2	Amended and Restated Bylaws of Registrant (Incorporated by reference to Exhibit 3.4 to the Registrant's Current Report on Form 8-K (File No. 001-38901) filed with the Securities and Exchange Commission on May 17, 2019).
3.3	Amendment to the Amended and Restated Bylaws of Registrant (Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-38901) filed with the Securities and Exchange Commission on May 8, 2020).
4.1	Specimen Stock Certificate evidencing shares of common stock (Incorporated by reference to Exhibit 4.1 to the Registrant's Amendment No. 1 to the Registration Statement on Form S-1/A (File No. 333-230822) filed with the Securities and Exchange Commission on April 30, 2019).
4.2	Fifth Amended and Restated Investors' Rights Agreement among the Registrant and certain of its stockholders, dated November 30, 2018 (Incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-230822) filed with the Securities and Exchange Commission on April 12, 2019).
4.3	Description of the Registrant's Securities (incorporated by reference to Exhibit 4.3 to the Registrant's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 23, 2020).
10.1#	Retention Agreement, dated February 14, 2023, by and between Axcella Health Inc. and William Hinshaw (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 17, 2023).
10.2#	Retention Agreement, dated February 14, 2023, by and between Axcella Health Inc. and Margaret Koziel (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 17, 2023).
10.3#	Retention Agreement, dated February 14, 2023, by and between Axcella Health Inc. and Paul Fehlner (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 17, 2023).
31.1*	Certification of Principal Executive Officer Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*†	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101INS*	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101SCH*	Inline XBRL Taxonomy Extension Schema Document.
101CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101LAB*	Inline XBRL Taxonomy Extension Labels Linkbase Document.
101PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
101DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.
104*	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.)

* Filed herewith.

\# Indicates a management contract or any compensatory plan, contract or arrangement.

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

SIGNATURES

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

AXCELLA HEALTH INC.

Date: May 4, 2023

By: /s/ William R. Hinshaw, Jr.

William R. Hinshaw, Jr.
President, Chief Executive Officer and Director

AXCELLA HEALTH INC.

Date: May 4, 2023

By: /s/ Marie Washburn

Marie Washburn
Vice President, Finance and Corporate Controller (Principal Financial Officer and Principal Accounting Officer)

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, William R. Hinshaw, Jr., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended March 31, 2023 of Axcella Health Inc.;

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

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

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

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

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

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

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

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

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

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

Date: May 4, 2023

By: /s/ William R. Hinshaw, Jr.

William R. Hinshaw, Jr.
President, Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Marie Washburn, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended March 31, 2023 of Axcella Health Inc.;

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

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

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

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

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

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

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

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

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

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

Date: May 4, 2023

By: /s/ Marie Washburn

Marie Washburn
Vice President, Finance and Corporate Controller
(Principal Financial Officer)

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Axcella Health Inc. (the "Company") for the quarterly period ended March 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned, William R. Hinshaw, Jr., Chief Executive Officer, President and Director of the Company, and Marie Washburn, Vice President, Finance and Corporate Controller of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his knowledge:

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

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

Date: May 4, 2023

By: /s/ William R. Hinshaw, Jr.

William R. Hinshaw, Jr.
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: May 4, 2023

By: /s/ Marie Washburn

Marie Washburn
Vice President, Finance and Corporate Controller
(Principal Financial Officer)