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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 June 30, 2022
OR

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

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

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.)**
840 Memorial Drive Cambridge, Massachusetts **(Address of principal executive offices)**	02139 **(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 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 and post 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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of August 9, 2022, the registrant had 52,643,309 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 Quarterly 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:

- 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, including our IND submissions and Clinical Trials for AXA1125 and AXA1665;
- 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 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;
- the financing needs and sufficiency of our funds to support company operations and business plans through certain periods of time, including funding necessary to complete further development of our product candidates, and, if successful, commercialization of these candidates as drug or non-drug products;
- 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;
- 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 on any of the foregoing; and
- other risks and uncertainties, including those discussed in Part II, Item 1A, Risk Factors in this Quarterly Report.

Any forward-looking statements in this Quarterly Report reflect our current views with respect to future events and with respect to our future financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that may cause actual results to differ materially from current expectations include, among other things, those described under Part I, Item 1A, Risk Factors and elsewhere in 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.

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

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 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 below 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	
	June 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 34,077	$ 23,574
Marketable securities	10,323	31,474
Prepaid expenses and other current assets	1,744	1,598
Total current assets	46,144	56,646
Property and equipment, net	937	870
Operating lease right-of-use asset	2,686	—
Other assets	211	211
Total assets	$ 49,978	$ 57,727
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,995	$ 4,301
Accrued expenses and other current liabilities	8,216	5,849
Current portion of long-term debt	3,467	—
Operating lease liability	1,497	—
Total current liabilities	17,175	10,150
Long-term debt, net of current portion and discount	21,701	25,070
Operating lease liability, net of current portion	1,391	—
Other liabilities	413	499
Total liabilities	40,680	35,719
Commitments and contingencies (Note 10)	—	—
Stockholders' equity:		
Common stock, $0.001 par value; 150,000,000 shares authorized, 53,058,369 and 39,605,701 shares issued and 52,639,388 and 39,186,720 shares outstanding at June 30, 2022 and December 31, 2021, respectively	53	40
Additional paid-in capital	386,897	359,261
Treasury stock, 418,981 shares at cost	—	—
Accumulated other comprehensive loss	(66)	(52)
Accumulated deficit	(377,586)	(337,241)
Total stockholders' equity	9,298	22,008
Total liabilities and stockholders' equity	$ 49,978	$ 57,727

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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 16,866	$ 10,298	$ 30,410	$ 20,538
General and administrative	3,753	4,946	8,539	9,202
Total operating expenses	20,619	15,244	38,949	29,740
Loss from operations	(20,619)	(15,244)	(38,949)	(29,740)
Other income (expense):				
Interest income	65	48	87	83
Interest expense	(752)	(734)	(1,456)	(1,462)
Other expense	—	(5)	(27)	(5)
Total other income (expense), net	(687)	(691)	(1,396)	(1,384)
Net loss	$ (21,306)	$ (15,935)	$ (40,345)	$ (31,124)
Net loss per share, basic and diluted	$ (0.40)	$ (0.42)	$ (0.86)	$ (0.83)
Weighted average common shares outstanding, basic and diluted	52,616,279	37,732,196	47,052,105	37,692,398
Comprehensive loss:				
Net loss	$ (21,306)	$ (15,935)	$ (40,345)	$ (31,124)
Other comprehensive income (loss):				
Unrealized gains (losses) on marketable securities	4	18	(14)	25
Comprehensive loss	$ (21,302)	$ (15,917)	$ (40,359)	$ (31,099)

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)

	Six Months Ended June 30,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (40,345)	$ (31,124)
Adjustment to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	159	132
Stock-based compensation	2,103	3,105
Non-cash interest expense	263	325
Non-cash lease expense	(26)	—
Other non-cash items	163	419
Changes in current assets and liabilities:		
Prepaid expenses and other current assets	(146)	424
Accounts payable	(137)	36
Accrued expenses and other current liabilities	2,437	(1,684)
Net cash used in operating activities	(35,529)	(28,367)
Cash flows from investing activities:		
Purchases of property and equipment	(202)	(296)
Purchases of marketable securities	—	(23,234)
Proceeds from sales and maturities of marketable securities	20,974	13,576
Net cash provided by (used in) investing activities	20,772	(9,954)
Cash flows from financing activities:		
Proceeds from issuance of common stock, net of issuance costs	25,456	578
Offering costs paid	(193)	—
Proceeds from exercise of common stock options and ESPP	90	140
Repayments of the principal portion of finance lease	(93)	(47)
Net cash provided by financing activities	25,260	671
Net increase (decrease) in cash and cash equivalents	10,503	(37,650)
Cash and cash equivalents, beginning of period	23,574	71,590
Cash and cash equivalents, end of period	$ 34,077	$ 33,940
Supplemental cash flow information:		
Cash paid for interest	$ 1,200	$ 1,137
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	$ 26	$ 17
Offering costs incurred but unpaid at period end	$ —	$ 53
Property and equipment acquired through a capital lease	$ —	$ 534

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 and Six Months Ended June 30, 2021					
	Common stock		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total stockholders' equity
	Shares	Par value				
BALANCE - January 1, 2021	38,022,273	$ 38	$ 347,990	$ (34)	$ (272,613)	$ 75,381
Costs incurred for the issuance of common stock			4			4
Exercise of common stock options	27,143	—	27			27
Vesting of restricted stock units	60,000	—	—			—
Stock-based compensation			1,428			1,428
Unrealized gain on marketable securities				7		7
Net loss					(15,189)	(15,189)
BALANCE - March 31, 2021	38,109,416	$ 38	$ 349,449	$ (27)	$ (287,802)	$ 61,658
Issuance of common stock, net of issuance costs of $71	126,527	1	555			556
Exercise of common stock options	3,257	—	6			6
Vesting of restricted stock units	4,604	—	—			—
Issuance of common stock related to ESPP	30,465	—	107			107
Stock-based compensation			1,677			1,677
Unrealized gain on marketable securities				18		18
Net loss					(15,935)	(15,935)
BALANCE - June 30, 2021	38,274,269	$ 39	$ 351,794	$ (9)	$ (303,737)	$ 48,087

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

	Three and Six Months Ended June 30, 2022					
	Common stock		Additional paid-in capital	Accumulated other comprehensive income (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 $222,639	13,321,602	13	25,413			25,426
Exercise of common stock options	8,499	—	6			6
Vesting of restricted stock units	59,019	—	—			—
Stock-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
Costs incurred for the issuance of common stock	—	—	30			30
Exercise of common stock options						—
Vesting of restricted stock units	5,797	—	—			—
Issuance of common stock related to ESPP	57,751	—	84			84
Stock-based compensation			594			594
Unrealized gain on marketable securities				4		4
Net loss					(21,306)	(21,306)
BALANCE - June 30, 2022	53,058,369	$ 53	$ 386,897	$ (66)	$ (377,586)	$ 9,298

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 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.

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.

Going Concern

The accompanying condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business. Consequently, management has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company’s ability to continue as a going concern within 12 months after the date the annual financial statements herein are issued.

Historically, the Company has funded its operations with proceeds from sales of preferred and common stock and borrowings under a loan and security agreement. The Company may never commercialize a product and achieve profitability, and unless and until it does, the Company will need to raise additional capital. The Company has had recurring losses since inception and incurred losses of $21.3 million and $40.3 million during the three and six months ended June 30, 2022, respectively, and an accumulated deficit of $377.6 million. Net cash used in operations for the six months ended June 30, 2022 was $35.5 million. The Company has spent, and expects to continue to spend, significant funds to continue development of its current and potential future pipeline candidates and continue to generate operating losses for the foreseeable future. As of June 30, 2022, the Company had cash, cash equivalents and marketable securities of $44.4 million. In accordance with its loan and security agreement with SLR Investment Corp., the Company is required to comply with an unrestricted minimum cash level of $20.0 million until certain clinical trial data conditions are met, and there is a risk that the Company may be unable to remain in compliance with those financial covenants in the future in which case the debt may become immediately due and payable. Based on its current operating plan, the Company believes that it has sufficient cash, cash equivalents and marketable securities to fund its operations into the first quarter of 2023, provided that, if the Company is unable to satisfy the financial covenants, and SLR Investment Corp. seeks immediate repayment of the loan in full, the Company believes that its cash, cash equivalents and marketable securities will be sufficient to fund its operations into the fourth quarter of 2022. The Company does not have sufficient cash, cash equivalents, and marketable securities to support current operations through a full 12 months from the issuance date of this Quarterly Report on Form 10-Q.

Accordingly, the foregoing conditions, taken together, raise substantial doubt about the Company’s ability to continue as a going concern for one year from the issuance of these condensed consolidated financial statements. These condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

In response to these conditions, in March 2022, the Company secured approximately $24.8 million in net proceeds through a registered direct offering of common stock. The Company will also be seeking additional financing options to raise additional capital going forward. However, there is no assurance the Company will be successful in obtaining such additional financing on terms acceptable to it, if at all, and it may not be able to enter into other arrangements to obtain additional financing, and therefore cannot be deemed probable. As a result the Company has concluded that these plans do not alleviate substantial doubt about the Company’s ability to continue as a going concern.

If the Company is unable to obtain additional financing, it could be forced to delay, reduce or eliminate the Company’s research and development programs, expansion or commercialization efforts, which could adversely affect its business prospects and ability to continue operations.

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. On January 1, 2022, the Company adopted ASU No. 2016-02, *Leases (Topic 842)* and the related accounting policies. Other than the adoption of *Topic 842*, 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, 2021, which was filed with the SEC on March 30, 2022. 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, 2021. 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 June 30, 2022, the results of its operations for the three and six months ended June 30, 2022 and 2021, its cash flows for the six months ended June 30, 2022 and 2021, and its statements of stockholders' equity for the three and six months ended June 30, 2022 and 2021.

The results for the three and six months ended June 30, 2022 are not necessarily indicative of the results to be expected for the year ending December 31, 2022, 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, 2021, 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, 2021.

Principles of Consolidation

The accompanying condensed consolidated financial statements include the accounts of Axcella Health Inc. and its wholly owned subsidiaries. All intercompany transactions and balances have been eliminated in consolidation.

Segment Information

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the CEO, 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.

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 also be cash equivalents.

Marketable Securities

The Company's marketable securities, which consisted of corporate debt obligations as of June 30, 2022, are classified as available-for-sale and are reported at fair value. Unrealized gains and losses on available-for-sale securities are reported as a component of accumulated other comprehensive income (loss) in stockholders' equity. Realized gains and losses and declines in value determined to be other than temporary are based on the specific identification method and are included as a component of other income (expense), net in the condensed consolidated statements of operations and comprehensive loss.

The Company evaluates its marketable securities with unrealized losses for other-than-temporary impairment. When assessing marketable securities for other-than-temporary declines in value, the Company considers such factors as, among other things, how significant the decline in value is as a percentage of the original cost, how long the market value of the investment has been less than its original cost, the Company's ability and intent to retain the investment for a period of time sufficient to allow for any anticipated recovery in fair value and market conditions in general. If any adjustment to fair value reflects a decline in the value of the investment that the Company considers to be "other than temporary," the Company reduces the investment to fair value through a charge to the condensed consolidated statements of operations and comprehensive loss. No such adjustments were necessary during the periods presented.

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, cash equivalents and marketable securities. The Company's cash equivalents and marketable securities as of June 30, 2022 consisted of bank deposits, money market funds that invest in U.S. treasury securities, and corporate obligations. The Company invests in high-quality financial instruments and it's portfolio does not consist of any instrument with a maturity duration in excess of twenty-four months, which the Company believes limits it's credit risk.

In addition, 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 and marketable securities 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. The carrying value of the long-term debt approximates fair value as evidenced by the recent amendment to the Company's debt facility.

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 and six months ended June 30, 2022, the Company's only element of other comprehensive loss was unrealized gains (losses) on marketable securities.

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 February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, as amended by various subsequently issued ASUs. The standard requires lessees to recognize an operating lease with a term greater than one year on their balance sheets as a right-of-use asset and corresponding lease liability, measured at the present value of the lease payments. Under the standard, disclosures are required to enable financial statement users to assess the amount, timing, and uncertainty of cash flows arising from the leases. Companies are also required to recognize and measure leases existing at, or entered into after, the adoption date using a modified retrospective approach, with certain practical expedients available. Comparative periods prior to adoption have not been retrospectively adjusted.

Effective January 1, 2022, the Company adopted ASU 2016-02, using the required modified retrospective approach and utilizing January 1, 2022 as its date of initial application. As a result, prior periods are presented in accordance with the previous guidance in ASC 840, *Leases (Topic 840)*.

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present in the arrangement. Leases with a term greater than one year are recognized on the balance sheet as right-of-use assets and short-term and long-term lease liabilities, as applicable. The Company does not have material financing leases.

Operating lease liabilities and their corresponding right-of-use assets are initially recorded based on the present value of lease payments over the expected remaining lease term. Certain adjustments to the right-of-use asset may be required for items such as incentives received. The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate to discount lease payments, which reflects an internally developed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. Prospectively, the Company will adjust the right-of-use assets for straight-line rent expense or any incentives received and remeasure the

lease liability at the net present value using the same incremental borrowing rate that was in effect as of the lease commencement or transition date.

The Company has elected not to recognize leases with an original term of one year or less on the balance sheet. The Company typically only includes an initial lease term in its assessment of a lease arrangement. Options to renew a lease are not included in the Company's assessment unless there is reasonable certainty that the Company will renew.

ASC 842 transition practical expedients and application of transition provisions to leases at the transition date

The Company elected the following practical expedients, which must be elected as a package and applied consistently to all of its leases at the transition date (including those for which the entity is a lessee or a lessor): i) the Company did not reassess whether any expired or existing contracts are or contain leases; ii) the Company did not reassess the lease classification for any expired or existing leases (that is, all existing leases that were classified as operating leases in accordance with ASC 840 are classified as operating leases, and all existing leases that were classified as capital leases in accordance with ASC 840 are classified as finance leases); and iii) the Company did not reassess initial direct costs for any existing leases.

For leases that existed prior to the date of initial application of ASC 842 (which were previously classified as operating leases), a lessee may elect to use either the total lease term measured at lease inception under ASC 840 or the remaining lease term as of the date of initial application of ASC 842 in determining the period for which to measure its incremental borrowing rate. In transition to ASC 842, the Company utilized the remaining lease term of its leases in determining the appropriate incremental borrowing rates.

Application of ASC 842 policy elections to leases post adoption

The Company has made certain policy elections to apply to its leases executed post adoption, or subsequent to January 1, 2022, as further described below.

In accordance with ASC 842, components of a lease should be split into three categories: lease components, non-lease components, and non-components. The fixed and in-substance fixed contract consideration (including any consideration related to non-components) must be allocated based on the respective relative fair values to the lease components and non-lease components.

Entities may elect not to separate lease and non-lease components. Rather, entities would account for each lease component and related non-lease component together as a single lease component. The Company has elected to account for lease and non-lease components together as a single lease component for all underlying assets and allocate all of the contract consideration to the lease component only.

ASC 842 allows for the use of judgment in determining whether the assumed lease term is for a major part of the remaining economic life of the underlying asset and whether the present value of lease payments represents substantially all of the fair value of the underlying asset. The Company applies the bright line thresholds referenced in ASC 842-10-55-2 to assist in evaluating leases for appropriate classification. The aforementioned bright lines are applied consistently to the Company's leases.

On January 1, 2022, the Company recorded right-of-use asset of $3.3 million and lease liability of $3.6 million. The standard did not have a material impact on the statement of operations or statement of cash flows. Additionally, there is no tax impact from the adoption as the net increase in deferred tax assets is fully offset with an increase to the valuation allowance.

Accounting Pronouncements Issued and Not Adopted

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 Company is required to adopt this standard effective January 1, 2023 and the Company is evaluating the impact the guidance will have on its condensed consolidated financial statements.

3. MARKETABLE SECURITIES

As of June 30, 2022, and December 31, 2021, marketable securities by security type consisted of the following (in thousands):

	June 30, 2022			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate obligations	$ 10,388	$ —	$ (66)	$ 10,322

	December 31, 2021			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate obligations	$ 31,526	$ —	$ (52)	$ 31,474

The amortized cost of marketable securities is adjusted for amortization of premiums and accretion of discounts to maturity. At June 30, 2022 and December 31, 2021, the balance in accumulated other comprehensive loss was comprised solely of activity related to marketable securities. For the six months ended June 30, 2022, the Company recognized realized losses on the sale or maturity of marketable securities of less than $0.1 million, as a result, the Company reclassified amounts out of accumulated other comprehensive loss during the period. There were no realized gains or losses on the sale or maturity of marketable securities for the three months ended June 30, 2021.

The aggregate fair value of marketable securities by contractual maturity were as follows (in thousands):

Contractual Maturities	June 30, 2022	December 31, 2021
Mature in one year or less	$ 10,322	$ 28,220
Mature in two years or less	—	3,254
Total	$ 10,322	$ 31,474

As of June 30, 2022, the Company did not intend to sell, and was more than likely not required to sell, the debt securities in a loss position before recovery of their amortized cost bases. As a result, the Company determined it did not hold any investments with any other-than-temporary impairment at June 30, 2022.

There were sales of marketable securities during the six months ended June 30, 2022 worth $8.9 million. No such sales occurred during the three months ended June 30, 2022 or the three and six months ended June 30, 2021.

4. 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 June 30, 2022 using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 31,577	$ —	$ —	$ 31,577
Marketable securities:				
Corporate obligations	—	10,322	—	10,322
Total	$ 31,577	$ 10,322	$ —	$ 41,899

	Fair Value Measurements at December 31, 2021 using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 23,021	$ —	$ —	$ 23,021
Marketable securities:				
Corporate obligations	—	31,474	—	31,474
Total	$ 23,021	$ 31,474	$ —	$ 54,495

As of June 30, 2022 and December 31, 2021, the Company's cash equivalents were invested in money market funds and were valued based on Level 1 inputs. The Company's marketable securities consist of corporate obligations which are adjusted to fair value at each balance sheet date, based on quoted prices, which are considered Level 2 inputs. During the three months ended June 30, 2022 and 2021, there were no transfers between Level 1, Level 2 and Level 3.

5. PROPERTY AND EQUIPMENT

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

	June 30, 2022	December 31, 2021
Laboratory equipment	$ 3,564	$ 3,426
Leasehold improvements	564	564
Office and computer equipment	236	148
Furniture and fixtures	122	122
Property and equipment	4,486	4,260
Less: accumulated depreciation and amortization	(3,549)	(3,390)
Property and equipment, net	$ 937	$ 870

Depreciation and amortization expense was $0.2 million and $0.1 million for the six months ended June 30, 2022 and 2021, respectively. There were no disposals for the six months ended June 30, 2022. Property and equipment totaling $0.3 million was disposed of for the six months ended June 30, 2021, and no gains or losses were recorded.

6. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

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

	June 30, 2022	December 31, 2021
Accrued employee compensation and benefits	$ 2,516	$ 3,005
Accrued external research and development expenses	4,870	2,000
Accrued professional fees	650	601
Other	180	243
Total accrued expenses and other current liabilities	$ 8,216	$ 5,849

7. DEBT FINANCING

Long-term debt consisted of the following (in thousands):

	June 30, 2022	December 31, 2021
Principal amount of long-term debt	$ 26,000	$ 26,000
Debt discount	(175)	(196)
Deferred financing fees	(657)	(734)
Current portion of long-term debt	(3,467)	—
Long-term debt, net of current portion and discount	$ 21,701	$ 25,070

In 2021, the Company entered into a loan and security agreement (the "New Loan and Security Agreement") with SLR Investment Corp., formerly known as Solar Capital Ltd., for term loans in an aggregate principal amount of $26.0 million. The New Loan and Security Agreement replaced the prior loan and security agreement between the Company and SLR Investment Corp. (the "Prior Loan and Security Agreement").

The term loans under the New Loan and Security Agreement will accrue interest at an annual rate equal to 8.60% plus the greater of (a) the thirty (30) day U.S. Dollar LIBOR rate and (b) 0.10%, payable monthly in arrears. The interest rate was 9.72% as of June 30, 2022. The monthly principal payments of $0.6 million will be paid over a period of 45 months beginning in January 2023 through the final maturity date of September 1, 2026. Per the New Loan and Security Agreement, the date on which repayment of principal commences can be further extended to July 2023 and January 2024, provided we satisfy certain equity related conditions. The term loans are also subject to a prepayment fee of 3.00% if prepayment occurs within the first year subsequent to September 2, 2021, 2.00% in the second year and 1.00% in the third year through final maturity.

The New Loan and Security Agreement also contains certain financial covenants, including an unrestricted minimum cash level until certain clinical trial study data conditions are met. Customary representations and warranties, as well as certain non-financial covenants, including engaging in any change of control transaction or incurring additional indebtedness or liens are included in the New Loan and Security Agreement as well. As security for its obligations under the New Loan and Security Agreement, the Company granted SLR Investment Corp. a first priority perfected security interest in all of the Company’s existing and after-acquired assets, including intellectual property.

The scheduled principal maturity of the long-term debt as of June 30, 2022 is as follows (in thousands):

Year Ending December 31,	
2022	$ —
2023	6,933
2024	6,933
2025	6,934
2026	5,200
	$ 26,000

8. STOCKHOLDERS' EQUITY

Common Stock

On June 5, 2020, the Company entered into a sales agreement with SVB Leerink LLC (“SVB Leerink”) pursuant to which the Company may offer and sell shares of its common stock having an aggregate offering price of up to $35.0 million from time to time through SVB Leerink, acting as its agent (the “ATM Offering”). During the six months ended June 30, 2022, the Company sold an aggregate of 232,600 shares of its common stock under the ATM Offering for net cash proceeds of $0.6 million, after deducting commissions and expenses of less than $0.1 million.

In March 2022, the Company completed a registered direct offering and in this transaction, and sold 13,089,002 shares of common stock were sold at the market for a purchase price of $1.91 per share, yielding net proceeds of approximately $24.8 million, after deducting expenses of $0.2 million.

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 1,034,033 as of June 30, 2022.

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 788,670 shares as of June 30, 2022.

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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Research and development	$ 275	$ 440	$ 841	$ 850
General and administrative	319	1,237	1,262	2,255
Total stock-based compensation expense	$ 594	$ 1,677	$ 2,103	$ 3,105

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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Risk-free interest rate	2.89 %	1.03 %	2.01 %	0.82 %
Expected option life (in years)	5.75	5.92	6.08	6.00
Expected dividend yield	— %	— %	— %	— %
Expected volatility	95.3 %	96.5 %	91.9 %	97.0 %

Stock Option Activity

The following table summarizes the Company's stock option activity for the six months ended June 30, 2022:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Life (in Years)	Intrinsic Value (in thousands)
Outstanding as of January 1, 2022	6,197,288	$ 5.72		
Granted	2,154,259	1.86		
Exercised	(8,499)	0.72		
Canceled	(552,714)	4.58		
Outstanding as of June 30, 2022	7,790,334	$ 4.74	7.52	$ 865
Exercisable as of June 30, 2022	4,133,540	$ 6.14	5.98	$ 167
Vested or expected to vest as of June 30, 2022	7,465,334	$ 4.67	7.12	$ 735

The intrinsic value of options exercised during the six months ended June 30, 2022 and 2021 was nominal.

The weighted-average grant date fair value of the options granted during the six months ended June 30, 2022 and 2021 was $1.09 and $4.39 per share, respectively.

As of June 30, 2022, there was $7.3 million of unrecognized compensation expense that is expected to be recognized over a weighted-average period of approximately 2.5 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 six months ended June 30, 2022:

	Number of Shares	Weighted Average Grant Date Fair Value per Share
Outstanding as of January 1, 2022	275,350	$ 4.15
Granted	47,059	1.70
Vested	(64,816)	4.56
Forfeited	(75,000)	3.13
Outstanding as of June 30, 2022	182,593	$ 3.80

As of June 30, 2022, there was $0.3 million of unrecognized compensation expense that is expected to be recognized over a weighted-average period of approximately 1.6 years.

9. 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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Numerator:				
Net loss	$ (21,306)	$ (15,935)	$ (40,345)	$ (31,124)
Denominator:				
Weighted average common shares outstanding, basic and diluted	52,616,279	37,732,196	47,052,105	37,692,398
Net loss per share, basic and diluted	$ (0.40)	$ (0.42)	$ (0.86)	$ (0.83)

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:

	Six Months Ended June 30,	
	2022	2021
Options to purchase common stock	7,790,334	6,135,310
Unvested restricted stock units	182,593	357,513
Shares issuable under employee stock purchase plan	65,790	8,280
	8,038,717	6,501,103

10. 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.

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 and six months ended June 30, 2022 (in thousands, except weighted average figures):

Operating leases	Three Months Ended June 30, 2022	Six Months Ended June 30, 2022
Lease cost		
Operating lease cost	$ 401	$ 803
Variable lease cost	160	353
Total lease cost	$ 561	$ 1,156
Other information		
Operating cash flows used for operating leases	$ 578	$ 1,181
Weighted average remaining lease term (years)	1.8	1.8
Weighted average discount rate (percentage)	9.0 %	9.0 %

For the three and six months ended June 30, 2022, the Company incurred $0.6 million and $1.2 million in operating lease expense, respectively, and made lease payments of $0.6 million and $1.2 million, respectively, with such amounts reflected in the condensed consolidated statements of cash flows in operating activities.

As the result of adopting ASU 2016-02 using the modified retrospective transition method, we did not restate periods prior to the adoption date of January 1, 2022. These periods continue to be presented in accordance with ASC 840. Future minimum lease payments and lease liabilities as of June 30, 2022 and December 31, 2021 were as follows (in thousands):

	As of	
Maturity of lease liabilities	**June 30, 2022**	**December 31, 2021**
2022	$ 844	$ 1,672
2023	1,722	1,722
2024	580	580
Total future minimum lease payments	$ 3,146	$ 3,974
Less: imputed interest	(258)	
Total lease liability	$ 2,888	
Reported as:		
Operating lease liability	$ 1,497	
Operating lease liability, net of current portion	1,391	
Total lease liability	$ 2,888	

Other Commitments

We enter 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.

11. RELATED-PARTY TRANSACTIONS

The chairman of the Company's Board of Directors had received compensation for consulting services under a consulting agreement by and between the chairman and the Company. In March 2022, the chairman and the Company mutually agreed to terminate the consulting agreement, with such termination to be effective immediately. The consulting agreement was terminated in connection with a new compensation arrangement for the chairman’s service as the non-executive chairman of the Board.

12. SUBSEQUENT EVENTS

The Company has evaluated subsequent events for financial statement purposes occurring through the date these condensed consolidated financial statements were issued and determined that there are no material recognized or unrecognized subsequent events requiring disclosure.

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, 2022. 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

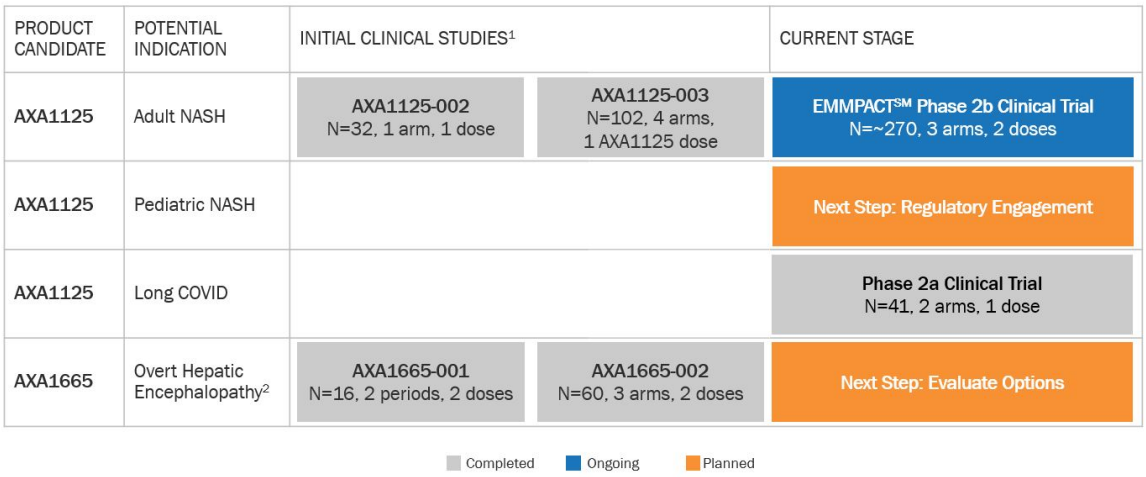
We are a clinical-stage biotechnology company focused on pioneering a new approach to treat complex diseases using compositions of endogenous metabolic modulators, or EMMs. Our product candidates are comprised of multiple EMMs that are engineered in distinct combinations and ratios with the goal of simultaneously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

Using our discovery platform, we have efficiently designed product candidates that are comprised of amino acids and their derivatives, which have a general history of safe use. The orally administered EMM compositions that we have tested clinically to date in our development model have shown the potential to generate multifactorial effects in our initial Clinical Studies.

To date, we have funded our operations with proceeds from the sale of preferred stock and common stock, and borrowing of debt. Since our inception, we have incurred significant operating losses. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our current or future product candidates. Our net losses were $21.3 million and $40.3 million for the three and six months ended June 30, 2022, respectively. Net losses for the same periods ended June 30, 2021 were $15.9 million and $31.1 million, respectively. As of June 30, 2022, we had an accumulated deficit of $377.6 million. We expect to continue to incur significant expenses for at least the next several years as we continue to develop our product candidates.

As of June 30, 2022, we had cash, cash equivalents and marketable securities of $44.4 million. We are required to comply with an unrestricted minimum cash level of $20.0 million in accordance with our loan and security agreement with SLR Investment Corp. until certain clinical trial data conditions are met, and there is a risk that we may be unable to remain in compliance with those financial covenants in the future in which case the debt may become immediately due and payable. Based on our current operating plan, we believe that we have sufficient cash, cash equivalents and marketable securities to fund our operations into the first quarter of 2023, provided that, if we are unable to satisfy the financial covenants contained in our loan and security agreement with SLR Investment Corp., and SLR Investment Corp. seeks immediate repayment of our loan in full, we believe that our cash, cash equivalents and marketable securities will be sufficient to fund our operations into the fourth quarter of 2022. We do not have sufficient cash, cash equivalents and marketable securities to support current operations through a full 12 months from the issuance date of this Quarterly Report on Form 10-Q. We will need substantial additional funding to continue development of our current and potential future pipeline candidates. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of equity offerings, debt re-financings, collaboration agreements, strategic alliances and licensing arrangements. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all, including as a result of market volatility following the COVID-19 pandemic. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions. Further, inflation may affect our use of capital resources by increasing our cost of labor and clinical trial expenses. We also intend to continue to evaluate options to refinance our outstanding debt with SLR Investment Corp. The amounts involved in any such transactions, individually or in the aggregate, may be material. These factors individually and collectively raise substantial doubt about our ability to continue as a going concern.

An overview of our current therapeutic product candidates and their planned next development steps is illustrated below:



1. Initial Clinical Studies refers to Non-IND Clinical Studies initiated prior to a development path decision.
2. In May 2022, we terminated our EMMPOWER Phase 2 Clinical Trial studying AXA1665 for the reduction in risk of Overt Hepatic Encephalopathy recurrence in adult patients with liver cirrhosis. We plan to explore alternate indications for AXA1665.

AXA1125 for Nonalcoholic Steatohepatitis (NASH)

AXA1125 is currently being developed as an oral product candidate for the treatment of NASH. In 2021, our IND for this candidate was cleared by the FDA, enabling us to proceed directly into a global Phase 2b Clinical Trial that was initiated in the second quarter of 2021. We branded this global trial EMMPACT based on the potential for AXA1125, an EMM composition, to deliver meaningful, multifactorial clinical benefits to patients with NASH. Based on AXA1125's differentiated, multi-targeted design and data from our earlier Clinical Studies, we believe this candidate holds the potential, if approved, to serve as a first-line NASH monotherapy for both adult and pediatric patients and be used in combination with other agents if required.

We have conducted two prior Clinical Studies of AXA1125 in subjects with presumed NASH. AXA1125 was generally well tolerated in both of these studies with meaningful and sustained reductions shown in key measures of hepatic fat, insulin resistance, inflammation and fibrosis. In 2020, Axcella completed its most recent Clinical Study of AXA1125, AXA1125-003. This was a 16-week (with a two-week follow-up), randomized, single-blind, placebo-controlled Clinical Study to assess safety, tolerability and impact on the liver structure and function of two distinct EMM compositions, AXA1125 and AXA1957, in 102 adult subjects with NAFLD. Key inclusion criteria for this study included having at least 10% fat by MRI-PDFF and a corrected T1, or cT1, a measure of liver injury by multiparametric MRI, of at least 830 mSec. Subjects were stratified by the presence or absence of T2D. In this study, subjects received either AXA1125, two different doses of AXA1957 or a calorie-matched placebo control twice a day, or BID. Results from the study showed that AXA1125 and AXA1957 were generally well-tolerated, with sustained reductions noted for both product candidates versus placebo in key biomarkers of metabolism, inflammation and fibrosis over 16 weeks.

Following FDA clearance of an IND application for AXA1125, we initiated our EMMPACT Phase 2b Clinical Trial for this candidate in the second quarter of 2021. This global randomized, double-blind, placebo-controlled, multi-center Clinical Trial is evaluating the efficacy, safety and tolerability of AXA1125 in adult patients with biopsy-confirmed F2/F3 NASH. Approximately 270 patients will be enrolled and randomized 1:1:1 to receive either 45.2 or 67.8 grams per day of AXA1125 or a matched placebo in two divided doses for 48 weeks, with a four-week safety follow-up period. Patients will be stratified based on the presence or absence of type 2 diabetes.

The Clinical Trial's primary endpoint will assess the proportion of patients with a biopsy-confirmed ≥2-point improvement in their NAFLD Activity Score (NAS) after the 48-week treatment period. Secondary endpoints will include the proportion of patients achieving biopsy-confirmed resolution of NASH without worsening of fibrosis and the proportion of patients achieving a ≥1 stage improvement in fibrosis without worsening of NASH, as well as a range of non-invasive markers, such as MRI-PDFF, vibration controlled transient elastography (Fibroscan™), liver enzymes and measures of insulin resistance.

AXA1125 for the Treatment of Long COVID

AXA1125 is also currently being developed as a product candidate for the treatment of Long COVID. In October 2021, we announced that our Clinical Trial Authorisation application, or CTA, for this candidate was cleared by the Medicines and Healthcare products Regulatory Agency, or MHRA, in the United Kingdom, enabling us to proceed directly into a Phase 2a Clinical Trial, which was initiated in the fourth quarter of 2021. Based on AXA1125's differentiated, multi-targeted design and data from our earlier Clinical Studies, we believe this candidate holds the potential, if approved, to serve as a first-line Long COVID therapy for patients.

Following clearance of the CTA, we initiated a Phase 2a Clinical Trial of AXA1125. The Phase 2a trial is a randomized, double-blind, placebo-controlled investigation to evaluate the efficacy and safety of AXA1125 in patients with exertional fatigue related to Long COVID. 41 patients were enrolled and randomized to receive either 67.8 grams per day of AXA1125 or a matched placebo in two divided doses for 28 days, with a one-week safety follow-up period. This same daily dose of AXA1125 has already been investigated in a 12-week Clinical Study in subjects with presumed NASH and was generally well tolerated.

The Phase 2a trial's primary endpoint was change in phosphocreatine (PCr) recovery time, as measured by ^{31}-phosphorus magnetic resonance spectroscopy (MRS), from baseline to Day 28 as an assessment of improvement of mitochondrial function within the skeletal muscle. PCr recovery time is a well-established and highly sensitive measure that has been strongly correlated with the 6-minute walk test (6MWT), a functional measure that has been used as a registrational endpoint in several other diseases in which fatigue and muscle weakness play a central role. Key secondary endpoints include lactate levels, a 6MWT, patient reported fatigue scores assessed by the Chalder Fatigue Questionnaire (CFQ-11), and safety and tolerability. The CFQ-11 is a validated patient reported outcome measure of fatigue that has been used in measuring patient impact in fatigue states such as chronic fatigue syndrome. The Clinical Trial was conducted with researchers at Oxford University's Radcliffe Department of Medicine in the United Kingdom.

In May 2022, we completed patient enrollment in our Phase 2a Clinical Trial and on August 2, 2022, we reported topline results.

Subjects who received AXA1125 had improvements in measures of mental and physical fatigue that were both highly statistically significant and clinically relevant compared to those who received placebo. Mean changes in total, physical and mental scores in the CFQ-11 versus placebo were -4.30 (p=0.0039), -2.94 (p=0.0097) and -1.32 (p=0.0097), respectively. Clinically meaningful shifts in the severity of physical and mental fatigue were also noted in subjects who received AXA1125 compared to those who received placebo. There was a statistically significant correlation of improvement in fatigue score and greater distance achieved in the 6MWT (p=0.0027), an objective measure of physical ability, only observed in subjects who received AXA1125 when compared to those receiving placebo. There was a notable trend toward significant improvement in serum lactate levels after a 6MWT in AXA1125 subjects (p=0.0730). AXA1125 was safe and well tolerated with no significant emergent adverse events or serious adverse events reported by study subjects.

Baseline PCr among all subjects was significantly higher and had a higher degree of inter-subject variability (92.46 seconds + 35.3 seconds) than previously reported in the literature. These findings support the hypothesis that there is significant mitochondrial dysfunction in these patients but limits the utility of this parameter in a clinical trial. The trial did not meet this exploratory primary endpoint of showing a change from baseline to week four in the PCr recovery rate following moderate exercise between subjects receiving AXA1125 and placebo.

AXA1665 for the Reduction in Risk of Overt Hepatic Encephalopathy (OHE) Recurrence

AXA1665 is a product candidate for the reduction in risk of OHE recurrence in adult patients with liver cirrhosis. In 2021, we announced that our IND for this candidate was cleared by the FDA, enabling us to proceed directly into a Phase 2 Clinical Trial, which was initiated in the second quarter of 2021. We have branded the Phase 2 trial EMMPOWER based on the potential for AXA1665, an EMM composition, to help patients, physicians and other caregivers overcome significant challenges associated with cirrhosis and OHE. Based on AXA1665's differentiated, multi-targeted design and data gathered to date, we believe this candidate holds the potential to reduce OHE events and improve the quality of life for cirrhotic patients.

We have conducted two prior Clinical Studies of AXA1665 in subjects with mild (Child Pugh A) and moderate (Child Pugh B) hepatic insufficiency. AXA1665 was generally well tolerated in both studies, with multifactorial effects seen in subjects. In 2020, Axcella completed its most recent Clinical Study of AXA1665, AXA1665-002. This was a 12-week (with a four-week follow-up) randomized, placebo-controlled Clinical Study to assess AXA1665's safety, tolerability and impact on normal liver and muscle structures and functions in approximately 60 subjects with mild (Child A) and moderate (Child B) hepatic insufficiency. Results from the study showed that AXA1665 demonstrated dose dependent improvements across all three psychometric tests that were utilized.

Following FDA clearance of an IND application for AXA1665, we initiated our EMMPOWER Phase 2 Clinical Trial for this candidate in the second quarter of 2021. This global randomized, double-blind, placebo-controlled, multi-center investigation is evaluating the efficacy and safety of AXA1665 in patients who have experienced at least one prior OHE event and have neurocognitive dysfunction at screening. Approximately 150 patients on lactulose ± rifaximin (stratified by rifaximin use) will be randomized 1:1 to receive either 53.8 grams per day of AXA1665 or a matched placebo in three divided doses for 24 weeks, with a four-week safety follow-up period.

The Clinical Trial's primary endpoint will assess the proportion of patients with a ≥2-point increase in the psychometric hepatic encephalopathy score (PHES) after the 24-week treatment period. Key secondary endpoints will focus on the proportion of patients experiencing an OHE breakthrough event and time to first OHE breakthrough event, including time to hospitalization. Other secondary endpoints include changes in physical function and patient-reported outcomes.

In May 2022, we terminated our EMMPOWER Phase 2 Clinical Trial of AXA1665 for reduction in risk of recurrent OHE. We plan to evaluate options for AXA1665.

Effects of 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.

Research and development expenses may fluctuate from period to period depending upon the stage of certain projects and the stage of preclinical and clinical activities and development. 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” 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. We expect research and development expenses to increase as we advance existing product candidates into additional Clinical Trials and Clinical Studies and develop new 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 general and administrative expenses will increase in the future to support our continued research and development of our product candidates. Additionally, if and when we believe a regulatory approval of a product candidate appears likely, we anticipate an increase in payroll and expense as a result of our preparation for commercial operations, especially as it relates to the sales and marketing of our product candidate.

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 consists of interest on outstanding borrowings under a loan and security agreement, the amortization expense of the debt discount and debt issuance costs, and interest paid for leased capital equipment.

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 June 30, 2022 and 2021

The following table summarizes our results of operations for the three months ended June 30, 2022 and 2021 (in thousands):

	Three Months Ended June 30,		
	2022	**2021**	**Change**
Operating expenses:			
Research and development	$ 16,866	$ 10,298	$ 6,568
General and administrative	3,753	4,946	(1,193)
Total operating expenses	20,619	15,244	5,375
Loss from operations	(20,619)	(15,244)	(5,375)
Other income (expense):			
Other income (expense), net	(687)	(691)	4
Total other income (expense), net	(687)	(691)	4
Net loss	$ (21,306)	$ (15,935)	$ (5,371)

Research and Development Expenses

The following table summarizes our research and development expenses incurred during the three months ended June 30, 2022 and 2021 (in thousands):

	Three Months Ended June 30,		
	2022	2021	Change
Salary and benefits-related	$ 4,263	$ 3,437	$ 826
Clinical research and outside services	11,414	5,729	5,685
Facility-related and other	1,189	1,132	57
Total research and development expenses	$ 16,866	$ 10,298	$ 6,568

Salary and benefits-related costs increased by $0.8 million due to higher headcount and related compensation. Clinical research and outside services costs increased by $5.7 million due to expenses incurred for our AXA1125 EMMPACT Phase 2b Clinical Trial to treat NASH, AXA1125 Phase 2a Clinical Trial to treat Long COVID, and the closure of our AXA1665 EMMPOWER Phase 2 Clinical Trial, which was terminated in May 2022.

General and Administrative Expenses

The following table summarizes our general and administrative expenses incurred during the three months ended June 30, 2022 and 2021 (in thousands):

	Three Months Ended June 30,		
	2022	2021	Change
Salary and benefits-related	$ 2,051	$ 3,193	$ (1,142)
Other contract services and outside costs	1,470	1,464	6
Facility-related and other	232	289	(57)
Total general and administrative expenses	$ 3,753	$ 4,946	$ (1,193)

Salary and benefits-related costs decreased by $1.1 million due to lower stock based compensation and employee-related costs.

Other Income (Expense), Net

Other income (expense), net was $0.7 million for the three months ended June 30, 2022 and June 30, 2021. Other income (expense), net consists primarily of interest expense on a loan and security a loan and security agreement in both periods presented.

Comparison of the Six Months Ended June 30, 2022 and 2021

The following table summarizes our results of operations for the six months ended June 30, 2022 and 2021 (in thousands):

	Six Months Ended June 30,		
	2022	**2021**	**Change**
Operating expenses:			
Research and development	$ 30,410	$ 20,538	$ 9,872
General and administrative	8,539	9,202	(663)
Total operating expenses	38,949	29,740	9,209
Loss from operations	(38,949)	(29,740)	(9,209)
Other income (expense):			
Other income (expense), net	(1,396)	(1,384)	(12)
Total other income (expense), net	(1,396)	(1,384)	(12)
Net loss	$ (40,345)	$ (31,124)	$ (9,221)

Research and Development Expenses

The following table summarizes our research and development expenses incurred during the six months ended June 30, 2022 and 2021 (in thousands):

	Six Months Ended June 30,		
	2022	**2021**	**Change**
Salary and benefits-related	$ 8,445	$ 6,789	$ 1,656
Clinical research and outside services	19,685	11,149	8,536
Facility-related and other	2,280	2,600	(320)
Total research and development expenses	$ 30,410	$ 20,538	$ 9,872

Salary and benefits-related costs increased by $1.7 million due to higher headcount and related compensation. Clinical research and outside services costs increased by $8.5 million due to expenses incurred for our AXA1125 EMMPACT Phase 2b Clinical Trial to treat NASH, AXA1125 Phase 2a Clinical Trial to treat Long COVID, and the closure of our AXA1665 EMMPOWER Phase 2 Clinical Trial, which was terminated in May 2022. Facility-related and other costs decreased by $0.3 million due to lower corporate expenses.

General and Administrative Expenses

The following table summarizes our general and administrative expenses incurred during the six months ended June 30, 2022 and 2021 (in thousands):

	Six Months Ended June 30,		
	2022	2021	Change
Salary and benefits-related	$ 5,055	$ 5,857	$ (802)
Other contract services and outside costs	2,984	2,756	228
Facility-related and other	500	589	(89)
Total general and administrative expenses	$ 8,539	$ 9,202	$ (663)

Salary and benefits-related costs decreased by $0.8 million due to lower stock based compensation and employee-related costs. Other contract services and outside costs increased by $0.2 million due to higher consulting and professional fees.

Other Income (Expense), Net

Other income (expense), net was $1.4 million for the six months ended June 30, 2022 and June 30, 2021. Other income (expense), net consists primarily of interest expense on a loan and security agreement in both periods presented.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have not generated any revenue and have incurred significant operating losses and negative cash flows from our operations. Our net losses were $21.3 million and $40.3 million for the three and six months ended June 30, 2022, respectively. Net losses for the same periods ended June 30, 2021 were $15.9 million and $31.1 million, respectively. As of June 30, 2022, we had an accumulated deficit of $377.6 million. We expect to incur net losses as we continue to develop our product candidates, and our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our current or future product candidates. Additionally, we are required to comply with an unrestricted minimum cash level in accordance with the New Loan and Security Agreement until certain clinical trial data conditions are met, and there is a risk that we may be unable to remain in compliance with those financial covenants in the future in which case the debt may become immediately due and payable.

To date, we have primarily financed our operations with proceeds from the sale of preferred and common stock and borrowing of debt, including the following significant transactions:

- On March 16, 2022, we entered into a Securities Purchase Agreement (the “Purchase Agreement”) with certain institutional purchasers and certain directors and officers of the Company named therein. Pursuant to the Purchase Agreement, we sold and issued an aggregate of 13,089,002 shares of common stock, at a purchase price of $1.91 per share in a registered direct offering for net proceeds of approximately $24.8 million after deducting estimated offering expenses payable by us.

- From time to time, we may offer and sell shares of our common stock having an aggregate offering price of up to $35.0 million through SVB Leerink LLC, acting as our agent (the "ATM Offering"). Cumulative through June 30, 2022, we have sold an aggregate of 3,285,308 shares of common stock under the ATM Offering for net cash proceeds of $14.7 million after deducting commissions and expenses of $0.9 million. During the six months ended June 30, 2022, we issued 232,600 shares of our common stock in a series of sales under the ATM Offering for aggregate net proceeds of $0.6 million after deducting nominal commissions and expenses.

As of June 30, 2022, we had cash, cash equivalents and marketable securities of $44.4 million. Our cash equivalents and marketable securities as of June 30, 2022 consisted of bank deposits, money market funds that invest in U.S. treasury securities, and corporate obligations, which enables us to achieve our liquidity and capital needs.

Cash Flows

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

	Six Months Ended June 30,	
	2022	**2021**
Cash used in operating activities	$ (35,529)	$ (28,367)
Cash provided by (used in) investing activities	20,772	(9,954)
Cash provided by financing activities	25,260	671
Net increase (decrease) in cash and cash equivalents	$ 10,503	$ (37,650)

Operating Activities

During the six months ended June 30, 2022, operating activities used $35.5 million of cash, primarily resulting from a net loss of $40.3 million, partially offset by non-cash charges of $2.7 million, including $2.1 million of stock-based compensation, and changes in our operating assets and liabilities of $2.2 million.

During the six months ended June 30, 2021, operating activities used $28.4 million of cash, primarily resulting from a net loss of $31.1 million and changes in our operating assets and liabilities of $1.2 million, both partially offset by non-cash charges of $4.0 million, including $3.1 million of stock-based compensation.

Investing Activities

During the six months ended June 30, 2022, net cash provided by investing activities includes proceeds from sales and maturities of marketable securities, partially offset by purchases of capital equipment.

During the six months ended June 30, 2021, net cash used in investing activities consisted of purchases of marketable securities and capital equipment, which were partially offset by proceeds from maturities of marketable securities.

Financing Activities

During the six months ended June 30, 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.

During the six months ended June 30, 2021, 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.

Loan and Security Agreement

On September 2, 2021, we entered into a loan and security agreement (the "New Loan and Security Agreement") with SLR Investment Corp., formerly known as Solar Capital Ltd., for term loans in an aggregate principal amount of $26.0 million. The New Loan and Security Agreement replaced the loan and security agreement between us and SLR Investment Corp., 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"). The term loans under the New Loan and Security Agreement will accrue interest at an annual rate equal to 8.60% plus the greater of (a) the thirty (30) day U.S. Dollar LIBOR rate and (b) 0.10%, payable monthly in arrears. The monthly principal payments of $0.6 million will be paid over a period of 45 months beginning in January 2023 through the final maturity date of September 1, 2026. Per the New Loan and Security Agreement, the date on which repayment of principal commences can be further extended to July 2023 and January 2024, provided we satisfy certain equity related conditions. The term loans are also subject to a prepayment fee of 3.00% if prepayment occurs within the first year subsequent to September 2, 2021, 2.00% in the second year and 1.00% in the third year through final maturity. The New Loan and Security Agreement also contains certain financial covenants, including an unrestricted minimum cash level until certain clinical trial study data conditions are met, and non-financial covenants. As security for our obligations under the New Loan and Security Agreement, we granted the lender a first priority perfected security interest in all of our existing and after-acquired assets, including intellectual property.

In conjunction with the execution of the New Loan and Security Agreement, we also agreed to a new terminal fee obligation totaling $1.7 million, which is due and payable on the earliest to occur of (i) the maturity of the New Loan and Security Agreement, (ii) the acceleration of the term loans, and (iii) the prepayment, refinancing, substitution or replacement of the term loans. The obligation is equal to 6.45% of the aggregate principal amount of $26.0 million.

Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance existing product candidates and develop new clinical and pre-clinical programs. Our cash requirements depend on numerous factors, including, without limitation, expenditures in connection with our research and development programs, including with respect to the timing and progress of Clinical Trials, Clinical Studies and preclinical development activities; payments to CROs, CMOs and other third-party providers; the cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights; our ability to raise additional equity or debt financing; potential repayments of our long-term debt; and our ability to enter into collaboration or license agreements and our receipt of any upfront, milestone or other payments thereunder. Changes in our research and development plans or other changes affecting our operating expenses may result in changes in the timing and amount of expenditures of our capital resources. Further, inflation may affect our use of capital resources by increasing our cost of labor and clinical trial expenses. See “Risk Factors” for further discussion of these and additional risks and uncertainties that may significantly affect the timing and amount of expenditures of our capital resources.

We are required to comply with an unrestricted minimum cash level of $20.0 million in accordance with our loan and security agreement with SLR Investment Corp. until certain clinical trial data conditions are met, and there is a risk that we may be unable to remain in compliance with those financial covenants in the future in which case the debt may become immediately due and payable. Based on our current operating plan, we believe that we have sufficient cash, cash equivalents and marketable securities to fund our operations into the first quarter of 2023, provided that, if we are unable to satisfy the financial covenants contained in our loan and security agreement with SLR Investment Corp., and SLR Investment Corp. seeks immediate repayment of our loan in full, we believe that our cash, cash equivalents and marketable securities will be sufficient to fund our operations into the fourth quarter of 2022. We do not have sufficient cash, cash equivalents, and marketable securities to support current operations through a full 12 months from the issuance date of this Quarterly Report on Form 10-Q. We will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of equity offerings, debt re-financings, collaboration agreements, strategic alliances and licensing arrangements. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all, including as a result of market volatility following the COVID-19 pandemic. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions. Further, inflation may affect our use of capital resources by increasing our cost of labor and clinical trial expenses. We also intend to continue to evaluate options to refinance our outstanding long-term debt. The amounts involved in any such transactions, individually or in the aggregate, may be material. These factors individually and collectively raise substantial doubt about our ability to continue as a going concern.

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. On January 1, 2022, we adopted ASU 2016-02, *Leases (Topic 842)* and the related accounting policies. Other than the adoption of the lease standard, 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, 2021, which was filed with the SEC on March 30, 2022.

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 $1.07 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 and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of June 30, 2022. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of June 30, 2022 were effective at a reasonable assurance level in ensuring that information required to be disclosed by us in reports that we file or submit under the Exchange Act (i) is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms; and (ii) accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely discussions regarding required disclosure. We believe that a control system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the control system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

Changes in Internal Control over Financial Reporting

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 June 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, do not expect that our disclosure controls or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

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

Careful consideration should be given to the following risk factors, in addition to the other information set forth in this Quarterly Report and in other documents that we file with the SEC, in evaluating the Company and our business. Investing in our common stock involves a high degree of risk. If any of the following risks and uncertainties actually occur, our business, prospects, financial condition and results of operations could be materially and adversely affected. The risks described below are not intended to be exhaustive and are not the only risks that we face. New risk factors can emerge from time to time, and it is not possible to predict the impact that any factor or combination of factors may have on our business, prospects, financial condition and results of operations.

Risks Related to Our Financial Position and Capital Needs

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 are a biotechnology company with a limited operating history. Investment in product development in the healthcare industry, including of biotechnology products, is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate an adequate effect or an acceptable safety profile, gain regulatory approval and/or become commercially viable. At this time, we are pursuing development of AXA1125 in a Clinical Trial under an IND for the treatment of NASH. Additionally, we initiated a Clinical Trial of AXA1125 for the treatment of Long COVID under a CTA in December 2021, in which we completed enrollment of patients in May 2022. We have no products approved for commercial sale, have not generated any revenue from product sales to date and continue to incur significant research and development and other 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. Our net loss was $40.3 million for the six months ended June 30, 2022 and $31.1 million for the six months ended June 30, 2021. As of June 30, 2022, we had an accumulated deficit of $377.6 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of our product candidates in Clinical Studies, Clinical Trials for any product candidate we elect to develop as a drug product candidate under an IND or non-U.S. equivalent and as we seek regulatory approvals, as necessary, for and commercialize our product candidates, if approved. In addition, inflationary pressure could adversely impact our financial results. We anticipate that our expenses will increase substantially if, and as, we:

- conduct preclinical studies, Clinical Studies, and for those product candidates that we elect to develop as therapeutics, Clinical Trials or their equivalent in non-U.S. jurisdictions;
- incur setbacks or delays to the initiation or completion of preclinical studies, product development, Clinical Studies and/or Clinical Trials due to the COVID-19 pandemic;
- further develop our proprietary human-focused product development platform;
- continue to develop our current product candidates as well as additional product candidates;
- maintain, expand and protect our intellectual property portfolio;
- hire or contract additional clinical, scientific, manufacturing, quality and commercial personnel to support our product research, development and commercialization efforts;

- continue to develop, scale and validate a manufacturing process and specifications for our product candidates, including under requirements for drug development;
- incur any disruption or delays to the supply of our product candidates due to the COVID-19 pandemic;
- continue to establish in-house manufacturing capabilities for our research and product development efforts;
- establish a commercial manufacturing source and secure supply chain capacity sufficient to provide preclinical study material, Clinical Study material, Clinical Trial material for any product candidate we elect to develop as a drug product candidate under an IND or non-U.S. equivalent, and commercial quantities of any product candidates that we may commercialize as drug or non-drug products, following receipt of any necessary approvals or authorizations;
- acquire or in-license other product candidates and technologies;
- seek various non-drug product marketing pathways and, if applicable, drug regulatory authorizations;
- establish a sales, marketing and distribution infrastructure to commercialize any product candidates for which we may obtain regulatory approval or identify an alternate regulatory pathway to market; and
- add operational, compliance, financial and management information systems and personnel to support our operations as a public company.

To become and remain profitable, we or any potential future collaborator must develop and eventually commercialize products with significant market potential at an adequate profit margin after cost of goods sold and other expenses. This will require us to be successful in a range of challenging activities, including, but not limited to: completing preclinical studies, Clinical Studies and Clinical Trials for any product candidate we elect to develop as a drug product candidate under an IND or non-U.S. equivalent; obtaining marketing approval or identifying alternate regulatory pathways for product candidates; manufacturing, marketing and selling products for which we may obtain marketing approval; or successfully satisfying any pre- or post-marketing requirements. We may never succeed in any or all of these activities and, even if we do, we may never generate revenue that is significant enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company, which could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company also could cause you to lose all or part of your investment. Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business, which may be significant. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

Substantial doubt exists as to our ability to continue as a going concern.

As of June 30, 2022, we had cash, cash equivalents and marketable securities of $44.4 million, and an accumulated deficit of $377.6 million. We believe that we will require additional working capital to fund our planned operations through a full 12 months from the issuance date of this Quarterly Report on Form 10-Q. In March 2022, we sold common stock through a registered direct offering for net proceeds of approximately $24.8 million after deducting estimated offering expenses payable by us. Additional funding will be necessary beyond this point to continue to fund our research and development activities. We are required to comply with an unrestricted minimum cash level in accordance with our loan and security agreement with SLR Investment Corp. until certain clinical trial data conditions are met, and there is a risk that we may be unable to remain in compliance with those financial covenants in the future in which case the debt may become immediately due and payable. Our plans to alleviate our financing requirements include, among other things, pursuing the sale of our common stock and funding through the establishment of a collaboration(s) with a potential partner(s) to further advance our product pipeline, none of which can be guaranteed or are entirely within our control. If we are unable to alleviate our financing requirements via these means, we could be forced to discontinue some of our operations or develop and implement a plan to further extend payables, reduce overhead or scale back our current operating plan until sufficient additional capital is raised to support further operations. These factors individually and collectively raise substantial doubt about our ability to continue as a going concern, and; therefore, it may be more difficult for us to attract investors. Unless we are able to raise additional capital to finance our operations, our long-term business plan may not be accomplished, and we may be forced to cease, reduce, or delay operations.

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.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts for our current and future programs: to conduct further research and development, preclinical studies, Clinical Studies and/or Clinical Trials for any product candidates we elect to develop as a drug product candidate under an IND or non-U.S. equivalent; to validate the manufacturing process and specifications for our product candidates; to seek regulatory approvals for or identify alternate regulatory pathways to market for our product candidates; and to launch and commercialize any products for which we receive regulatory approval or identify an alternate regulatory pathway to market, including potentially building our own commercial organization. As of June 30, 2022, we had $44.4 million of cash, cash equivalents and marketable securities. Based on our current operating plan, we believe that our existing cash, cash equivalents and marketable securities balance is not sufficient to fund our operating expenses, capital expenditure requirements and loan and security agreement obligations through at least the next 12 months following the filing date of this Quarterly Report on Form 10-Q. Our future capital requirements and the period for which our existing resources will support our operations may vary significantly from our expectations, and we will in any event require additional capital in order to complete clinical development of any of our current product candidates. Our monthly spending levels will vary based on new and ongoing development and corporate activities. Because the length of time and activities associated with development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and commercialization activities. Our future funding requirements, both near- and long-term, will depend on many factors, including, but not limited to:

- our decisions regarding the development path under which we will develop our product candidates (e.g., either continuing to develop a product candidate as a non-drug product, or initiating development as drug product candidate under an IND or non-U.S. equivalent);
- the initiation, progress, timing, costs and results of preclinical studies, Clinical Studies, Clinical Trials, and any need to conduct additional studies as may be required by a regulatory authority, including additional studies that may be required by a regulatory authority in order to allow the initiation of Clinical Trials under an IND or the non-U.S. equivalent for any of our product candidates;
- any clinical development plans we establish for these product candidates;

- any setbacks or delays to the initiation or completion of preclinical studies, Clinical Studies and/or Clinical Trials due to the COVID-19 pandemic;
- further development of our development platform and supporting infrastructure;
- the number and characteristics of product candidates that we develop or may in-license;
- the terms of any partnership or collaboration agreements we may choose to initiate or conclude;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA, any other regulatory authorities in the United States, and, when applicable, comparable foreign regulatory authorities, such as the EMA;
- the effect of changes in regulations or policy relating to the development and commercialization of our product candidates by the FDA, any other regulatory authorities in the United States and, when applicable, other comparable foreign regulatory authorities, such as the EMA;
- the cost of establishing, maintaining and overseeing a system to ensure our ongoing and planned Clinical Trials are compliant with Good Clinical Practice, or GCP;
- the costs of establishing, maintaining and overseeing a quality system compliant with current Good Manufacturing Practice, or cGMP, and other quality standards applicable to non-drug and drug product development and a supply chain for the development and manufacture of our product candidates;
- any disruption or delays to the supply of our product candidates due to the COVID-19 pandemic;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us related to our product candidates or our development platform, or other technologies;
- the effect of competing technological and market developments;
- the cost and timing of establishing, expanding and scaling compliance programs related to our activities and product candidate development and commercialization and related legal activities, including defense of any potential litigation against us;
- the cost and timing of establishing, expanding and scaling of manufacturing capabilities, or contracting with third parties for access to such capabilities; and
- the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval or identify alternate regulatory pathways in regions where we choose to commercialize our products.

We do not have any committed external source of funds or other support for our development efforts and we cannot be certain that additional funding will be available on acceptable terms, or at all. Until we can generate sufficient product revenue or, if we were to enter into third-party agreements, sufficient royalty revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. Further, to the extent that we raise additional capital through the sale of common stock or securities convertible into or exchangeable for common stock, your ownership interest will be diluted. If we raise additional capital through debt financing, we would be subject to fixed payment obligations and may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends or acquiring or licensing intellectual property rights. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. We also could be required to seek collaborators for one or more of our current or future product candidates at an earlier stage than otherwise would be desirable or relinquish our rights to product candidates or technologies that we otherwise would seek to develop or commercialize ourselves. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may be forced to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates or one or more of our other research and development initiatives, significantly reduce our operating expenses, including by reductions in staff, complete a strategic transaction, and/or limit or cease and wind-down operations. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline, causing you to lose all or part of your investment.

Clinical development is a lengthy and expensive process, with a highly 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.

To obtain the requisite regulatory approvals to commercialize any of our product candidates that we decide to develop as a drug product candidate, such as AXA1125, we must demonstrate through extensive preclinical studies and Clinical Trials that our product candidates are safe and effective in humans for their intended use. Clinical Studies to commercialize non-drug products also require a significant financial investment to generate data that supports claims about effects on normal structure and function of the body we may make for such products and establish their safety and tolerability. Clinical testing is expensive, difficult to design and implement and can take many years to complete, and its outcome is inherently uncertain. We may be unable to establish, where applicable, endpoints, dose levels and regimens or bioanalytical assay methods that applicable regulatory authorities would consider clinically meaningful or legally permissible. Results from preclinical studies, Clinical Studies, or Clinical Trials may demonstrate that our product candidates are not safe, not tolerable or have unanticipated impacts on the normal structure and function of the body and could result in data showing one or more product candidates to have harmful or problematic side effects or toxicities. 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. A Clinical Study or Clinical Trial can fail at any stage of testing. Additionally, our Clinical Studies, Clinical Trials or other preclinical studies may not result in data that supports intended claims for our product candidates. For example, Clinical Trial results may show any drug product candidate to be less effective than expected (e.g., a Clinical Trial could fail to meet its primary endpoint(s)) or have unacceptable side effects or toxicities. The outcome of preclinical studies, Clinical Studies and early Clinical Trials may not be predictive of the success of later preclinical studies, Clinical Studies and/or Clinical Trials, and interim results of these studies or trials do not necessarily predict final results. Interim and preliminary data are subject to the risk that one or more of the outcomes may materially change as subject enrollment continues, more subject data become available and as the study is completed. Preliminary or top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Material inconsistencies between preliminary or interim data and final data could significantly harm our business prospects. Further, differences in trial design between Clinical Studies and early-stage Clinical Trials and later-stage Clinical Trials make it difficult to extrapolate from the results of Clinical Studies and earlier Clinical Trials to the results from later Clinical Trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and Clinical Trials have nonetheless failed to obtain marketing approval of their product candidates, or have data that supports desirable marketing claims even where marketing approval is not required. Successful completion of Clinical Trials is a prerequisite to submitting a new drug application, or NDA, to the FDA, or its equivalent in other jurisdictions such as a marketing authorization application to the EMA, for each product candidate targeting therapeutic indication(s) and, consequently, a pre-requisite for the ultimate approval and commercial marketing of any product candidate for therapeutic indication(s).

We do not know whether we will be able to initiate or complete Clinical Trials for product candidates we decide to develop as drug product candidates on schedule, if at all. Additionally, we may determine as a result of factors in or out of control to terminate plans or efforts in connection with Clinical Studies or Clinical Trials. If we do not have sufficient funds to finance our Clinical Studies or Clinical Trials or the FDA or equivalent regulatory authority has requirements we are not able to comply with, or that we decide to not comply with, we may need to delay or cancel one or more of our Clinical Studies or Clinical Trials. For instance, in May 2022, we announced the termination of our Clinical Trial of AXA1665 for the reduction in risk of recurrent OHE, which is a rare disease of very ill patients with enrollment challenges and long timelines for approval, to focus our resources on our ongoing Long COVID and NASH programs.

We may experience delays in completing our preclinical studies and initiating or completing Clinical Studies and, for those product candidates that we decide to develop as drug product candidates, including AXA1125, Clinical Trials. We also may experience numerous unforeseen events during, or as a result of, any future Clinical Studies or Clinical Trials that we may conduct that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including, but not limited to:

- unforeseen events or events over which we have little to no control, such as the COVID-19 pandemic, can cause execution delays for our Clinical Studies or Clinical Trials;
- issues related to the quality, completeness and interpretability of our data that could result in significant delays or additional costs and impact development plans for our product candidates;
- we may be unable to generate sufficient preclinical, toxicology or other in vivo or in vitro data to support the initiation of Clinical Trials for therapeutic indications for any drug product candidates or the marketing of our products as non-drug products;
- results from one Clinical Study or Clinical Trial, particularly observation of a serious adverse event, may impact the other Clinical Study or Clinical Studies or Clinical Trial or Clinical Trials of the same product candidate;
- the FDA may not allow us to use data from our Clinical Studies to support a late-phase IND Clinical Trial or an IND Clinical Trial of any phase for a product candidate we decide to develop as a drug product candidate instead of a non-drug product candidate;
- the FDA or other regulatory authorities may disagree with the design, implementation or results of our Clinical Studies or Clinical Trials, which may delay or prevent us from pursuing certain regulatory pathways for product developments, or require us to submit additional data such as long-term toxicology studies or impose other requirements before permitting us to initiate or complete a Clinical Trial of any phase. For example, the FDA could require that we terminate a Clinical Study for a product candidate and continue such study only under an IND, and we may not be able to obtain such an IND, or we may be subject to an enforcement action for conducting a Clinical Study not under an IND;
- regulatory authorities, IRBs or ethics committees may not authorize us or our investigators to commence or conduct a Clinical Study or Clinical Trial at a prospective study or trial site or may request early termination of a Clinical Study or Clinical Trial;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective study or trial sites and prospective contract research organizations, or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and study or trial sites;
- preclinical studies, Clinical Studies or Clinical Trials of any of our product candidates may produce negative or inconclusive results and we may need to conduct additional preclinical studies, Clinical Studies, Clinical Trials or any other studies, or we may decide to abandon product development programs;
- the number of subjects or patients required for Clinical Studies or Clinical Trials of any of our product candidates may be larger than we anticipate, or we may fail to execute the Clinical Studies or Clinical Trials as a result of slow enrollment, subjects dropping out of the Clinical Studies or Clinical Trials or other factors, including some which are out of our control, such as COVID-19, length of time to achieve clinical endpoints, additional time requirements for data analysis, or an inability to validate the manufacturing process or to achieve cGMP compliance for our product candidates;

- we may need to add new or additional Clinical Study or Clinical Trial sites for various reasons, for example, our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the Clinical Study or Clinical Trial protocol or stop providing services for the study or trial, which may require that we add new clinical study or trial sites or investigators;
- the cost of preclinical studies, Clinical Studies, Clinical Trials or any other studies of any product candidates may be more than we anticipate or more than our available financial resources; and
- the supply or quality of our product candidates or other materials necessary to conduct Clinical Studies and Clinical Trials, for which we expect to continue to rely on third party manufacturers and suppliers, may be insufficient or inadequate and may not achieve compliance with applicable cGMP and other quality standards applicable to drug or non-drug product development for various reasons including any potential failure of our oversight of their services or any potential inability of such third parties to successfully execute services in compliance with applicable rules and regulations.

We could also encounter delays if a preclinical study, Clinical Study or Clinical Trial is suspended or terminated for any reason. A suspension or termination may be imposed due to a number of factors, including failure to conduct the Clinical Study or Clinical Trial in accordance with regulatory requirements or our clinical protocols, inspection of the Clinical Study or Clinical Trial operations or trial site by the FDA, comparable foreign regulatory authorities or IRB resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, including death of a study subject, failure to demonstrate a benefit from using a product or treatment, failure to establish or achieve clinically meaningful or legally permissible endpoints, changes in governmental regulations or administrative actions or lack of adequate funding to continue the Clinical Study or Clinical Trial. Many of the factors that cause, or lead to, a delay in the commencement or completion of Clinical Studies or Clinical Trials may also ultimately lead to the denial of regulatory approval of our product candidates for therapeutic indications, where applicable, or the failure to meet applicable regulatory requirements to support and commercialize non-drug products. Further, the FDA or comparable foreign regulatory authorities may change the requirements for regulatory approval of a drug even after they have reviewed and commented on the design for our preclinical studies, Clinical Studies or Clinical Trials.

Our product development costs will increase, or our operations may be hindered or prevented if we experience delays in clinical testing and marketing approvals, if applicable, or otherwise meeting regulatory requirements to commercialize our product candidates, including, but not limited to, delays in NDA preparation, the need to submit a New Dietary Ingredient, or NDI, notification or other filings with the FDA, discussions with the FDA and comparable foreign regulatory authorities in jurisdictions we target or pursue, responding to an FDA request or other regulatory authority for additional preclinical or clinical data or unexpected safety or manufacturing issues. We do not know whether any of our preclinical studies, Clinical Studies or Clinical Trials, if applicable, will begin or be completed as planned, will need to be restructured or will be completed on schedule, or at all. Significant delays in our preclinical studies, Clinical Studies or Clinical Trial also could shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations. Any delays in our preclinical or future clinical development programs may harm our business, financial condition and prospects significantly, and could impair our ability to fund our operations or obtain financing on acceptable terms, or at all.

Risks Related to Our Business, Technology and Industry

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.

The development of EMM compositions with defined ratios and formulations, and the potential drug and non-drug applications of these product candidates represents a novel approach. Our product candidates in general may not be successfully developed or commercialized or gain the acceptance of the public or the medical community. For any product candidate that we choose to develop as a drug product candidate, our success will depend upon physicians who specialize in the treatment of diseases targeted by our product candidates, prescribing potential treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments with which they are more familiar and for which greater clinical data may be available. For any product candidate that we choose to develop as a non-drug product candidate, our success will depend on finding partners in a non-drug market who can help successfully commercialize product candidates as non-drug product candidates, such as dietary supplements and medical foods. In addition, our success will also depend on consumer acceptance and adoption of our products that we, or a future partner, commercialize, if any. Adverse events, which may include death, in Clinical Studies and Clinical Trials of our product candidates or in studies or Clinical Trials of other parties developing similar products and the resulting publicity, as well as any other adverse events in the field of EMMs and metabolic pathways, could result in a decrease in demand for any product that we may develop. In addition, responses by the U.S. federal, state or foreign governments to negative public perception or ethical concerns may result in new legislation or regulations that could limit our ability to develop or commercialize any product candidates, obtain or maintain regulatory approval, if applicable, identify alternate regulatory pathways to market or otherwise achieve profitability. More restrictive statutory regimes, government regulations or negative public opinion would have an adverse effect on our business, financial condition, results of operations and prospects, and may delay or impair the development and commercialization of our product candidates or demand for any products we may commercialize.

We face significant competition from other healthcare companies, and our operating results will suffer if we fail to compete effectively.

The healthcare industry is characterized by intense competition and rapid innovation. Our competitors may be able to develop other drug or non-drug products that are able to achieve similar or better results. Our potential competitors include major multinational pharmaceutical, established biotechnology companies, specialty pharmaceutical companies and universities, nutritional foods companies, and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff, experienced marketing and manufacturing organizations and well-established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel drugs or to in-license novel drugs that could make any product candidate that we develop as a drug product candidate obsolete. Mergers and acquisitions in the healthcare industry may result in even more resources being concentrated amongst our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on exclusive non-drug products that are safer, more easily commercialized or less costly than our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products.

We believe the key competitive factors that will affect the development and commercial success of our product candidates are efficacy, safety, tolerability, reliability, convenience of use, price and reimbursement, if applicable depending on the development path we choose. We also anticipate that we will face increased competition in the future as additional companies enter our market and scientific developments surrounding other non-drug products and drugs targeted at metabolic pathways continue to accelerate.

In addition, there are additional companies that are working on modulating specific metabolic pathways involved in various health and disease conditions. Although we are not aware of any company creating products targeting metabolic multifactorial activity for the same indications and targets as us, Entrinsic Biosciences, Inc. is developing amino acid combinations to treat gastrointestinal disorders and other conditions associated with dysfunctional transport membrane proteins. Companies with clinical programs that could compete with our current pipeline of product candidates include 89bio, Inc., Ageless Rx, AIM ImmunoTech, Akero Therapeutics, Inc., Bausch Health, Bristol-Myers Squibb Co., Esperion Therapeutics, Inc., Genfit SA, Gilead Sciences, Inc., Intercept Pharmaceuticals, Inc., Kaleido Biosciences, Inc., Madrigal Pharmaceuticals, Inc., Mallinckrodt plc, Novartis AG, OrganiCell, Resolve Therapeutics, Scholar Rock Holding Corporation, and Viking Therapeutics, Inc., among others.

Even if we obtain regulatory approval to market our product candidates as drugs or are successful in identifying alternate regulatory pathways to market our product candidates under regulations that would apply to non-drug products, the availability and price of our competitors' products could limit the demand and the price we are able to charge for our product candidates. We may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of consumers to accept of our product candidates and choose them over other competitive products on the market or, for product candidates we develop as drugs, of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances.

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.

Our ability to compete in the highly competitive biotechnology industry depends upon our ability to attract and retain highly qualified managerial, scientific, medical and other personnel. We are highly dependent on our management, scientific and medical personnel. The loss of the services of any of our executive officers, other key employees and other scientific and medical advisors, and our inability to find suitable replacements could result in delays in product development and harm our business. We conduct our operations in Massachusetts. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice.

Employment of our key employees is at-will, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain "key man" insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel.

COVID-19 may materially and adversely affect our business and our financial results.

The COVID-19 pandemic has resulted in significant governmental measures being implemented to control the spread of the virus, including quarantines, travel restrictions, supply chain disruptions, business shutdowns and clinical site closures to non-essential care and clinical trials. For example, our AXA1957-002 Clinical Study was temporarily suspended in March 2020 due to COVID-19's impact on our Clinical Study sites. Subsequently, based on positive data in our AXA1125-003 Clinical Study announced on May 6, 2020, we decided against reinitiating our AXA1957-002 Clinical Study and to move forward with AXA1125 as our NASH product candidate for both adult and pediatric patients. Although we cannot presently predict the full scope and severity of COVID-19, these developments and measures could materially and adversely affect our business, our results of operation and financial condition. Furthermore, the COVID-19 pandemic may adversely impact our ability to complete our ongoing and planned Clinical Trials of AXA1125 in a timely manner or at all due to patient or principal investigator recruitment or availability challenges, Clinical Trial site shutdowns or other interruptions. Additionally, we may also experience potential limitations on the quality, completeness and interpretability of data we are able to collect. For instance, on May 7, 2020, a subject death was reported as a result of COVID-19 by one of our principal investigators in our AXA1665-002 Clinical Study. This serious adverse event and any others that may result from COVID-19 may impact the quality, completeness and interpretability of the data that we were able to collect. The supply chain disruptions that resulted from COVID-19-related manufacturing shutdowns, global transportation changes, and loss of workers in key industries could affect access to raw materials and operations for manufacturing our product candidates, and distribution of product candidates to clinical sites or for commercialization. In addition, as a result of the COVID-19 pandemic, we or our key third-party service providers may be not able to complete key program and product development milestones on time or at all; quarantines, shelter-in-place and similar government orders may impact personnel at third-party manufacturing facilities that negatively impact the availability or cost of materials used in our product candidates; market volatility and conditions may limit our ability to raise additional capital to finance our business plans on attractive terms or at all; our business continuity plans may not be effective at limiting operational disruptions or delays; we may suffer negative impacts to operations that may be vulnerable as a result of government or company measures taken to control the spread of COVID-19; potential shutdowns of government agencies such as the SEC or FDA may limit our ability to raise capital and negatively impact our product development timelines; the passage of new legislation may increase our operating costs or limit our operations, such as the Families First Coronavirus Response Act; we may suffer negative consequences due to vulnerabilities that emerge as a result of our limited operations, such as a cybersecurity incident; or one of our key executives, scientists or other personnel may become incapacitated by COVID-19.

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 operation and financial condition.

We have a limited operating history, which may make it difficult to evaluate our technology and product development capabilities and predict our future performance.

As an organization, we have not yet completed any Clinical Trials. We completed our AXA1125-003 Clinical Study in 2020 and initiated a Phase 2b Clinical Trial of AXA1125 in the second quarter of 2021, in which we are enrolling patients with NASH. We also initiated a Phase 2a Clinical Trial of AXA1125 for the treatment of Long COVID in December 2021, in which we completed enrollment of patients in May 2022.

We were formed in 2008, have no products approved for commercial sale as drugs or marketed via other regulatory pathways (e.g., non-drug products such as dietary supplements) and have not generated any revenue from product sales. Our ability to generate product revenue or profits, which we do not expect will occur for many years, if ever, will depend on the successful development and eventual commercialization of our product candidates, which may never occur.

Our limited operating history may make it difficult to evaluate our technology and industry and predict our future performance. Specifically, to date, we have conducted Clinical Studies for our product candidates to evaluate safety and tolerability and impact on normal structure and function only in healthy subjects or subjects with certain disease conditions. For product candidates we develop under an IND or non-U.S. equivalent with patient populations reflecting the desired indication for such product candidate, the physiological structure and function data we observed in our Clinical Studies for such product candidate may not be replicated in or be consistent with results from Clinical Trials and such product candidate may not meet therapeutic efficacy endpoints in Clinical Trials. For instance, while we previously announced positive top-line data in our AXA1125-003 Clinical Study, including reductions in liver fat content and markers of fibroinflammation, such results may not be replicated in Clinical Trials.

Our short history as an operating company makes any assessment of our future success or viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by early-stage companies in evolving fields. If we do not address these or other risks successfully, our business will suffer. Similarly, we expect that our financial condition, expenditures and operating results will fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. As a result, our stockholders should not rely upon the results of any quarterly or annual period as an indicator of future operating performance.

In addition, as an early-stage company, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown circumstances, which may be significant. Given the initiation of our Clinical Trials for AXA1125 for the treatment of NASH and for the treatment of Long COVID, we will need to transition from a company that has undertaken relatively small, early-stage Clinical Studies to a company capable of completing larger scale, global, late-stage Clinical Trials and, if successful, commercial activities. We may not be successful in such transitions.

Our planned, ongoing, and future Clinical Studies and Clinical Trials, or those of our future collaborators may reveal significant adverse events not seen in our preclinical studies, Clinical Studies or other Clinical Trials and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates.

Before obtaining regulatory approvals for the commercial sale of any products for therapeutic indications, we must demonstrate through lengthy, complex and expensive preclinical studies, Clinical Studies and Clinical Trials that our product candidates are both safe and effective for use in each target indication. Any non-drug products must also be demonstrated to be safe and tolerable. Our product candidates have been generally well tolerated in our Clinical Studies to date, but we cannot be certain that we will be able to dose subjects or patients at a high enough dose in any future Clinical Trials of product candidates we may develop as drugs so as to demonstrate efficacy without unacceptable safety risk.

Product candidates in later stages of Clinical Studies may fail to show the desired safety profile despite having progressed through successful preclinical studies and earlier Clinical Studies. Product candidates that we decide to develop as drug product candidates and that progress to Clinical Trials may fail to show the desired safety and efficacy profile despite having progressed successfully through preclinical studies, Clinical Studies and, if applicable, initial Clinical Trials. A number of companies in the healthcare industry have suffered significant setbacks in later development, notwithstanding promising results in earlier trials. Most product candidates that commence Clinical Trials are never approved as products for therapeutic indications, and there can be no assurance that any of our current or future Clinical Studies or Clinical Trials will ultimately be successful or support further clinical development of any of our product candidates.

If significant adverse events, which may include death, or other side effects are observed in any of our current or future Clinical Studies or Clinical Trials, we may have difficulty recruiting subjects or patients for our Clinical Studies or Clinical Trials, subjects or patients may drop out of our Clinical Studies or Clinical Trials or we may be required to significantly redesign or abandon Clinical Studies or Clinical Trials or our development efforts of one or more product candidates altogether. We, the FDA or other applicable regulatory authorities or an IRB may suspend Clinical Studies or Clinical Trials of a product candidate at any time for various reasons, including a belief that subjects or patients in such Clinical Studies or Clinical Trials are being exposed to unacceptable health risks or adverse side effects or FDA or other applicable regulatory authorities could determine that our Clinical Studies need to be stopped and any further research for a product candidate needs to be conducted under a Clinical Trial instead. Some potential non-drug products and drug product candidates that initially showed promise for further development in early-stage testing, including in Clinical Studies or Clinical Trials, have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude a product candidate from obtaining or maintaining marketing approval, if applicable, or being commercialized, undesirable side effects may inhibit market acceptance of the commercialized product due to its tolerability versus other non-drug products or drugs. Any of these developments could materially harm our business, financial condition and prospects.

If we encounter difficulties enrolling subjects or patients in our Clinical Studies or Clinical Trials, our development activities could be delayed or otherwise adversely affected.

We may experience difficulties in subject and patient enrollment in our Clinical Studies and Clinical Trials for a variety of reasons. The timely completion of Clinical Studies or Clinical Trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of subjects or patients who remain in the Clinical Study or Clinical Trial until its conclusion. The enrollment of subjects or patients depends on many factors, including, but not limited to:

- the severity of the disease or condition under investigation in the case of a Clinical Trial conducted under an IND or non-U.S. equivalent for a drug product candidate;
- the subject or patient eligibility and exclusion criteria defined in the protocol;
- the size of the study subject or patient population required for analysis of the primary endpoint(s) of the Clinical Study or Clinical Trial;
- the proximity of subjects or patients to study and trial sites;
- the design of the Clinical Study or Clinical Trial;
- our ability to recruit investigators with the appropriate competencies and experience;
- clinicians', subjects' or patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available drugs or non-drug products, as applicable;
- the efforts to facilitate timely enrollment in Clinical Studies or Clinical Trials;
- the subject or patient referral practices of physicians;
- the ability to monitor subjects or patients adequately during and after study product administration;
- our ability to obtain and maintain subject and patient consents;
- factors we may not be able to control, such as potential pandemics that may limit subject, principal investigator or staff and clinical site availability (e.g. the COVID-19 pandemic); and
- the risk that subjects or patients enrolled in Clinical Studies or Clinical Trials will drop out of the Clinical Studies or Clinical Trials before completion.

In addition, our Clinical Studies and Clinical Trials will compete with other clinical studies or trials for product candidates that are in the same target markets as our product candidates, and this competition will reduce the number and types of subjects or patients available to us, because some individuals who might have opted to enroll in our Clinical Studies or Clinical Trials may instead opt to enroll in a study or trial being conducted by one of our competitors. Because the number of qualified clinical investigators is limited, we expect to conduct some of our Clinical Studies or Clinical Trials at the same sites that some of our competitors use, which will reduce the number of subjects or patients who are available for our Clinical Studies and Clinical Trials in such sites. Moreover, because our product candidates represent a departure from more commonly used methods in the non-drug and drug areas we may pursue, potential subjects or patients and their doctors may be inclined to use conventional products or therapies, rather than enroll subjects or patients in any future clinical study or trial.

Delays in subject or patient enrollment, or Clinical Study or Clinical Trial delays may result in increased costs or may affect the timing or outcome of our planned and ongoing Clinical Studies or Clinical Trials, which could prevent their completion or otherwise may negatively impact the quality, completeness and interpretability of data that we are able to collect and adversely affect our ability to advance the development of our product candidates.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our research and development activities may involve the use of biological and hazardous materials and may produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes.

We cannot eliminate the risk of contamination or injury from these materials, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may negatively impact our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of biological waste or hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological waste or hazardous waste insurance coverage, workers compensation or property and casualty and general liability insurance policies that include coverage for damages and fines arising from biological or hazardous waste exposure or contamination.

If product liability claims or lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of testing our product candidates in Clinical Studies and Clinical Trials and will face an even greater risk if we commercialize any products. For example, we may be sued, or claims may be made against us, if our informed consents for subjects or patients in any Clinical Studies or Clinical Trials are or are alleged to be inadequate or inaccurate in any way or fail to fully inform subjects or patients of any potential risks involved with their participation or other material or required information. We may also be sued, or claims may be made against us, if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during Clinical Studies, Clinical Trials, manufacturing, marketing or after sale. Any such product liability claims may include, without limitation, allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, marketing or promotional claims or a breach of warranties. Claims could also be asserted under state consumer protection or other statutes or regulations. If we cannot successfully defend ourselves against product liability claims or any other claims related to our products, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims could have a material adverse effect on our business and operations, and may result in, among other things:

- inability to bring a product candidate to the market;
- decreased demand for and decline in the price charged for our products;
- damage to our reputation;
- withdrawal of Clinical Study or Clinical Trial subjects or patients and inability to enroll future subjects or patients or continue Clinical Studies or Clinical Trials;
- initiation of investigations by regulatory authorities or other regulatory action;
- costs to defend the related litigation;
- diversion of management's time and our resources;
- substantial monetary awards to subjects or patients;
- product recalls, withdrawals or labeling, packaging, marketing or promotional modifications or restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidates via any regulatory pathway; and
- decline in our share price.

We maintain clinical trial insurance. We review our clinical trial insurance policy annually and we believe that our coverage is currently adequate to cover any claims that may arise in connection with our Clinical Studies or Clinical Trials. There is no guarantee that we will be able to obtain additional clinical trial insurance at an acceptable cost in the future, which could prevent or inhibit the ongoing development of our products.

Since we have not yet commenced marketing of any products, we do not yet hold product liability insurance for commercialization of our products. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with collaborators. If and when coverage is secured, our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no or inadequate coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

The market opportunities for our product candidates may be limited and our estimates of the incidence and prevalence of our target populations may be inaccurate.

Our projections of both the non-drug and drug market sizes we may target, and the incidence and prevalence of our target populations are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, input from key opinion leaders, patient foundations or secondary market research databases, and other sources and may prove to be incorrect. Further, new studies may change the estimated market sizes or the incidence or prevalence of target diseases we may target with potential drug product candidates. For those product candidates we develop under an IND or non-U.S. equivalent, regulatory approvals may include limitations for use or contraindications that decrease the addressable patient population. The number of subject individuals may turn out to be lower than expected. Additionally, the potentially addressable patient population for our drug product candidates may be limited or may not be amenable to treatment with such product candidates. For instance, we estimate that up to 40 million people in the U.S. alone are living with NASH. Even if we obtain significant market share for our product candidates, because certain potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications for drugs or expanding the target market size for non-drug products.

We are early in our development efforts and may not be successful in our efforts to use our development platform to build a successful pipeline of product candidates and develop marketable products.

We are developing our product candidates with our development platform to reprogram metabolism and maintain and restore metabolic health and have decided to pursue development of some of our product candidates as potential therapeutics under INDs or non-U.S. equivalents. However, our development platform has not yet led, and may never lead, to marketable drug or non-drug products. We are developing our initial product candidates for liver conditions and Long COVID. We may have problems applying our technologies to these and other future target areas, and our product candidates may not demonstrate a comparable ability in supporting or maintaining health or treating disease, where applicable. Even if we are successful in identifying additional product candidates, they may not be suitable for clinical development as a result of limited efficacy, unacceptable safety profiles or other characteristics that indicate that they are unlikely to be products that will receive marketing approval or achieve market acceptance. The success of our product candidates will depend on several factors, including the following:

- successful enrollment in, and completion of, preclinical studies, Clinical Studies and Clinical Trials with positive results;
- clearance of INDs or non-U.S. equivalents for Clinical Trials for product candidates that we decide to develop as drug product candidates;
- receipt of regulatory approvals from applicable regulatory authorities for drug product candidates or, alternatively, compliance with regulatory requirements applicable to non-drug products;
- overcoming any delays or interruptions to our supply chain, Clinical Studies or Clinical Trials as a result of the COVID-19 pandemic;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity, as available, for our product candidates;

- establishing cGMP-compliant supply and commercial manufacturing operations or making arrangements with cGMP-compliant third-party manufacturers for supply and commercial manufacturing;
- launching commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- entering into new collaborations throughout the development process as appropriate, from preclinical studies through to commercialization;
- acceptance of our products, if and when approved or launched for commercialization under applicable regulations, by patients, consumers, the medical community and third-party payors;
- effectively competing with other drugs and non-drug products, depending on the development pathway that we choose for a product candidate;
- obtaining and maintaining coverage and adequate reimbursement by third-party payors, including government payors, for our product candidates developed as drug products, if approved by the FDA;
- protecting our rights in our intellectual property portfolio;
- operating without infringing or violating the valid and enforceable patents or other intellectual property of third parties;
- achieving and remaining in compliance with applicable laws and regulations that apply to the research, development and commercialization of our product candidates and having productive interactions and positive regulatory decisions that lead to successful product commercialization;
- maintaining a continued acceptable safety profile of the products following approval or commercialization; and
- maintaining and growing an organization of scientists and businesspeople who can develop and commercialize our products and technology.

If we do not successfully develop and commercialize product candidates using our development platform, we will not be able to obtain product revenue in future periods, which could result in significant harm to our financial position and adversely affect our stock price.

Even if a drug product candidate or a non-drug product candidate receives marketing approval, or otherwise is commercialized, respectively, such products may fail to achieve the degree of market acceptance by physicians, patients, third-party payors, consumers and others in the medical or healthcare community or other target markets necessary for commercial success.

If any drug product candidate receives marketing approval or otherwise is commercialized under applicable regulations as a non-drug product, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors, consumers and others in the medical or health community or other target markets. If the product candidates we develop do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of any product candidate, if approved for commercial sale, will depend on a number of factors, including, but not limited to:

- efficacy (for any drug product candidate), safety and potential advantages compared to alternative products;
- the labeled uses or limitations for use, including age limitations or contraindications, for our product candidates compared to alternative products;
- convenience and ease of administration compared to alternative products;
- the willingness of the target patient or consumer population to try new drug product candidates or non-drug products, respectively;

- the willingness of physicians to prescribe our drug product candidates to patients;
- the willingness of healthcare professionals to recommend our non-drug products to consumers;
- public perception of new drugs and non-drug products, including our product candidates;
- the strength of marketing and distribution support;
- any impacts to market health as a result of COVID-19;
- the ability for us to partner in the manufacturing and distribution of these products;
- the ability to offer our products, if approved, as applicable, for sale at competitive prices;
- the ability to obtain sufficient third-party insurance coverage and adequate reimbursement, as applicable depending on the development path we pursue; and
- the prevalence and severity of any side effects.

We will need to grow the size of our organization and we may experience difficulties in managing this growth.

As our research, development, manufacturing and commercialization plans and strategies develop, and as we transition into operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including, but not limited to:

- identifying, recruiting, compensating, integrating, maintaining and motivating additional employees;
- managing our internal research and development efforts effectively, including identification of clinical candidates, scaling our manufacturing process and navigating product candidate clinical development and the FDA's, or other comparable regulatory agency's, review process for our product candidates; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain organizations, advisors and consultants to provide certain services, including many aspects of legal, intellectual property, regulatory affairs, clinical management and manufacturing. There can be no assurance that the services of these organizations, advisors and consultants will continue to be available to us on a timely basis when needed or that we can find qualified replacements in a timely manner or at all. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical development may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for our product candidates, if required, or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants, or key employees to provide needed services on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Our current operations are located in Massachusetts; and we or the third parties upon whom we depend on may be adversely affected by natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our current operations are located in Massachusetts. Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics, including any potential effects from COVID-19, power shortage, telecommunication failure or other natural or man-made accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party contract manufacturers, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or interruption of our business operations. Natural disasters or pandemics such as the COVID-19 pandemic could further disrupt our operations and have a material and adverse effect on our business, financial condition, results of operations and prospects. For example, we have instituted a temporary work from home policy for non-essential office personnel and it is possible that this could have a negative impact on the execution of our business plans and operations. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our research facilities or the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure our investors that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities or the manufacturing facilities of our third-party contract manufacturers are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption may have a material and adverse effect on our business, financial condition, results of operations and prospects.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our CROs, contract manufacturing organizations, or CMOs, manufacturers of the raw materials used in our product candidates and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, derechos, fires, extreme weather conditions, medical epidemics, including the current global spread of COVID-19, and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. For our Clinical Studies, we rely on third-party manufacturers to produce our product candidates, on CROs for conducting various portions of such studies and on various consultants throughout the study process. For materials to be used in any future Clinical Trials, we plan to rely on an external CMO for the entire manufacturing supply chain and plan to continue using CROs and consultants in connection with conducting such trials. Our ability to obtain supplies of our product candidates and services from CROs and consultants could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

Our internal computer systems, or those used by our CROs, CMOs or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our CROs, CMOs and other contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. While we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of data from any future Clinical Trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we currently rely on third parties for the manufacture of our product candidates, and to conduct Clinical Studies, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the development and commercialization of our product candidates, could be delayed.

Regulatory authorities globally are also imposing greater monetary fines for privacy violations. For example, in 2016, the European Union adopted a new regulation governing data practices and privacy called the General Data Protection Regulation, or GDPR, which became effective on May 25, 2018. The GDPR applies to any company that collects and uses personal data in connection with offering goods or services to individuals in the European Union or the monitoring of their behavior. Non-compliance with the GDPR may result in monetary penalties of up to €20 million or 4% of worldwide revenue, whichever is higher. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of personal data, such as healthcare data or other sensitive information, could greatly increase the cost of providing our product candidates, if approved, or even prevent us from offering our product candidates, if approved, in certain jurisdictions.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless or negligent conduct that fails to comply with the laws of the FDA and other similar foreign, state or local regulatory bodies, provide true, complete and accurate information to the FDA and other similar foreign, state or local regulatory bodies, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the United States and similar foreign, state or local fraudulent misconduct laws or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates, as may be necessary for any product candidates we decide to develop as drugs, or otherwise able to commercialize those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research subjects, as well as proposed and future sales, marketing and education programs.

A variety of risks associated with testing and developing our product candidates internationally could materially adversely affect our business.

In addition to researching, developing and commercializing our product candidates in the United States, we also intend to engage in these activities outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries, if our product candidates are approved, including, but not limited to:

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;

- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practices Act, or FCPA, or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism.

Additionally, we intend to contract with third parties to conduct some of our Clinical Studies and Clinical Trials outside the United States, which will subject us to additional risks and regulations. These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations.

Changes in tax law could adversely affect our business and financial condition.

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock.

Our ability to use NOLs and research and development credits to offset future taxable income may be subject to certain limitations.

We have a history of cumulative losses and anticipate that we will continue to incur significant losses in the foreseeable future; thus, we do not know whether or when we will generate taxable income necessary to utilize our net operating losses, or NOLs, or research and development tax credit carryforwards. As of December 31, 2021, we had U.S. federal and state net operating loss, or NOL, carryforwards of $302.2 million and $294.3 million, respectively. These amounts begin to expire in 2030. The federal net operating losses generated in 2018 and 2019 can be carried forward indefinitely. As of December 31, 2021, we also had U.S. federal and state research and development tax credit carryforwards of $8.6 million and $2.9 million, respectively, both of which expire at various dates through 2041. These net operating loss and tax credit carryforwards could expire unused and be unavailable to offset future taxable income or tax liabilities, respectively.

In general, under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law, a corporation that undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, is subject to limitations on its ability to utilize its pre-change NOLs and research and development tax credit carryforwards to offset future taxable income. We have not conducted a study to assess whether any such ownership changes have occurred. We may have experienced such ownership changes in the past and may experience such ownership changes in the future through subsequent changes in our stock ownership (which may be outside our control). As a result, if, and to the extent that, we earn net taxable income, our ability to use our pre-change NOLs and research and development tax credit carryforwards to offset such taxable income may be subject to limitations.

There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise become unavailable to offset future income tax liabilities. The CARES Act includes changes to U.S. federal tax rates and the rules governing NOL carryforwards that may significantly impact our ability to utilize our NOLs to offset taxable income in the future. In addition, state NOLs generated in one state cannot be used to offset income generated in another state. For these reasons, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes.

Unstable market and economic and political conditions may have serious adverse consequences on our business, financial condition and stock price.

As widely reported, global credit and financial markets have experienced extreme volatility and disruptions in the past, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. In addition, the current military conflict between Russia and Ukraine could disrupt or otherwise adversely impact our operations and those of third parties upon which we rely. Related sanctions, export controls or other actions that may be initiated by nations including the U.S., the European Union or Russia (e.g., potential cyberattacks, disruption of energy flows, etc.), which could adversely affect our business and/or our supply chain, our CROs, CMOs and other third parties with which we conduct business. There can be no assurance that future volatility, disruption or deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets continue to be volatile or are disrupted or deteriorate, including as a result of COVID-19 or the military conflict between Russia and Ukraine, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

As of June 30, 2022, we had cash, cash equivalents and marketable securities of $44.4 million. While we are not aware of any downgrades, material losses or other significant deterioration in the fair value of our cash equivalents and marketable securities since June 30, 2022, no assurance can be given that further deterioration of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents and marketable securities or our ability to meet our financing objectives. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

Our loan agreement subjects us to operating restrictions and financial covenants and may restrict our business and financing activities.

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

Our obligations under the New Loan and Security agreement are secured by a first priority perfected security interest in our assets, including intellectual property. The New Loan and Security Agreement also contains customary representations and warranties, as well as customary affirmative and negative covenants. Among other restrictions, the negative covenants, subject to exceptions, prohibit or limit our ability to: maintain collateral accounts; declare dividends or redeem or purchase equity interests; incur additional liens; make investments; incur additional indebtedness; engage in mergers, acquisitions and asset sales; transact with affiliates; undergo a change in control; add or change business locations; and engage in businesses that are not related to its existing business. The New Loan and Security Agreement also contains certain financial covenants, including an unrestricted minimum cash level until certain study data conditions are met. These covenants may restrict our ability to finance our operations and to pursue our business activities and strategies. Furthermore, such restrictions may limit our flexibility in planning for or reacting to, changes in our business and industry; and they may place us at a competitive disadvantage compared to our peers and competitors that have no restrictions or more favorable terms with credit lenders. Our ability to comply with these covenants may also be affected by events beyond our control.

Additionally, there is no guarantee that we will have sufficient funds available to repay the amounts outstanding when due under the New Loan and Security Agreement. If we default under the facility, the lenders may accelerate all of our repayment obligations and, if we are unable to access funds to meet those obligations or to renegotiate our agreement, the lenders could sweep cash directly from our controlled accounts, take control of our pledged assets, including our intellectual property, and we may need to immediately cease operations. If we were to renegotiate our agreement under such circumstances, the terms may be significantly less favorable to us. If we were liquidated, the lender’s right to repayment would be senior to the rights of our stockholders to receive any proceeds from the liquidation. Any declaration of the Collateral Agent of an event of default could significantly harm our liquidity, financial condition, operating results, business, and prospects and cause the price of our common stock to decline.

Risks Related to Government Regulation

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.

Based on the large body of studies and scientific literature on the human exposure to and safety profiles of certain amino acids, the FDA's promulgation of regulations governing the use of certain amino acids under certain conditions as safe and permissible food additives when used as nutrients, our own data on amino acids used in product candidates and the fact that we use amino acids in our product candidates within amounts previously studied safely in humans, we believe we have designed our product candidates to have acceptable safety profiles, and we have further evaluated or will evaluate the safety and tolerability of these product candidates in Clinical Studies and/or Clinical Trials. Under the FDA's framework governing studies of non-drug products, we believe that use of our product candidates containing amino acids may be studied for safety and tolerability without an IND in human food studies. However, the FDA or comparable foreign regulatory authorities may disagree with this approach and determine that our studies should be conducted under an IND or non-U.S. equivalent, which may result in negative consequences.

In prior or future studies or trials of our product candidates, we may have or will expressly or implicitly characterize or classify such candidates as encompassed within a specific regulatory scheme (e.g., as foods or dietary supplements). Regulatory authorities may not agree with the regulatory classification of the product candidates used in our Clinical Studies or any subsequent classification of such candidates prior to commercialization. To date, we have submitted and the FDA has cleared an IND for our Phase 2 Clinical Trial of AXA1665, which we initiated in the second quarter of 2021 and terminated in the second quarter of 2022. Additionally, we have submitted and the FDA has cleared an IND for our Phase 2b Clinical Trial of AXA1125 for the treatment of NASH, which we initiated in the second quarter of 2021. We have also submitted and the United Kingdom's MHRA has accepted a CTA for our Phase 2a Clinical Trial of AXA1125 for the treatment of Long COVID, which we initiated in December 2021. We have not discussed the development of our other product candidates evaluated in Clinical Studies or our utilization of specific regulatory pathways for our other product candidates with the FDA or comparable foreign regulatory authorities and any such regulator may not agree with our current activities or future approach or plans for further development. The FDA may determine that our product candidates are not safe or appropriate for use in Clinical Studies or are not governed by food regulations and therefore may classify any of our product candidates as being ineligible for investigation in Clinical Studies without an IND. The FDA or other regulatory authorities may also take enforcement action, or otherwise delay or prevent further development or commercialization of our product candidates.

Any delay in the regulatory consultation process, or a warning, finding or determination that any of our operations or product candidates do not meet the regulatory requirements of the FDA, including but not limited to any applicable GRAS, food additive or NDI requirements, could subject the Company to regulatory enforcement action or other legal action, and/or cause a delay in or prevent the commercialization of one or more of our product candidates, which may lead to reduced acceptance by the public or others for any products we are able to commercialize and could materially adversely affect our business.

The FDA may determine that the only pathway for conducting studies of our product candidates is under an IND or that our Clinical Studies already conducted should have been conducted under an IND. Any such determination could prevent our reliance on existing regulatory frameworks to conduct Clinical Studies for other product candidates or prevent us from relying on or including data from our Clinical Studies in any regulatory submissions to support further clinical development or marketing approval, and could significantly increase the cost of and delay the development or commercialization of our product candidates. If the FDA disagrees with our determination that we may conduct Clinical Studies without filing an IND, they could require that we halt any Clinical Studies we have commenced, or we may be subject to enforcement action. Should we choose to commercialize our product candidates as non-drug products and if the FDA determines our product candidates fall outside the food regulations, we may be subject to regulatory enforcement action and we could be required to stop selling, withdraw, recall, re-label or re-package any products we have commercialized as non-drug products on the market. In addition, if new safety issues are raised by Clinical Studies in advance of deciding whether to file an IND that suggest safety concerns for all of our product candidates, then the FDA could ask us to modify approved labeling for or withdraw from the market any previously approved products for therapeutic uses or products being commercialized for non-drug uses. A decision by the FDA that we cannot conduct Clinical Studies without filing an IND would significantly impact our current business model and we may incur significant expense and operational difficulties.

Changes in the legal and regulatory environment could limit our future business activities, increase our operating or regulatory costs, reduce demand for our product candidates or result in litigation.

The conduct of our current and planned business activities, including, but not limited, to the development, testing, production, storage, distribution, sale, display, advertising, marketing, labeling, packaging, health and safety practices, regulatory classification and approval, where necessary, and use of our product candidates, is subject to various laws and regulations administered by federal, state and local governmental agencies in the United States, as well as to laws and regulations administered by government entities and agencies outside the United States in markets in which we conduct Clinical Studies or Clinical Trials under foreign food or drug regulations or in which our product candidates and components thereof (such as packaging) may be manufactured or sold.

These laws and regulations and interpretations thereof may change, sometimes dramatically, as a result of a variety of factors, including political, economic or social events. Such changes may include changes in:

- food and drug laws, including FDA regulations;
- laws related to product labeling;
- advertising and marketing laws and practices;
- laws and programs restricting the sale and advertising of certain product candidates;
- laws and programs aimed at regulating, restricting or eliminating ingredients present in certain of our product candidates;
- increased regulatory scrutiny of, and increased litigation involving, product claims and concerns regarding the actual or possible effects or side effects of ingredients in, or attributes of, certain of our product candidates;
- state and federal consumer protection and disclosure laws;
- changes in law due to unforeseen events such as COVID-19 that may result in additional costs or disruptions in our operations, such as the Families First Coronavirus Response Act, or local government orders or restrictions which could limit our business operations;
- laws related to the approval framework for generic drugs; and
- increased sponsor or company obligations under privacy laws such as the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, and GDPR.

New laws, regulations or governmental policy and their related interpretations, or changes in any of the foregoing, may alter the environment in which we do business and, therefore, may impact our operating results or increase our costs or liabilities.

Obtaining and maintaining regulatory approval of our drug product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval or identifying a similar alternate regulatory pathway for our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval for drug product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval or identify and maintain an alternate regulatory pathway in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process or path to market in others. For example, even if the FDA grants marketing approval of a drug product candidate for therapeutic indications, comparable foreign regulatory authorities could take opposing positions and decline to approve the manufacturing, marketing and promotion of such product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States. Preclinical studies, Clinical Studies and Clinical Trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval and the approved price may not lead to profitability or acceptable margins.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States may have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

If we are not able to meet certain regulatory requirements for our product candidates or to obtain, or timely obtain, required regulatory approvals for our drug product candidates, we will not be able to commercialize or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired.

Our product candidates and the activities associated with their development and commercialization as a drug product, including but not limited to their design, testing, manufacture, safety, efficacy, recordkeeping, packaging, labeling, storage, holding, approval, advertising, promotion, sale, distribution, import and export are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Before we can commercialize any of our product candidates as a drug, we must obtain marketing approval. We have not received approval to market any of our product candidates as drugs from regulatory authorities in any jurisdiction, and it is possible that none of our product candidates will ever obtain regulatory approval, where applicable, or meet other applicable regulatory requirements to reach the market.

We, as a company, have no experience in filing and supporting the applications necessary to gain regulatory approvals for drugs and expect to work with or rely on third-party CROs or regulatory consultants to assist us in this process. For example, the FDA and Federal Trade Commission, or FTC, require substantiating data or evidence for marketing claims and may require other regulatory submissions before they can be sold. With respect to drug product candidates, securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the drug candidate's safety and efficacy. If we fail to execute competently on these requirements, as applicable, our product candidates may never reach the market.

Securing regulatory approval for therapeutic indications also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Our drug product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

The process of obtaining regulatory approvals for therapeutic indications, both in the United States and abroad, is expensive, may take many years if additional Clinical Trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted IND, NDA or equivalent application types, may cause delays in the approval or rejection of an application. The FDA and comparable foreign regulatory authorities have substantial discretion in the approval process of our drug product candidates and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. Our drug product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design, including study population, dose level, dose regimen, efficacy endpoints and bioanalytical assay methods, or implementation of our Clinical Trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a drug candidate is safe and effective for its proposed indication;
- the results of our Clinical Trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies, Clinical Studies or Clinical Trials;

- the data collected from our Clinical Studies and Clinical Trials for our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of drugs in development, only a small percentage successfully complete the FDA or comparable foreign regulatory approval processes and are commercialized. The lengthy approval process as well as the unpredictability of future Clinical Trial results may result in our failing to obtain regulatory approval to market our applicable drug product candidates as drugs, which would significantly harm our business, results of operations and prospects.

If we decide to develop any product candidate in the therapeutic path and submit an NDA, the FDA may also require a panel of experts, or an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support approval for therapeutic indications. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain approval of any drug product candidates based on the completed Clinical Trials.

In addition, even if we were to obtain approval for use of our product candidates as drugs, regulatory authorities may approve any of our product candidates for fewer or more limited therapeutic indications than we request, may include limitations for use or contraindications that limit the suitable patient population, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing Clinical Trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that drug product candidate. Similarly, regulatory authorities may limit or prohibit label claims that limit the market, price or other factors that are necessary or desirable for the successful commercialization of candidates developed as non-drug products. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

Additionally, as of May 26, 2021, the FDA noted it is continuing to ensure timely reviews of applications for medical products during the ongoing COVID-19 pandemic in line with its user fee performance goals and conducting mission critical domestic and foreign inspections to ensure compliance of manufacturing facilities with FDA quality standards. However, the FDA may not be able to continue its current pace and approval timelines could be extended, including where a pre-approval inspection or an inspection of clinical sites is required and due to the ongoing COVID-19 pandemic and travel restrictions FDA is unable to complete such required inspections during the review period. During the COVID-19 public health emergency, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications.

If we experience delays or failures in obtaining regulatory approvals, where applicable, or otherwise experience delays or failures in complying with regulatory requirements for commercialization of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

The FDA and comparable foreign regulatory authorities such as the EMA may implement additional regulations or restrictions on the development and commercialization of products that act on metabolic pathways, which may be difficult to predict.

The FDA and comparable foreign regulatory authorities such as the EMA have expressed interest in further regulating biotechnology products and product candidates such as ours. Agencies at both the federal and state level in the United States, as well as the U.S. Congressional committees and other governments or governing agencies, have also expressed interest in further regulating the biotechnology industry. Such action may delay or prevent commercialization of some or all of our product candidates. Adverse developments in Clinical Studies or Clinical Trials of our product candidates or similar products conducted by others may cause the FDA or comparable foreign regulatory authorities to change the requirements for approval of any of our product candidates. The FDA or comparable foreign regulatory authorities may impose unexpected, onerous requirements on our products because they are composed of multiple amino acids, requiring a clinical demonstration of the functionality and contribution of each component of our product candidates. Such requirements may include additional studies or analyses. Similarly, the EMA and member states govern the development of product candidates as drugs in the European Union and member state regulatory bodies govern the development of product candidates under non-drug regulations and may issue new guidelines concerning the development and marketing authorization for our product candidates and require that we comply with these new guidelines. These regulatory review agencies and committees and the new requirements or guidelines they promulgate may lengthen the regulatory review process, require us to perform additional Clinical Trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant limitations or restrictions. As we advance our product candidates, we will be required to consult with these regulatory agencies and comply with applicable requirements and guidelines. If we fail to do so, we may be required to delay or discontinue development of such product candidates. These additional processes may, for our drug product candidates, result in a review and approval process that is longer than we otherwise would have expected and delays as a result of an increased or lengthier regulatory approval process or further restrictions on the development of our product candidates can be costly and could negatively impact our ability to complete Clinical Trials and commercialize our current and future product candidates in a timely manner, if at all.

The regulatory pathway for AXA1125 for treatment of patients with Long COVID is still evolving, and may result in unexpected or unforeseen challenges.

The speed at which parties are acting to create and test therapeutics and vaccines for COVID-19 is unusual. Evolving or changing plans or priorities within the FDA and comparable regulatory authorities, including those based on new knowledge of COVID-19, Long COVID and how these conditions affect the human body, may significantly affect the clinical and regulatory timelines for our product candidates. Results from ongoing clinical trials and discussions with regulatory authorities may raise new questions and require us to redesign proposed clinical trials, including revising proposed endpoints or adding new clinical trial sites or cohorts of subjects. Any such developments could delay the development timeline for our product candidates and materially increase the cost of the development for such candidates.

A Fast Track designation by the FDA may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our product candidates will receive marketing approval.

If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA Fast Track designation for a particular indication. We have been granted Fast Track designation for AXA1125 for the treatment of NASH with liver fibrosis. We may seek Fast Track designation for other indications or for certain of our future product candidates, but there is no assurance that the FDA will grant this status to any of our other proposed product candidates. Marketing applications filed by sponsors of products in Fast Track development may qualify for priority review under the policies and procedures offered by the FDA, but the Fast Track designation does not assure any such qualification or ultimate marketing approval by the FDA. The FDA has broad discretion whether or not to grant Fast Track designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even if we do receive Fast Track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures, and receiving a Fast Track designation does not provide assurance of ultimate FDA approval. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. In addition, the FDA may withdraw any Fast Track designation at any time.

Even if we receive regulatory approval of any drug product candidates, we will be subject to ongoing regulatory compliance obligations or continued regulatory review, which may result in significant additional expense. Additionally, any of our product candidates, if approved or commercialized, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

If any of our product candidates are approved for therapeutic indications, they will be subject to ongoing regulatory requirements for manufacturing, processing, labeling, packaging, storage, holding, testing, distribution, quality, safety, sale, marketing, advertising, promotion, sampling, record-keeping, export, import, conduct of post-marketing studies and submission of safety, efficacy or other post-market information. Such requirements may be imposed as federal and state requirements in the United States or by comparable foreign regulatory authorities. In addition, we will be subject to continued compliance with cGMP requirements as applicable to drug products and GCP requirements for any Clinical Trials that we conduct post-approval, if applicable.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA, and comparable foreign regulatory authority requirements, including ensuring that quality assurance, quality control and manufacturing procedures conform to the respective cGMP regulations and applicable product tracking and tracing requirements. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any NDA, if applicable, or other marketing application or submission, and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, quality assurance and quality control.

The FDA has significant post-marketing authority, including, for example, the authority to require labeling or packaging changes based on the use of improper product claims or new safety or other information and, where applicable, to require post-marketing studies or Clinical Trials to evaluate serious safety risks related to the use of a drug. With respect to products developed as drugs, any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which a drug may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 Clinical Trials and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a Risk Evaluation and Mitigation Strategy, or REMS, program as a condition of approval of drug product candidates, which could entail requirements for long-term patient follow-up, a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates as drugs for therapeutic uses, we will have to comply with requirements including submissions of safety and other post-marketing information and reports and registration.

The FDA or comparable foreign regulatory authorities may take regulatory enforcement action or other legal action or, in the case of drugs, impose consent decrees or withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in potential consequences, including, among other things:

- in the case of drug product candidates, revisions to the approved labeling to add new safety information and required regulatory submissions; imposition of post-market studies or Clinical Trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program;
- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- re-labeling or re-packaging;
- fines, warning or untitled enforcement letters or holds on Clinical Trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA and FTC strictly regulate marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses for drugs, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. Additionally, FDA and other regulatory authorities can take action against a company that makes misleading or inaccurate claims regarding efficacy and safety of an approved product. Non-drug products are prohibited from making any claims, whether express or implied, that the product is intended to "diagnose, mitigate, treat, cure or prevent disease," and doing so may subject a non-drug product to classification as a drug product and regulatory enforcement action. If the FDA or other regulatory agency determines that any of our product candidates make impermissible claims, we may be subject to any of the aforementioned consequences or other legal challenges that may have an adverse effect on our business and operations.

The policies of the FDA and of other comparable foreign regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval, where applicable, and commercialization, and continued commercialization, of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained for any drugs, or may no longer be able to market or sell products we develop as non-drug products, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. It is difficult to predict how any executive actions, including any executive orders, will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If any executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. In addition, if we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, where applicable, our ability to continue to market and sell our products and we may not achieve or sustain profitability.

Non-compliance by us or any future collaborator with regulatory requirements, including safety monitoring or pharmacovigilance requirements, where applicable, can also result in significant financial penalties.

Healthcare insurance coverage and reimbursement may be limited or unavailable in certain market segments for our drug product candidates, if approved, which could make it difficult for us to sell any such drug product profitably.

In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. The success of our product candidates, if approved for therapeutic indications, depends on the availability of adequate coverage and reimbursement from third-party payors, including governmental healthcare programs, such as Medicare and Medicaid, commercial payors and health maintenance organizations. In addition, because our product candidates have the potential to represent a relatively new approach to the treatment of the diseases, we cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our product candidates or assure that coverage and reimbursement will be available for any product that we may develop. See section entitled "*Business – Regulation of Drug Product Candidates and Drugs – Coverage and Reimbursement*" in Part I Item 1, Business of our Annual Report on Form 10-K for the year ended December 31, 2021.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs and commercial payors are critical to new product acceptance. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of product candidates. Patients are unlikely to use our product candidates unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost of our product candidates. Because our product candidates may have a higher cost of goods than conventional therapies, and may require long-term follow-up evaluations, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater. There is significant uncertainty related to insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

The pricing of prescription pharmaceuticals is also subject to governmental control outside the United States. In these other countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a Clinical Trial that compares the cost effectiveness of our product candidates to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our ability to generate revenues and become profitable could be impaired.

Healthcare insurance often does not cover non-drug products administered outside of the hospital setting. This may impact our product candidates if we decide to commercialize them as non-drug products.

Payors, whether domestic or foreign, or governmental or private, are developing increasingly sophisticated methods of controlling healthcare costs and those methods are not always specifically adapted for new technologies such as those we are developing.

In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. Among policy-makers and payers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access to healthcare. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. There have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. See section entitled "*Business – Regulation of Drug Product Candidates and Drugs – Current and Future Healthcare Reform Legislation*" in Part I Item 1, Business of our Annual Report on Form 10-K for the year ended December 31, 2021.

The continuing efforts of the government, insurance companies, managed care organizations and other payers of healthcare services to contain or reduce costs of healthcare may adversely affect:

- the demand for any of our product candidates, if approved;
- the ability to set a price that we believe is fair for any of our product candidates, if approved;
- our ability to generate revenues and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical and biologic products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs.

We expect that the healthcare reform measures that have been adopted and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products.

For our drug product candidates, our relationships with healthcare providers, physicians and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the U.S., our operations may be directly, or indirectly through our future, potential customers and third-party payors, subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act ("FCA"), and data privacy and physician sunshine laws and regulations. These laws or their relevant foreign counterparts may impact, among other things, our proposed sales, marketing, and education programs and our relationships with healthcare providers, physicians and other parties through which we market, sell and distribute our products for which we obtain marketing approval. In addition, we may be subject to patient privacy regulation by the federal government and the states in the U.S. as well as other jurisdictions. See section entitled "*Business – Regulation of Drug Product Candidates and Drugs – Other Healthcare and Privacy Laws*" in Part I Item 1, Business of our Annual Report on Form 10-K for the year ended December 31, 2021.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming, costly, and can divert a company's attention from the business.

It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, curtailment of our operations, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, any of which could adversely affect our ability to operate our business and our results of operations.

In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

Failure to comply with health and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation or adverse publicity and could negatively affect our operating results and business.

We and any potential collaborators may be subject to federal, state and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws and federal and state consumer protection laws (e.g., Section 5 of the FTC Act), that govern the collection, use, disclosure and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. For instance, California recently enacted the California Consumer Privacy Act, or CCPA, which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide certain disclosures to consumers about its data collection, use and sharing practices, and to provide affected California residents with ways to opt-out of certain sales or transfers of personal information. The CCPA went into effect on January 1, 2020, and the California Attorney General commenced enforcement actions against violators beginning July 1, 2020. As currently written, the CCPA may impact our business activities; however, there continues to be uncertainty about how the law will be interpreted and enforced. The uncertainty surrounding the implementation of CCPA exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

In addition, we may obtain health information from third parties (including research institutions from which we obtain Clinical Trial data) that are subject to privacy and security requirements under HIPAA, as amended by HITECH. Depending on the facts and circumstances, we could be subject to civil, criminal and administrative penalties if we knowingly obtain, use or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. HIPAA requires covered entities and business associates to develop and maintain policies and procedures with respect to PHI that is used or disclosed, including the adoption of administrative, physical and technical safeguards to protect such information and ensure the confidentiality, integrity and availability of electronic PHI. HIPAA also implemented the use of standard transaction code sets and standard identifiers that covered entities must use when submitting or receiving certain electronic healthcare transactions, including activities associated with the billing and collection of healthcare claims. The United States Office of Civil Rights may impose penalties on a covered entity for a failure to comply with a requirement of HIPAA. Penalties will vary significantly depending on factors such as the date of the violation, whether the covered entity knew or should have known of the failure to comply, or whether the covered entity's failure to comply was due to willful neglect. These penalties include significant civil monetary penalties, criminal penalties and, in certain instances, imprisonment. HIPAA also authorizes state attorneys general to file suit on behalf of their residents. Courts may award damages, costs and attorneys' fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to sue us in civil court for violations of HIPAA, its standards have been used as the basis for duty of care in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI. Furthermore, in the event of a breach as defined by HIPAA, the covered entity has specific reporting requirements under HIPAA regulations. In the event of a significant breach, the reporting requirements could include notification to the general public. Enforcement activity can result in reputational harm, and responses to such enforcement activity can consume significant internal resources. Additionally, if we are unable to properly protect the privacy and security of PHI, we could be found to have breached our contracts. Determining whether PHI has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and we cannot be sure how these regulations will be interpreted, enforced or applied to our operations.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data or, in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with these laws and regulations could result in government enforcement actions (which could include civil, criminal and administrative penalties), private litigation or adverse publicity and could negatively affect our operating results and business. Moreover, Clinical Study and Clinical Trial subjects, employees and other individuals about whom we or our potential collaborators obtain personal information, as well as the providers who share this information with us, may limit our ability to collect, use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

European data collection is governed by restrictive regulations governing the use, processing and cross-border transfer of personal information.

We plan to conduct Clinical Trials in the European Union or the United Kingdom, which may subject us to additional privacy restrictions. The collection, use, storage, disclosure, transfer, and other processing of personal data, including health data in the European Union is governed by the provisions of the GDPR, which became effective on May 25, 2018. It imposes several requirements relating to the processing health and other sensitive data, the consent of the individuals to whom the personal data relates, the information provided to the individuals, notification of data processing obligations to the competent national data protection authorities and the security and confidentiality of the personal data, implementation of safeguards to protect the security and confidentiality of personal data. The GDPR also imposes strict rules on the transfer of personal data out of the European Union to third countries, such as the United States (see below). Failure to comply with the requirements of the GDPR, and the related national data protection laws of the European Union Member States may result in fines and other administrative penalties. Non-compliance with the GDPR may result in monetary penalties of up to €20 million or 4% of worldwide revenue, whichever is higher. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR.

In addition, further to the United Kingdom's exit from the European Union on January 31, 2020, the GDPR ceased to apply in the United Kingdom at the end of the transition period on December 31, 2020. However, as of January 1, 2021, the United Kingdom's European Union (Withdrawal) Act 2018 incorporated the GDPR (as it existed on December 31, 2020 but subject to certain UK specific amendments) into United Kingdom law (referred to as the 'UK GDPR'). The UK GDPR and the UK Data Protection Act 2018 set out the UK's data protection regime, which is independent from but aligned to the European Union's data protection regime. Non-compliance with the UK GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher. In this document, "GDPR" refers to both the EU and the UK GDPR, unless specified otherwise.

The GDPR imposes strict rules on the transfer of personal data out of the EEA/UK to third countries, including the United States. A decision by the Court of Justice of the European Union, or CJEU, in 2020 invalidated the EU-U.S. Privacy Shield Framework, which was one of the primary mechanisms used by U.S. companies to import personal information from the EEA in compliance with the GDPR's cross-border data transfer restrictions, and raised questions about whether the European Commission's Standard Contractual Clauses, or SCCs, one of the primary alternatives to the Privacy Shield, can lawfully be used for personal information transfers from the EEA to the United States or most other countries. Furthermore, on June 4, 2021, the European Commission issued new forms of standard contractual clauses for data transfers from controllers or processors in the EEA, or otherwise subject to the GDPR, to controllers or processors established outside the EEA, and not subject to the GDPR. The new forms of standard contractual clauses have replaced the standard contractual clauses that were adopted previously under the Data Protection Directive. The UK is not subject to the European Commission's new standard contractual clauses but has published its own transfer mechanism, the International Data Transfer Agreement, which enables transfers from the UK. If we conduct Clinical Trials in the European Union or the United Kingdom, we will be required to transition to the new forms of standard contractual clauses and doing so will require significant effort and cost. Although the United Kingdom is regarded as a third country under the EU GDPR, the European Commission has issued a decision recognizing the United Kingdom as providing adequate protection under the EU GDPR and, therefore, transfers of personal data originating in the EEA to the United Kingdom remain unrestricted. Like the EU GDPR, the UK GDPR restricts personal data transfers outside the United Kingdom to countries not regarded by the United Kingdom as providing adequate protection. The United Kingdom government has confirmed that personal data transfers from the United Kingdom to the European Economic Area remain free flowing.

The GDPR regulations may impose additional responsibility and liability in relation to personal data that we process, and we may be required to put in place additional mechanisms ensuring compliance with these or new data protection rules. This may be onerous and adversely affect our business, financial condition, prospects and results of operations.

European Union drug marketing and reimbursement regulations may materially affect our ability to market and receive coverage for any drug product candidate in the European Member States.

We intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the European Union, the pricing of pharmaceutical products is subject to governmental control and other market regulations which could put pressure on the pricing and usage of our product candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of product candidates. The requirements governing drug pricing vary widely from country to country. For example, Member States in the European Union are able to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the European Union do not follow price structures of the U.S. and generally prices tend to be significantly lower.

In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidates and may be affected by existing and future healthcare reform measures.

Much like the federal Anti-Kickback Statute prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the European Union. The provision of benefits or advantages to induce improper performance is typically governed by the national anti-bribery laws of European Union Member States, and the Bribery Act 2010 in the UK. Infringement of these laws could result in substantial fines and imprisonment.

Payments made to physicians in certain European Union Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization or the regulatory authorities of the individual European Union Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the European Union Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain products outside of the United States and require us to develop and implement costly compliance programs.

If we expand our operations outside of the United States, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The FCPA prohibits any U.S. individual or business from paying, offering and authorizing payment, or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the Company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection to Clinical Trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain ex-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

We are subject to certain U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations. We can face serious consequences for violations.

Among other matters, U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions and other trade laws and regulations, which are collectively referred to as Trade Laws, prohibit companies and their employees, agents, CROs, legal counsel, accountants, consultants, contractors and other partners from authorizing, promising, offering, providing, soliciting or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We also expect our ex-U.S. activities to increase in time. We plan to engage third parties for Clinical Trials or to obtain necessary permits, licenses, patent registrations and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents or partners, even if we do not explicitly authorize or have prior knowledge of such activities.

Changes in funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products or take action with respect to other regulatory matters can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed or approved, or for other actions to be taken, by relevant government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Similarly, a prolonged government shutdown could prevent the timely review of our patent applications by the United States Patent and Trademark Office, or USPTO, which could delay the issuance of any U.S. patents to which we might otherwise be entitled. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly execute our business plans.

Risks Related to Our Intellectual Property

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.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our product candidates, development platform and other technologies we may develop. We seek to protect our proprietary position by filing patent applications in the United States and abroad relating to our product candidates and development platform, as well as other technologies that are important to our business. Given that the development of our technology and product candidates is at an early stage, our intellectual property portfolio with respect to certain aspects of our technology and product candidates is also at an early stage. As of June 30, 2022, we have 10 granted U.S. patents covering certain of our product candidates and other technologies, and we have filed or intend to file patent applications on our product candidates, certain aspects of our development platform and other technology; however, there can be no assurance that any such patent applications will issue as granted patents. Furthermore, in some cases, we have only filed provisional patent applications on certain aspects of our technology and product candidates and each of these provisional patent applications is not eligible to become an issued patent until, among other things, we file a non-provisional patent application within 12 months of the filing date of the applicable provisional patent application. Any failure to file a non-provisional patent application within this timeline could cause us to lose the ability to obtain patent protection for the inventions disclosed in the associated provisional patent applications.

Composition of matter patents for biological and pharmaceutical products are generally considered to be the strongest form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. We cannot be certain, however, that the claims in our pending patent applications covering the composition of matter of our product candidates will be considered patentable by the USPTO or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered valid and enforceable by courts in the United States or foreign countries. Furthermore, in some cases, we may not be able to obtain issued claims covering compositions of matter relating to our product candidates and proprietary product platform, as well as other technologies that are important to our business, and instead may need to rely on filing patent applications with claims covering a method of use or method of manufacture. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for a use that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their products for our targeted indications of any product candidates we decide to develop as drug products, physicians may prescribe these products "off-label" for those uses that are covered by our method of use patents. Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute. There can be no assurance that any such patent applications will issue as granted patents, and even if they do issue, such patent claims may be insufficient to prevent third parties, such as our competitors, from utilizing our technology. Any failure to obtain or maintain patent protection with respect to our product candidates and development platform could have a material adverse effect on our business, financial condition, results of operations and prospects.

The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patents and patent applications at a reasonable cost or in a timely manner. Disruptions at the USPTO or other government agencies may also slow the time necessary for patent applications to be reviewed by the USPTO, which could adversely affect our patent portfolio. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in any of our owned or pending patent applications, or that we were the first to file for patent protection of such inventions.

If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical technology and product candidates would be adversely affected.

The patent position of healthcare companies generally is highly uncertain, involves complex legal and factual questions and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our product candidates, development platform or other technologies or which effectively prevent others from commercializing competitive technologies and product candidates.

No consistent policy regarding the scope of claims allowable in patents in the biotechnology field has emerged in the United States. The patent situation outside of the United States is similarly uncertain. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions and enforce our intellectual property rights, and more generally could affect the value of our intellectual property. In particular, our ability to stop third parties from making, using, selling, offering to sell or importing products that infringe our intellectual property will depend in part on our success in obtaining and enforcing patent claims that cover our technology, inventions and improvements.

With respect to intellectual property that we own, we cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our products and the methods used to manufacture those products. Moreover, even our issued patents do not guarantee us the right to practice our technology in relation to the commercialization of our products. The area of patent and other intellectual property rights in biotechnology is an evolving one with many risks and uncertainties, and third parties may have blocking patents that could be used to prevent us from commercializing our patented product candidates and practicing our proprietary technology. Our issued patents and those that may issue in the future may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products or limit the length of the term of patent protection that we may have for our product candidates. In addition, the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies. For these reasons, we may have competition for our product candidates. Moreover, because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any particular product candidate can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we own issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own may be challenged, narrowed, circumvented or invalidated by third parties. Consequently, we do not know whether our product candidates or other technologies will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and patents that we own may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third party preissuance submission of prior art to the USPTO or to foreign patent authorities or become involved in opposition, derivation, revocation, reexamination, post-grant and *inter partes* review or interference proceedings or other similar proceedings challenging our owned patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our owned patent rights, allow third parties to commercialize our product candidates, development platform or other technologies and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post-grant challenge proceedings, such as *inter partes* reviews, post-grant reviews or derivation proceedings at the USPTO or oppositions in a foreign patent office, that challenge our priority of invention or other features of patentability with respect to our owned patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our product candidates, development platform and other technologies. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us.

In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

We may in the future co-own patent rights relating to future product candidates and our development platform with third parties. We may need the cooperation of any such co-owners of our patent rights in order to enforce such patent rights against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Our rights to develop and commercialize our product candidates and development platform may be subject, in part, to the terms and conditions of future licenses granted to us by others.

We may rely upon licenses to certain patent rights and proprietary technology from third parties that are important or necessary to the development of our product candidates and development platform. Patent rights that we in-license in the future may be subject to a reservation of rights by one or more third parties. As a result, any such third parties may have certain rights to such intellectual property.

In addition, subject to the terms of any such license agreements, we may not have the right to control the preparation, filing, prosecution and maintenance, and we may not have the right to control the enforcement, and defense of patents and patent applications covering the technology that we license from third parties. We cannot be certain that any in-licensed patent applications (and any patents issuing therefrom) that are controlled by any potential licensors will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business. If our licensors fail to prosecute, maintain, enforce and defend such patent rights, or lose rights to those patent applications (or any patents issuing therefrom), the rights we have licensed may be reduced or eliminated, our right to develop and commercialize any of our product candidates, development platform technologies and other technologies that are subject of such licensed rights could be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. Moreover, we cannot be certain that such activities by our potential future licensors will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. In addition, even where we may have the right to control patent prosecution of patents and patent applications that we may license to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of our potential future licensees, licensors and their counsel that took place prior to the date of assumption of control over patent prosecution.

We may not be able to protect our intellectual property and proprietary rights throughout the world.

Filing, prosecuting and defending patents on our product candidates, development platform technologies and other technologies in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Furthermore, the amino acids that we expect to incorporate into our products are available for purchase separately from a variety of retail outlets, and our intellectual property rights will not prevent these sales from continuing in the future.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally.

Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

Obtaining and maintaining our patent protection depends on compliance with various procedural requirements, document submission, fee payment and other requirements imposed by government patent agencies and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned patents and applications. The USPTO and various ex-U.S. government agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first-inventor-to-file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. Thus, a third party that files a patent application before we do in the USPTO after March 2013 could be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to file any patent application related to our product candidates, development platform or other technologies.

The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned patent applications and the enforcement or defense of our owned issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

From time-to-time the U.S. Supreme Court, other federal courts, the U.S. Congress or the USPTO, may change the standards of patentability and any such changes could have a negative impact on our business. For instance, on June 13, 2013, in *Association for Molecular Pathology v. Myriad Genetics*, the Supreme Court held that a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated. The Supreme Court did not address the patentability of any innovative method claims involving the manipulation of isolated genes. On January 7, 2019, the USPTO released guidance entitled "2019 Revised Subject Matter Eligibility Guidance." This memorandum provides guidelines for the USPTO's new examination procedure for subject matter eligibility under 35 U.S.C. §101 for claims embracing natural products or natural principles. Although the guidelines do not have the force of law, patent examiners have been instructed to follow them. Some aspects of our technology involve processes or molecules that may be subject to this evolving standard and we cannot guarantee that any of our pending process claims will be patent eligible, or issued claims will remain patent eligible, as a result of such evolving standards. Changes in either the patent laws or in interpretations of patent laws in the United States or other countries could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. We may not develop additional proprietary products, methods and technologies that are patentable.

Issued patents covering our product candidates and any patents that may issue covering our development platform and other technologies, could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.

If we initiated legal proceedings against a third party to enforce a patent covering our product candidates, development platform or other technologies, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may raise claims challenging the validity or enforceability of our owned patents before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, *inter partes* review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to our patents in such a way that they no longer cover our product candidates, development platform or other technologies. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates, development platform or other technologies. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations and prospects.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time

Patents have a limited lifespan. In most countries, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest national filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new product candidates, it is possible that patents protecting our product candidates might expire before or shortly after we commercialize those candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we do not obtain patent term extension and/or data exclusivity for any product candidates we decide to develop as drug product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we decide to develop as drug product candidates, one or more of our owned U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent term extension of up to five years to compensate for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar extensions to compensate for patent term lost during regulatory review processes are also available in certain foreign countries and territories, such as in Europe under a Supplementary Protection Certificate. However, we may not be granted an extension in the United States and/or foreign countries and territories because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. We may not be eligible for patent term extension, or PTE, as it is only available in the US if any component of a product candidate has never been approved as a drug substance. If we are unable to obtain patent term extension or the term of any such extension is shorter than what we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our owned patent rights, trade secrets or other intellectual property as an inventor or co-inventor. For example, we may have disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates, development platform or other technologies. Litigation may be necessary to defend against these and other claims challenging inventorship or our ownership of our owned patent rights, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates, development platform and other technologies. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patents for our product candidates, development platform and other technologies, we also rely on trade secrets and confidentiality agreements to protect our unpatented know-how, technology and other proprietary information and to maintain our competitive position. Trade secrets and know-how can be difficult to protect. We expect our trade secrets and know-how to over time be disseminated within the industry through independent development, the publication of journal articles describing the methodology and the movement of personnel from academic to industry scientific positions.

We currently, and may in the future continue to, rely on third parties to assist us in developing and manufacturing our product candidates. Accordingly, we must, at times, share know-how and trade secrets, including those related to our development platform, with them. We may in the future also enter into research and development collaborations with third parties that may require us to share know-how and trade secrets under the terms of our research and development partnerships or similar agreements. We seek to protect our know-how, trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements, and including in our vendor and service agreements terms protecting our confidential information, know-how and trade secrets, with parties who have access to such information, such as our employees, scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants as well as train our employees not to bring or use proprietary information or technology from former employers to us or in their work, and we remind former employees when they leave their employment of their confidentiality obligations. However, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. We also seek to preserve the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems.

Despite our efforts, any of the aforementioned parties may breach the agreements and disclose our proprietary information, including our trade secrets, or there may be lapses or failures in our physical and electronic security systems that lead to our proprietary information being disclosed, and we may not be able to obtain adequate remedies in the event of any such breaches. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of our scientific advisors, employees, contractors and consultants who are parties to these agreement breaches or are in violation of the terms of any of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Moreover, if confidential information that is licensed or disclosed to us by our partners, collaborators or others is inadvertently disclosed or subject to a breach or violation, we may be exposed to liability to the owner of that confidential information. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed.

We rely on our development platform to identify product candidates. Our competitive position could be materially harmed if our competitors develop a similar platform and develop rival product candidates.

We rely on know-how, inventions and other proprietary information to strengthen our competitive position. We consider know-how to be our primary intellectual property with respect to our development platform. Our Clinical Studies and Clinical Trials allow us to collect clinical data, which we use in a feedback loop to make improvements to our development platform. In particular, we anticipate that, with respect to this platform, this data may over time be disseminated within the industry through independent development, the publication of journal articles describing the method and the movement of skilled personnel.

We cannot rule out that our competitors may have or will obtain the knowledge necessary to analyze and characterize similar data to our known data for the purpose of identifying and developing products that could compete with any of our product candidates. Our competitors may also have significantly greater financial, product development, technical and human resources and access to data. Further, our competitors may have significantly greater experience in using translational science methods to identify and develop product candidates.

We may not be able to prohibit our competitors from using technology or methods that are the same as or similar to our development platform to develop their own product candidates. If our competitors develop associated therapies, our ability to develop and market a promising product or product candidate may diminish substantially, which could have a material adverse effect on our business, financial condition, prospects and results of operations.

We may not be successful in obtaining, through acquisitions, in-licenses or otherwise, necessary rights to our product candidates, development platform technologies or other technologies.

We may need to, or want to for strategic purposes, acquire rights to certain intellectual property, through licenses from third parties, to create new products or advancements to our development platform or further develop our product candidates and development platform technologies. Some healthcare companies and academic institutions are competing with us in the field of EMMs and metabolic pathways and may have patents and have filed and are likely filing patent applications potentially relevant to our business. In order to avoid infringing these third-party patents, we may find it necessary or prudent to obtain licenses to such patents from such third-party intellectual property holders. We may also require licenses from third parties for certain technologies that we may evaluate for use with our current or future product candidates. However, we may be unable to secure such licenses or otherwise acquire or in-license any compositions, methods of use, processes or other intellectual property rights from third parties that we identify as necessary for our current or future product candidates and our development platform at a reasonable cost or on reasonable terms, if at all. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all.

In the event that we try to obtain rights to required third party intellectual property rights, and are ultimately unsuccessful, we may be required to expend significant time and resources to redesign our technology, product candidates or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates or continue to utilize our existing development platform technology, which could harm our business, financial condition, results of operations and prospects significantly.

We may be subject to claims that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Many of our employees, consultants and advisors are currently or were previously employed at universities or other healthcare companies, including our competitors and potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations and prospects.

Third-party claims of intellectual property infringement, misappropriation or other violation against us or our collaborators may prevent or delay the development and commercialization of our product candidates, development platform technologies and other technologies.

The field of developing drug or non-drug products that target metabolic pathways is competitive and dynamic. Due to the focused research and development that is taking place by several companies, including us and our competitors, in this field, the intellectual property landscape is in flux, and it may remain uncertain in the future. As such, there may be significant intellectual property related litigation and proceedings relating to our owned, and other third party, intellectual property and proprietary rights in the future.

Our commercial success depends in part on our and our collaborators' ability to avoid infringing, misappropriating and otherwise violating the patents and other intellectual property rights of third parties. There is a substantial amount of complex litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. As discussed above, recently, due to changes in U.S. law referred to as patent reform, new procedures including *inter partes* review and post-grant review have been implemented. As stated above, this reform adds uncertainty to the possibility of challenge to our patents in the future.

Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist relating to technologies and fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates, development platform and other technologies may give rise to claims of infringement of the patent rights of others. We cannot assure you that our product candidates, proprietary product platform technologies and other technologies that we have developed, are developing or may develop in the future will not infringe existing or future patents owned by third parties. We may not be aware of patents that have already been issued and that a third party, for example, a competitor in the fields in which we are developing our product candidates, development platform and other technologies might assert they have been infringed upon by our current or future product candidates, development platform or other technologies, including claims to compositions, formulations, methods of manufacture or methods of use or treatment that cover our product candidates, development platform or other technologies. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our product candidates, development platform or other technologies, could be found to be infringed by our product candidates, development platform or other technologies. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates, development platform or other technologies may infringe. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, including our development platform technologies, manufacturing methods, product candidates or future methods or products resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

Third parties may have patents or obtain patents in the future and claim that the manufacture, use or sale of our product candidates, development platform or other technologies infringes upon these patents. In the event that any third party claims that we infringe their patents or that we are otherwise employing their proprietary technology without authorization and initiates litigation against us, even if we believe such claims are without merit, a court of competent jurisdiction could hold that such patents are valid, enforceable and infringed by our product candidates, development platform or other technologies. In this case, the holders of such patents may be able to block our ability to commercialize the applicable product candidate or technology unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be held invalid or unenforceable. Such a license may not be available on commercially reasonable terms or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be non-exclusive, which could result in our competitors gaining access to the same intellectual property. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, we may be unable to commercialize our product candidates, development platform or other technologies, or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business.

Defense of infringement claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, and may impact our reputation. In the event of a successful claim of infringement against us, we may be enjoined from further developing or commercializing our infringing product candidates, development platform or other technologies. In addition, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties and/or redesign our infringing product candidates or technologies, which may be impossible or require substantial time and monetary expenditure. In that event, we would be unable to further develop and commercialize our product candidates, development platform or other technologies, which could harm our business significantly.

Engaging in litigation to defend against third parties alleging that we have infringed, misappropriated or otherwise violated their patents or other intellectual property rights is very expensive, particularly for a company of our size, and time-consuming. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings against us could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition or results of operations.

We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents, or we may be required to defend against claims of infringement. In addition, our patents also may become involved in inventorship, priority or validity disputes. To counter or defend against such claims can be expensive and time-consuming. In an infringement proceeding, a court may decide that a patent owned by us is invalid or unenforceable, the other party's use of our patented technology falls under the safe harbor to patent infringement under 35 U.S.C. §271(e) or may refuse to stop the other party from using the technology at issue on the grounds that our owned patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our owned patents at risk of being invalidated or interpreted narrowly. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.

Intellectual property rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make products that are similar to our product candidates or utilize similar technology but that are not covered by the claims of the patents that we may own;
- we, or our future licensors or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we own now or in the future;
- we, or our future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned intellectual property rights;
- it is possible that our current or future pending owned patent applications will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;

- our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Our Reliance on Third Parties

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.

We depend upon third parties to conduct preclinical studies, Clinical Studies and Clinical Trials. We expect to have to negotiate budgets and contracts with CROs, which may result in delays to our development timelines and increased costs.

We have heavily relied upon, and will continue to heavily rely upon, third parties over the course of our planned and ongoing Clinical Studies and Clinical Trials. As a result, we will have limited control over and limited visibility into their day-to-day activities, including with respect to their compliance with the approved clinical protocol. Nevertheless, we are responsible for ensuring that each of our Clinical Studies and Clinical Trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with, among other things, GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of study or trial sponsors, clinical investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP requirements, the clinical data generated in our Clinical Studies or Clinical Trials may be deemed insufficient or unreliable and the FDA or comparable foreign regulatory authorities may require us to suspend or terminate these Clinical Studies or Clinical Trials or perform additional Clinical Studies or Clinical Trials before approving or otherwise permitting our marketing applications. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of our Clinical Studies or Clinical Trials comply with applicable regulatory requirements. In addition, our Clinical Trials for therapeutic indications must be conducted with drug products produced under cGMP requirements and may require a large number of patients.

Our failure or any failure by these third parties to comply with these regulations may require us to repeat Clinical Studies or Clinical Trials, which would delay the regulatory approval or commercialization process. Moreover, our business may be implicated if any of these third parties violates federal or state laws or regulations including fraud and abuse or false claims laws and regulations or healthcare privacy and security laws even without our prior knowledge.

Any parties conducting our planned and ongoing Clinical Studies or Clinical Trials, if any, generally will not be our employees and, except for remedies that may be available to us under our agreements with the third parties conducting such Clinical Studies or Clinical Trials, if any, we cannot directly control whether or not they devote sufficient time and resources to our ongoing preclinical and clinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting Clinical Studies or Clinical Trials or other product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, such as due to the impacts of the COVID-19 pandemic, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our Clinical Studies and Clinical Trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

If any of our relationships with these third-party CROs or others terminate, we may not be able to enter into contractual and other arrangements with alternative CROs or other third parties in a timely manner to meet projected clinical development deadlines or to do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO begins work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

Further, we expect to work with and/or rely upon third-party CROs and/or regulatory consultants to assist us with meeting regulatory requirements applicable to non-drug products. If we experience delays in meeting or fail to meet the regulatory requirements for commercialization of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

We may rely on academic and private non-academic institutions to conduct investigator-sponsored Clinical Studies or Clinical Trials of our product candidates. Any failure by the investigator-sponsor to meet its obligations with respect to the clinical development of our product candidates may delay or impair our ability to obtain regulatory approval or otherwise commercialize the applicable product candidates.

We may rely on academic and private non-academic institutions to conduct and sponsor Clinical Studies or Clinical Trials relating to our product candidates. We will not control the design or conduct of the investigator-sponsored trials, and it is possible that the FDA or comparable foreign regulatory authorities will not view these investigator-sponsored studies or trials as providing adequate support to allow for the initiation of Clinical Trials for those product candidates that we choose to develop as drug product candidates, whether controlled by us or independent investigators, for any one or more reasons, including elements of the design or execution of the trials or safety concerns or other trial results.

Such arrangements will likely provide us certain information rights with respect to the investigator-sponsored studies or trials, including access to and the ability to use and reference the data, including for our own regulatory filings, resulting from the investigator-sponsored studies or trials. However, we would not have control over the timing and reporting of the data from investigator-sponsored trials, nor would we own the data from the investigator-sponsored studies or trials. If we are unable to confirm or replicate the results from the investigator-sponsored studies or trials or if negative results are obtained, we would likely be further delayed or prevented from advancing further clinical development of our product candidates. Further, if investigators or institutions breach their obligations with respect to the clinical development of our product candidates or if the data proves to be inadequate compared to the first-hand knowledge we might have gained had the investigator-sponsored studies or trials been sponsored and conducted by us, then our ability to design and conduct any Clinical Trials ourselves may be adversely affected.

Additionally, the FDA or comparable foreign regulatory authorities may disagree with the sufficiency of our right of reference to the preclinical, manufacturing or clinical data generated by these investigator-sponsored studies or trials or our interpretation of preclinical, manufacturing or clinical data from these investigator-sponsored studies or trials. If so, the FDA or other comparable foreign regulatory authorities may require us to obtain and submit additional preclinical, manufacturing or clinical data before we may initiate our Clinical Trials or may not accept such additional data as adequate to initiate our Clinical Trials. In addition, it could limit or prevent our ability to commercialize product candidates for non-drug uses.

Third-party relationships are important to our business. If we are unable to enter into and maintain strategic collaborations or if these relationships are not successful, our business could be adversely affected.

We have limited capabilities for product development and do not yet have any capability for sales, marketing or distribution. Accordingly, we may need to enter into relationships with other companies to provide us with important technologies, services and resources and we may receive additional technologies and funding under these and other collaborations in the future. Relationships we enter into may pose a number of risks, including the following:

- third parties have, and future third-party collaborators may have, significant discretion in determining the efforts and resources that they will apply;
- third parties may not perform their obligations as expected, including as a result of impacts due to the COVID-19 pandemic;
- third parties may not pursue development and commercialization of any product candidates and that achieve regulatory approval, as may be necessary, or may elect not to continue or renew development or commercialization programs based on Clinical Study or Clinical Trial results, changes in the third parties' strategic focus or available funding, or external factors, such as a strategic transaction that may divert resources or create competing priorities;
- third parties may delay Clinical Studies or Clinical Trials, provide insufficient funding for a Clinical Study or Clinical Trial program, terminate a Clinical Study or Clinical Trial or abandon a product candidate, repeat or conduct new Clinical Studies or Clinical Trials or require a new formulation of product candidate for clinical testing;
- third parties could independently develop, or develop with other third parties, products that compete directly or indirectly with our products and product candidates if the third parties believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by our current or future third parties as competitive with their own product candidates or products, which may cause such third parties to cease to devote resources to the development or commercialization of our product candidates;
- third parties may fail to comply with applicable regulatory requirements regarding the development, manufacturing, processing, packaging, labeling, holding, testing, storage, distribution and/or marketing of a product candidate or product;
- third parties with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with third parties, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or terminations of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;

- third parties may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- third parties may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- if one of our third parties is involved in a business combination, the collaborator might de-emphasize or terminate the development or commercialization of any product candidate licensed to it by us; and
- relationships may be terminated by the collaborator, and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

If our relationships do not result in the successful discovery, development and commercialization of products or if a third-party terminates its agreement with us, or if for any other reason an agreement is terminated or cancelled, we may not receive any future research funding or milestone or royalty payments under such agreement. If we do not receive the funding, we expect under any third-party agreements we enter into, our development of our technology and product candidates could be delayed and we may need additional resources to develop product candidates and our technology. All of the risks relating to product development, regulatory compliance and/or approval and commercialization described herein also apply to the activities of any drug and non-drug collaborators we enter into relationships or agreements in the future.

Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. If we are unable to reach agreements with suitable third parties on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms, or at all. If we fail to enter into relationships or do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates, bring them to market and generate revenue or continue to develop our technology, and our business may be materially and adversely affected.

We expect to rely on third parties to manufacture our supply of product candidates, and we intend to rely on third parties to produce and process our products, if approved or commercialized.

We currently rely on outside vendors to supply raw materials and other important components, such as the amino acids and excipients that make up our product candidates. We have not yet caused any product candidates to be manufactured or processed on a large clinical or commercial scale and may not be able to do so for any of our product candidates. We will make changes as we work to optimize the manufacturing process for our product candidates, and we cannot be sure that even minor changes in the process will result in products that are safe and, where applicable, effective.

The facilities used to manufacture our drug product candidates must be approved by the FDA or other foreign regulatory agencies pursuant to inspections that could be conducted before or will be conducted after we submit a marketing application to the FDA or other foreign regulatory agencies. Since March 2020 when foreign and domestic inspections of facilities were largely placed on hold, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. Since April 2021, the FDA has conducted limited inspections and employed remote interactive evaluations, using risk management methods, to meet user fee commitments and goal dates. Ongoing travel restrictions and other uncertainties continue to impact oversight operations both domestic and abroad and it is unclear when standard operational levels will resume. The FDA is continuing to complete mission-critical work, prioritize other higher-tiered inspectional needs (e.g., for-cause inspections), and carry out surveillance inspections using risk-based approaches for evaluating public health. Should FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, the agency has stated that it generally intends to issue, depending on the circumstances, a complete response letter or defer action on the application until an inspection can be completed. During the COVID-19 public health emergency, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the ongoing COVID-19 pandemic and may experience delays in their regulatory activities.

Additionally, any facilities used for the manufacture of product candidates commercialized for non-drug uses will be subject to registration and inspection by the FDA and comparable foreign regulatory authorities. We do not currently control all aspects of the manufacturing process of, and are currently largely dependent on, our contract manufacturing partners for compliance with regulatory requirements, known as cGMP requirements, for manufacture of our product candidates, but we may be held ultimately responsible for such compliance. If we ever decide to open a manufacturing facility, we will be responsible for our own compliance with cGMP requirements. If we or our contract manufacturers cannot successfully manufacture in conformance with our specifications and the strict regulatory requirements of the FDA or comparable foreign regulatory authorities, we and they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities with respect to the manufacture of our product candidates. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates, where applicable, or if it withdraws any such approval in the future, or if it otherwise finds that a manufacturing facility is out of regulatory compliance, we may need to find alternative manufacturing facilities, which would significantly impact our ability to research, develop, obtain regulatory approval, where necessary, for and/or market our product candidates.

Risks Related to Manufacturing and Supply

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.

In reliance on third parties, we have limited experience manufacturing our product candidates for Clinical Trials as we have not yet completed a Clinical Trial. We similarly have limited experience with the manufacturing requirements for non-drug products at a commercial scale. Our cGMP manufacturing process development and scale-up is at an early stage. The actual cost to manufacture and process our product candidates could be greater than we expect and could materially and adversely affect the commercial viability of our product candidates. In the future, we may develop internal manufacturing capacity in part by expanding our own facilities or building additional facilities. This activity will require substantial additional funds and we would need to invest such funds in creating the proper manufacturing infrastructure and to hire and train a significant number of qualified employees to staff these facilities. We may not be able to develop cGMP-compliant manufacturing facilities that are adequate to produce materials for additional later-stage Clinical Studies, Clinical Trials, or commercialization, which may materially and adversely affect our business.

We combine multiple EMMs in novel combinations and ratios in our manufacturing process for product candidates. These combinations may result in unanticipated manufacturing and product quality issues that we may not be able to resolve without incurring significant expense or delays in our Clinical Studies or Clinical Trials, or at all. Furthermore, our manufacturing process may be susceptible to manufacturing issues associated with interruptions in the manufacturing process, contamination, equipment or reagent failure, improper installation or operation of equipment, vendor or operator error and variability in product characteristics. Even minor deviations from normal manufacturing processes at our third-party manufacturers could result in reduced production yields, lot failures, product defects, product recalls, product liability claims and other supply disruptions. If microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, production at such manufacturing facilities may be interrupted for an extended period of time to investigate and remedy the contamination. Further, as product candidates are developed through preclinical studies, Clinical Studies and/or Clinical Trials toward approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to scale-up and optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of Clinical Studies or Clinical Trials.

Although we continue to optimize our manufacturing process for our product candidates, doing so is a difficult and uncertain task, and there are risks associated with scaling to the level required for advanced Clinical Studies and Clinical Trials or commercialization, including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, lot consistency, supplier manufacturing capacity and timely availability of reagents and/or raw materials. We ultimately may not be successful in transferring our production system from our contract manufacturers to any manufacturing facilities we may establish ourselves or other contract manufacturers who can provide cost and process efficiencies, or our contract manufacturer may not have the necessary capabilities to complete the implementation and development process. If we are unable to adequately validate or scale-up the manufacturing process for our product candidates with each of our current manufacturers, we will need to transfer to other manufacturers and complete the manufacturing validation and scale-up processes, which can be lengthy. If we are able to adequately validate and scale-up the manufacturing process for our product candidates with a contract manufacturer, we will still need to negotiate with such contract manufacturer an agreement for commercial supply and it is not certain we will be able to come to agreement on terms acceptable to us. As a result, we may ultimately be unable to reduce the cost of goods for our product candidates to levels that will allow for an attractive return on investment if and when those product candidates are commercialized.

The manufacturing process for any drug product candidate is subject to the FDA and foreign regulatory authority approval process, and extensive oversight of manufacturing facilities and changes to manufacturing processes. Non-drug products that we may develop will also be subject to extensive legal and regulatory requirements, including those with respect to the manufacturing, packaging, labeling, holding, processing and distribution of such products under appropriate cGMPs, as indicated in other risk factor sections herein. As such, we will need to contract with manufacturers who can meet all applicable FDA, foreign or other regulatory authority requirements on an ongoing basis, including with respect to quality systems and standards. If we or our CMOs are unable to reliably produce products under conditions and to specifications acceptable to the Company and/or the FDA or comparable foreign regulatory authorities, we may not obtain or maintain the ability or, in the case of drugs, the requisite approvals to commercialize such products. There is no assurance that our CMOs will be able to manufacture the approved product to specifications acceptable to us, the FDA, comparable foreign regulatory authorities, even if we obtain regulatory approval for any of our product candidates for therapeutic indications, to produce product in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. In the case of product candidates for which a therapeutic pathway is pursued, any of these challenges could delay completion of Clinical Trials, require bridging Clinical Trials or the repetition of one or more Clinical Trials, increase Clinical Trial costs and delay approval of our product candidates. If any CMO with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different CMO, which we may not be able to do on reasonable terms, if at all. In either scenario, our clinical trials supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original CMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CMOs for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to the FDA or another regulatory authority. The delays associated with the verification of a new CMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a CMO may possess technology related to the manufacture of our product candidate that such CMO owns independently. This would increase our reliance on such CMO or require us to obtain a license from such CMO in order to have another CMO manufacture our product candidates. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

In the case of all product candidates that we choose to commercialize, any of these challenges could delay and/or impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations and growth prospects. Our future success depends on our ability to manufacture our product candidates on a timely basis with acceptable manufacturing costs, while at the same time maintaining good quality control and complying with applicable regulatory requirements, and an inability to do so could have a material adverse effect on our business, financial condition and results of operations. In addition, we could incur higher manufacturing costs if manufacturing processes or standards change, and we could need to replace, modify, design or build and install equipment, all of which would require additional capital expenditures. Specifically, because our product candidates may have a higher cost of goods than other drugs and/or non-drug products, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater.

In addition, we currently handle all batch release for our product candidates for our preclinical studies and Clinical Studies, but in the future may need to transfer such process to a third party, which would substantially increase the cost of this step of the manufacturing process.

In addition to raw materials and CMOs, we depend on third parties for clinical product supplies (e.g., clinical labeling and secondary packaging services) and will likely need to do the same for any future commercial supply, including, in some instances, a single supplier.

In addition to raw materials and CMOs, we depend on third-party suppliers for labeling secondary packaging and other services needed to produce Clinical Study and Clinical Trial ready supplies of our product candidates and will likely need to do the same for any future commercial supplies. We could be held responsible for the regulatory compliance of such labeling or packaging activities. These supplies may not always be available to us at the standards we require or on terms acceptable to us, or at all, and we may not be able to locate alternative suppliers in a timely manner, or at all. If we are unable to obtain necessary clinical or commercial supplies, our manufacturing operations and Clinical Studies and Clinical Trials and the clinical studies and trials of our collaborators may be delayed or disrupted and our business and prospects may be materially and adversely affected as a result.

We may rely on a sole supplier for certain of our supplies. If this sole supplier is unable to supply to us in the quantities we require, or at all, or otherwise defaults on its supply obligations to us, we may not be able to obtain alternative supplies from other suppliers on acceptable terms, in a timely manner, or at all.

Our product candidates rely on the availability of specialty raw materials, including significant quantities of amino acids, which may not be available to us on acceptable terms or at all.

Our product candidates require certain specialty raw materials, including significant quantities of amino acids, some of which we may obtain from third-party small companies with limited resources and experience to support a commercial product. The suppliers may be ill-equipped to support our needs, especially in non-routine circumstances like an FDA or foreign regulatory inspection or medical crisis, such as widespread contamination. Additionally, our suppliers may fail inspections or have other compliance issues with regulatory authorities that, even if unrelated to our supply chain and materials, may impact or cause delays in their ability to deliver agreed upon supplies in a timely manner which can have negative impacts on our business plans, including delays in initiating or continuing Clinical Studies or Clinical Trials. We do not currently have supply contracts in place with all of the suppliers that we may need at any point in time in the future, and if needed, may not be able to contract with them on acceptable terms or at all, in particular for large quantities of pharmaceutical grade raw materials, including amino acids. Accordingly, we may experience delays in receiving key raw materials to support clinical or commercial manufacturing.

Risks Related to Our Common Stock

The trading price of our stock is highly volatile.

Similar to the trading price of stock of other biopharmaceutical companies, the trading price of our common stock is highly volatile and is subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Quarterly Report, these factors include:

- any potential impact of COVID-19 on the financial markets generally, the biopharmaceutical industry and our business and operations, including with respect to our planned and ongoing Clinical Studies and Clinical Trials;
- the commencement, enrollment or results of our planned and ongoing Clinical Studies, Clinical Trials or changes in the development status of our product candidates;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings;
- adverse results from or delays in Clinical Studies or Clinical Trials of our product candidates, including as a result of clinical holds, safety events, enrollment or study or trial protocol amendments;

- our decision to initiate a Clinical Study or Clinical Trial, not to initiate a Clinical Study or Clinical Trial or to terminate an existing Clinical Study or Clinical Trial, or being required to do so by any regulatory authority;
- adverse regulatory decisions, including the FDA's disagreeing with our interpretation and application of applicable rules and regulations and any government actions that may arise from such disagreement and our failure to receive regulatory approval of our product candidates for therapeutic indications or to proceed on alternate regulatory pathways to market for our product candidates;
- changes in laws or regulations applicable to our products, including, but not limited to, Clinical Trial requirements for approvals of drugs or marketing of non-drug products;
- adverse developments concerning our manufacturers;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- our inability to establish collaborations, if needed;
- our failure to commercialize our product candidates;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates;
- introduction of new products or services by our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- the size and growth of our initial target markets;
- actual or anticipated variations in quarterly or annual operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- adoption of new accounting standards;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the market for healthcare/biotechnology companies in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. If the market price of our common stock does not increase, you may not realize any return on your investment in us and may lose some or all of your investment. Additionally, your ownership in our stock may be significantly diluted if we raise capital through equity issuances in private or public financings. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results or financial condition.

An active trading market for our common stock may not be sustainable, and you may not be able to resell your shares at or above the purchase price.

In May 2019, we closed our initial public offering. Prior to that offering, there was no public market for our common stock. Although we have completed our initial public offering and shares of our common stock are listed on The Nasdaq Global Market, an active trading market for our shares may not be sustained. You may not be able to sell your shares quickly or at the market price if trading in shares of our common stock is not active. As a result of these and other factors, it may be difficult for our stockholders to resell their shares of our common stock at or above the prices at which they acquired their shares or sell their shares at the time they would like to sell. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, our ability to pay cash dividends is currently restricted by the terms of our New Loan and Security agreement with SLR Investment Corp., formerly known as Solar Capital Ltd., and future debt or other financing arrangements may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Any return to stockholders will therefore be limited in the foreseeable future to the appreciation of their stock.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of June 30, 2022, our executive officers, directors and their affiliates and 5% stockholders held, in the aggregate, approximately 73.8% of our outstanding voting stock. Therefore, these stockholders have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that stockholders may feel are otherwise in their best interests.

We are an emerging growth company as well as a smaller reporting company, and we cannot be certain if the reduced reporting requirements applicable to us will make our common stock less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act, enacted in April 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years following the year in which we completed our IPO, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our IPO; (b) in which we have total annual gross revenue of at least $1.07 billion; or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed $700 million as of the prior June 30; and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected not to "opt out" of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we may adopt the new or revised standard at the time private companies adopt the new or revised standard and may do so until such time that we either (i) irrevocably elect to "opt out" of such extended transition period or (ii) no longer qualify as an emerging growth company. This may make comparison of our financial statements with the financial statements of another public company that is not an emerging growth company, or an emerging growth company that has opted out of using the extended transition period, difficult or impossible because of the potential differences in accounting standards used.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we may enter into license or collaboration agreements with other companies that include development funding and significant upfront and milestone payments and/or royalties, which may become an important source of our revenue. Accordingly, our revenue may depend on development funding and the achievement of development and clinical milestones under current and any potential future license and collaboration agreements and sales of our products, if approved. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next.

In addition, we measure compensation cost for stock-based awards made to employees, directors and non-employee consultants based on the fair value of the award on either the grant date or service completion date, and we recognize the cost as an expense over the recipient's service period. Because the variables that we use as a basis for valuing stock-based awards change over time, including our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly.

Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- any potential impact of COVID-19 on our business and operations, including with respect to our supply chain, planned and ongoing Clinical Studies and Clinical Trials;

- the timing and cost of, and level of investment in, research and development activities relating to our current and any future product candidates, which will change from time to time;
- our ability to enroll subjects in Clinical Studies or Clinical Trials and the timing of enrollment;
- the cost of manufacturing our current and any future product candidates, which may vary depending on FDA guidelines and requirements, the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we may incur to acquire or develop additional product candidates we develop as therapeutics and technologies;
- the timing and outcomes of any Clinical Trials for product candidates and any other future product candidates or competing product candidates;
- competition from existing and potential future products that compete with our current product candidates and any other future product candidates, and changes in the competitive landscape of our industry, including consolidation among our competitors or partners;
- any delays in regulatory review or approval or commercialization of our current product candidates or any other future product candidates;
- the level of demand for our current product candidates and any other future product candidates, if approved, which may fluctuate significantly and be difficult to predict;
- the risk/benefit profile, cost and reimbursement policies with respect to our products, if approved, and existing and potential future products that compete with our current product candidates and any other future product candidates;
- our ability to commercialize our current product candidates and any other future product candidates inside and outside of the United States, either independently or working with third parties;
- our ability to adequately support future growth;
- potential unforeseen business disruptions that increase our costs or expenses;
- future accounting pronouncements or changes in our accounting policies; and
- the changing and volatile global economic environment.

The cumulative effect of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue and/or earnings guidance we may provide.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control, which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

We may evaluate various acquisition opportunities and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including, but not limited to:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;

- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and marketing approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities, and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

Our amended and restated bylaws designate specific courts as the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.

Pursuant to our amended and restated bylaws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Chancery Court does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) will be the sole and exclusive forum for state law claims for (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, employees or agents to us or our stockholders; (iii) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law or our certificate of incorporation or bylaws; (iv) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws; or (v) any action asserting a claim governed by the internal affairs doctrine, which we refer to as the Delaware Forum Provision. The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. Our amended and restated bylaws further provide that, unless we consent in writing to an alternative forum, the United States District Court for the District of Massachusetts will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, which we refer to as the Federal Forum Provision. We have chosen the United States District Court for the District of Massachusetts as the exclusive forum for such Securities Act causes of action because our principal executive offices are located in Cambridge, Massachusetts. In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the Delaware Forum Provision and the Federal Forum Provision.

The forum selection clauses in our amended and restated bylaws may limit our stockholders' ability to obtain a favorable judicial forum for disputes with us. Additionally, these forum selection clauses may limit our stockholders’ ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the United States District Court for the District of Massachusetts may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

General Risk Factors

If securities or industry analysts publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock and its development will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

Pursuant to Section 404 of Sarbanes-Oxley, our management is required to report upon the effectiveness of our internal control over financial reporting. When we lose our status as an "emerging growth company," our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we may need to implement additional financial and management controls, reporting systems and procedures and may need to hire additional accounting and finance staff.

We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by The Nasdaq Global Market, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

We will continue to incur significant increased costs as a result of operating as a public company, and our management is required to devote substantial time to public company compliance initiatives.

As a public company, we will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Exchange Act, as amended, which requires, among other things, that we file with the SEC, annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and The Nasdaq Global Market to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas, such as "say on pay" and proxy access. The rules and regulations applicable to public companies have substantially increased and may further increase our legal and financial compliance costs and to make some activities more time-consuming and costly.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the facts that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Global economic uncertainty and unfavorable global economic conditions caused by political instability, changes in trade agreements and conflicts, such as the conflict between Russia and Ukraine, could adversely affect our business, financial condition, results of operations or prospects.

Our business, financial condition, results of operations or prospects could be adversely affected by general conditions in the global economy and in the global financial markets. A severe or prolonged economic downturn, economic uncertainties in various global markets caused by political instability and conflict, or additional global financial crises, could result in a variety of risks to our business, including weakened demand for our product candidates, if approved, or our inability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

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 17, 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).
10.1*#	Employment Agreement, by and between the Company and Daniel Kirby, dated as of May 26, 2022.
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.)

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

* Filed herewith.

** The certification furnished in Exhibit 32.1 hereto is deemed to accompany this 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: August 12, 2022

By: /s/ William R. Hinshaw, Jr.
William R. Hinshaw, Jr.
President, Chief Executive Officer and Director

AXCELLA HEALTH INC.

Date: August 12, 2022

By: /s/ Robert Crane
Robert Crane
Senior Vice President and Chief Financial Officer

Exhibit 10.1

EMPLOYMENT AGREEMENT

This Employment Agreement ("Agreement") is made as of the 26th Day of May 2022 between Axcella Health Inc., doing business as Axcella Therapeutics, a Delaware corporation (the "Company"), and Daniel Kirby (the "Executive").

WHEREAS, the Company and the Executive are parties to an Employment Agreement dated as of February 16, 2021 (the "Prior Agreement");

WHEREAS, the Company desires to promote the Executive and the Executive desires to be employed by the Company on the terms and conditions contained herein commencing on May 26, 2022, unless another date is agreed to by the parties. The Executive's first day of employment in this new capacity shall be the "Effective Date" of this Agreement; and

WHEREAS, the Company and the Executive desire to enter into this Agreement, which shall supersede, amend and restate in all respects the Prior Agreement;

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree as follows:

1. Employment.

(a) Term. The Company shall employ the Executive and the Executive shall be employed by the Company pursuant to this Agreement commencing as of the Effective Date and continuing until such employment is terminated in accordance with the provisions hereof (the "Term"). The Executive's employment with the Company shall be "at will," meaning that the Executive's employment may be terminated by the Company or the Executive at any time and for any reason subject to the terms of this Agreement.

(b) Position and Duties. During the Term, the Executive shall serve as Senior Vice President, Strategic Operations of the Company and shall have the powers, duties, and authority typically associated and commensurate with such position and such other powers and duties as may from time to time be prescribed by the Chief Executive Officer of the Company (the "CEO"). The Executive shall devote full working time and efforts to the business and affairs of the Company. Notwithstanding the foregoing, the Executive may serve on other boards of directors, with the approval of the Board of Directors of the Company (the "Board"), or engage in religious, charitable or other community activities as long as such services and activities are disclosed to the Board and do not interfere with the Executive's performance of duties to the Company. The Executive has disclosed that they do not serve on or engage in any of the foregoing, and will inform the CEO or Chief People Officer if this changes.

2. Compensation and Related Matters.

(a) Base Salary. During the Term, the Executive's initial annual base salary shall be paid at the rate of $375,000 per year. The Executive's base salary shall be reviewed annually by the Board or the Compensation Committee of the Board (the "Compensation Committee"). The base salary in effect at any given time is referred to herein as "Base Salary." The Base Salary shall be payable in a manner that is consistent with the Company's usual payroll practices for senior executives.

(b) Incentive Compensation. During the Term, the Executive shall be eligible to receive cash incentive compensation as determined by the Board or the Compensation Committee in their sole discretion from time to time. The Executive's target annual incentive compensation shall be 40% percent of the Base Salary (the "Target Bonus"). The Target Bonus pay-out will be prorated based on the Start Date based on the calendar year for the first year of employment. Except as otherwise provided herein, to earn incentive compensation, the Executive must be employed by the Company on the day such incentive compensation is paid.

(c) Expenses. The Executive shall be entitled to receive prompt reimbursement for all reasonable expenses incurred by the Executive during the Term in performing services hereunder, in accordance with the policies and procedures then in effect and established by the Company for its senior executives.

(d) Other Benefits. During the Term, the Executive shall be eligible to participate in or receive benefits under the Company's policies and employee benefit plans in effect from time to time, subject to the terms of such policies and plans and to the Company's ability to amend, modify, replace or terminate such policies and plans, including with respect to paid time off.

(e) Equity. Subject to approval by the Board promptly on or about the Effective Date, the Company shall grant the Executive an option to purchase 40,000 shares of the Company's Common Stock ("Option Award"), par value $0.001 per share ("Shares") with an exercise price per Share equal to the closing trading price per share of the Company's common stock on the Nasdaq Global Market ("FMV") on the date the grant is approved ("Grant Date"). The Option Award shall vest 25% on the first anniversary of the Effective Date, and the remaining 75% of the Option Award shall thereafter vest in equal installments on a quarterly basis over a period of three years following such first anniversary, provided that Executive remains employed by the Company on each vesting day.

In addition, subject to approval by the Board with the Option Award, the Company shall grant the Executive a retention award of an option to purchase 50,000 Shares of the Company's Common Stock ("Retention Award"), with an exercise price per Share equal to the closing trading price per share of the Company's common stock on the Nasdaq Global Market ("FMV") on the Grant Date. The Option Award shall vest 100% on a date 18 months after the Effective Date, provided that Executive remains employed by the Company on such vesting day.

Both the Option Award and the Retention Award are conditioned on Executive's execution of this Agreement, and subject to the terms of and contingent upon Executive's execution of a stock option award agreement issued pursuant to and under the terms of the Axcella Health Inc. 2019 Stock Option and Incentive Plan, as amended from time to time (the "Stock Plan"). To the extent permitted by law and subject to Board approval, the Option Award and Retention Award shall be granted in the form of an incentive stock option meeting the requirements of Section 422 of the Code except to the extent that Executive directs that the Option Award or Retention Award be granted in whole or in part in the form of a non-qualified stock option.

(f) In the case of inconsistency between this Agreement, and the Stock Plan, the provisions of the Stock Plan shall govern; in the case of inconsistency between this Agreement and any stock option award agreement, the provisions of the stock option agreement shall govern.

(g) Remote Working. Executive will be expected to work at Axcella's office located in Cambridge, Massachusetts and may work remotely at times with the approval of the CEO, which approval shall be at the CEO's sole discretion, subject to any applicable laws and regulations, and any Axcella policies with respect to remote working then in effect.

(h) Withholding; Tax Effect. All payments made by the Company to the Executive under this Agreement shall be net of any tax or other amounts required to be withheld by the Company under applicable law. Nothing in this Agreement shall be construed to require the Company to make any payments to compensate the Executive for any adverse tax effect associated with any payments or benefits or for any deduction or withholding from any payment or benefit.

3. Termination. During the Term, the Executive's employment hereunder may be terminated without any breach of this Agreement under the following circumstances:

(a) Death. The Executive's employment hereunder shall terminate upon their death.

(b) Disability. The Company may terminate the Executive's employment if they are disabled and unable to perform the essential functions of the Executive's then existing position or positions under this Agreement with or without reasonable accommodation for a period of 180 days (which need not be consecutive) in any 12-month period. If any question shall arise as to whether during any period the Executive is disabled so as to be unable to perform the essential functions of the Executive's then existing position or positions with or without reasonable accommodation, the Executive may, and at the request of the Company shall, submit to the Company a certification in reasonable detail by a physician selected by the Company to whom the Executive or the Executive's guardian has no reasonable objection as to whether the Executive is so disabled or how long such disability is expected to continue, and such certification shall for the purposes of this Agreement be conclusive of the issue. The Executive shall cooperate with any reasonable request of the physician in connection with such certification. If such question shall arise and the Executive shall fail to submit such certification, the Company's determination of such issue shall be binding on the Executive. Nothing in this Section 3(b) shall be construed to waive the Executive's rights, if any, under existing law including, without limitation, the Family and Medical Leave Act of 1993, 29 U.S.C. §2601 *et seq*. and the Americans with Disabilities Act, 42 U.S.C. §12101 *et seq.*:

(c) Termination by Company for Cause. The Company may terminate the Executive's employment hereunder for Cause. For purposes of this Agreement, "Cause" shall mean: (i) conduct by the Executive constituting a material act of misconduct in connection with the performance of their duties, including, without limitation, misappropriation of funds or property of the Company or any of its subsidiaries or affiliates other than the occasional, customary and de minimis use of Company property for personal purposes; (ii) the commission by the Executive of any felony or a misdemeanor involving moral turpitude, deceit, dishonesty or fraud, or any conduct by the Executive that would reasonably be expected to result in material injury or reputational harm to the Company or any of its subsidiaries and affiliates if their were retained in their position; (iii) willful or negligent failure to perform a material responsibility (other than by reason of the Executive's physical or mental illness, incapacity or disability) as reasonably determined in good faith by the CEO, which has continued for not less than 30 days following written notice from the CEO that identifies the unsatisfactory performance; (iv) a breach by the Executive of any of the provisions contained in the Restrictive Covenants Agreement (as defined below); (v) a material violation by the Executive of the Company's written employment policies; or (vi) failure to cooperate with a bona fide internal investigation or an investigation by regulatory or law enforcement authorities, after being instructed by the Company to cooperate, or the willful destruction or failure to preserve documents or other materials known to be relevant to such investigation or after receipt of a legal notice to preserve documents or other materials or the inducement of others to fail to cooperate or to produce documents or other materials in connection with such investigation or after receipt of a legal notice to preserve documents or other materials.

(d) Termination without Cause. The Company may terminate the Executive's employment hereunder at any time without Cause. Any termination by the Company of the Executive's employment under this Agreement which does not constitute a termination for Cause under Section 3(c) and does not result from the death or disability of the Executive under Section 3(a) or (b) shall be deemed a termination without Cause.

(e) Termination by the Executive. The Executive may terminate their employment hereunder at any time for any reason, including but not limited to Good Reason. For purposes of this Agreement, "Good Reason" shall mean that the Executive has complied with the "Good Reason Process" (hereinafter defined) following the occurrence of any of the following events: (i) a material diminution in the Executive's responsibilities, authority or duties; (ii) a material diminution in the Executive's Base Salary except for across-the-board salary reductions based on the Company's financial performance similarly affecting all or substantially all senior management employees of the Company; (iii) a material change in the geographic location at which the Executive provides services to the Company (relocation of the Company's office that results in an increase in Executive's one-way driving distance by more than 50 miles from Executive's then current principal residence is deemed to be a material change); or (iv) the material breach of this Agreement by the Company. "Good Reason Process" shall mean that (i) the Executive reasonably determines in good faith that a "Good Reason" event has occurred; (ii) the Executive notifies the Company in writing of the first occurrence of the Good Reason event within 60 days of the first occurrence of such event; (iii) the Executive reasonably cooperates in good faith with the Company's efforts, for a period not less than 30 days following such notice (the "Cure Period"), to remedy the event; (iv) notwithstanding such efforts, the Good Reason condition continues to exist; and (v) the Executive terminates their employment within 60 days after the end of the Cure Period. If the Company cures the Good Reason condition during the Cure Period, Good Reason shall be deemed not to have occurred.

(f) Notice of Termination. Except for termination as specified in Section 3(a), any termination of the Executive's employment by the Company or any such termination by the Executive shall be communicated by written Notice of Termination to the other party hereto. For purposes of this Agreement, a "Notice of Termination" shall mean a notice which shall indicate the specific termination provision in this Agreement relied upon.

(g) Date of Termination. "Date of Termination" shall mean: (i) if the Executive's employment is terminated by death, the date of death; (ii) if the Executive's employment is terminated on account of disability under Section 3(b) or by the Company for Cause under Section 3(c), the date on which Notice of Termination is given; (iii) if the Executive's employment is terminated by the Company under Section 3(d), the date on which a Notice of Termination is given or the date otherwise specified by the Company in the Notice of Termination; (iv) if the Executive's employment is terminated by the Executive under Section 3(e) other than for Good Reason, 30 days after the date on which a Notice of Termination is given unless the Company agrees to a shorter time period at the Executive's request, in which case the last sentence of this Section 3(g) shall not apply, and (v) if the Executive's employment is terminated by the Executive under Section 3(e) for Good Reason, the date on which a Notice of Termination is given after the end of the Cure Period. Notwithstanding the foregoing, in the event that the Executive gives a Notice of Termination to the Company, the Company may unilaterally accelerate the Date of Termination and such acceleration shall not result in a termination by the Company for purposes of this Agreement; provided, however, the Company shall continue to provide Executive with the compensation and benefits under Section 2 above and Executive shall continue to vest under any existing option agreement or other stock-based award agreement through the Date of Termination specified in the Notice of Termination as if Executive had remained employed and the Company had not unilaterally accelerated the Date of Termination.

4. Termination Generally. If the Executive's employment with the Company is terminated for any reason, the Company shall pay or provide to the Executive (or to their authorized representative or estate) (i) any Base Salary earned through the Date of Termination, unpaid expense reimbursements (subject to, and in accordance with, Section 2(c) of this Agreement) on or before the time required by law but in no event more than 30 days after the Executive's Date of Termination; and (ii) any vested benefits the Executive may have under any employee benefit plan of the Company through the Date of Termination, which vested benefits shall be paid and/or provided in accordance with the terms of such employee benefit plans (collectively, the "Accrued Benefit").

5. Termination by the Company without Cause or by the Executive for Good Reason. During the Term, if the Executive's employment is terminated by the Company without Cause as provided in Section 3(d), or the Executive terminates their employment for Good Reason as provided in Section 3(e), then the Company shall pay the Executive the Accrued Benefit. In addition, subject to the Executive (i) signing a separation agreement and release in a form and manner satisfactory to the Company, which shall include, without limitation, a general release of claims in favor of the Company and related persons and entities, a reaffirmation of the Executive's post-employment obligations as set forth in this Agreement, and in the Company's sole discretion, a one year noncompetition agreement that includes restrictions no more extensive than the restrictions in Section 8(c) of the Restrictive Covenants Agreement, and shall provide that, if the Executive breaches any of the post-employment obligations, all payment of the Severance Amount shall immediately cease (the "Separation Agreement and Release"), and (ii) the Separation Agreement and Release becoming irrevocable, all within 60 days after the Date of Termination:

(a) the Company shall pay the Executive an amount equal to nine (9) months of the Executive's Base Salary (the "Severance Amount"), provided in the event the Executive is entitled to any payments pursuant to the Restrictive Covenants Agreement, the Severance Amount received in any calendar year will be reduced by the amount the Executive is paid in the same such calendar year pursuant to the Restrictive Covenants Agreement (the "Restrictive Covenants Agreement Setoff"); and

(b) subject to the Executive's copayment of premium amounts at the active employees' rate and the Executive's proper election to receive benefits under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"), the Company shall pay the monthly employer contribution that the Company would have made to provide health insurance to the Executive if the Executive had remained employed by the Company until the earliest of (A) the nine (9) month anniversary of the Date of Termination; (B) the Executive's eligibility for group medical plan benefits under any other employer's group medical plan; or (C) the cessation of the Executive's continuation rights under COBRA; *provided*, *however*, if the Company determines that it cannot pay such amounts without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), then the Company will convert such payments to payroll payments directly to the Executive for the time period specified above. Such payments shall be subject to tax-related deductions and withholdings and paid on the Company's regular payroll dates. For the avoidance of doubt, the taxable payments described above may be used for any purpose, including, but not limited to, continuation coverage under COBRA.

(c) The amounts payable under Section 5(a) shall be paid out in substantially equal installments in accordance with the Company's payroll practice over 9 months commencing within 60 days after the Date of Termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, the Severance Amount shall begin to be paid in the second calendar year by the last day of such 60-day period; provided, further, that the initial payment shall include a catch-up payment to cover amounts retroactive to the day immediately following the Date of Termination. Each payment pursuant to this Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A- 2(b)(2).

(d) Notwithstanding anything to the contrary contained in this Agreement, the Separation Agreement and Release (i) shall not contain any terms or conditions that lessen the rights and benefits to which Executive is entitled under this Agreement, any applicable option agreement or other stock-based award agreement or the Stock Plan or increase Employee's obligations under Section 8 of the Restrictive Covenants Agreement and (ii) shall provide that the following claims are excluded from the Release: (a) any claims or rights which cannot be waived by law, including Executive's right to accrued and unused vacation pay; (b) any claims for the payments and benefits due under this Agreement or claims to enforce rights that accrue under this Agreement following termination of employment; (c) any claims or rights to any vested benefits or vested rights that Executive may have under any employee benefit, retirement, pension or equity plans; (d) non-termination related claims under the Employee Retirement Income Security Act (29 U.S.C. § 1001 et seq.), as amended; (e) any rights and/or claims under the Consolidated Omnibus Budget Reconciliation Act of 1985 ("COBRA") to elect continued group health plan coverage; (f) claims for reimbursement of approved business expenses incurred prior to the Date of Termination; (g) rights, if any, to defense and indemnification from the Company or its insurers for actions taken by Executive in the course and scope of Executive's employment with the Company, including, without limitation, rights of defense and indemnification under the Company's articles of incorporation or bylaws, as a matter of law or under any directors and officers insurance policies or indemnification agreement; (h) any right Executive may have at law to obtain contribution as permitted by law in the event of entry of judgment against Executive as a result of any act or failure to act for which Executive and the Company or its past, present and future trustees, officers, agents, administrators, representatives, employees, affiliates, or insurers are held jointly liable; or (i) any rights and/or claims Executive may have as a shareholder of the Company.

6. Change in Control Payment. The provisions of this Section 6 set forth certain terms of an agreement reached between the Executive and the Company regarding the Executive's rights and obligations upon the occurrence of a Change in Control of the Company. These provisions are intended to assure and encourage in advance the Executive's continued attention and dedication to their assigned duties and their objectivity during the pendency and after the occurrence of any such event. These provisions shall apply in lieu of, and expressly supersede, the provisions of Section 5 regarding severance pay and benefits upon a termination of employment, if such termination of employment occurs within 12 months after the occurrence of the first event constituting a Change in Control (the "Change in Control Period"). The provisions in this Section 6 shall terminate and be of no further force or effect beginning after the Change in Control Period has ended.

(a) Change in Control. During the Term, if during the Change in Control Period, the Executive's employment is terminated by the Company without Cause as provided in Section 3(d) or the Executive terminates their employment for Good Reason as provided in Section 3(e), then, subject to the signing of the Separation Agreement and Release by the Executive and the Separation Agreement and Release becoming irrevocable, during the time frame set forth in the Separation Agreement and Release but in no event more than 60 days after the Date of Termination:

(i) the Company shall pay the Executive a lump sum in cash in an amount equal to 1 times the sum of (A) the Executive's then current Base Salary (or the Executive's Base Salary in effect immediately prior to the Change in Control, if higher) plus (B) the Executive's Target Bonus for the then-current year (the "Change in Control Payment"), provided the Change in Control Payment shall be reduced by the amount of the Restrictive Covenants Agreement Setoff, if applicable, paid or to be paid in the same calendar year; and

(ii) notwithstanding anything to the contrary in any applicable option agreement or other stock-based award agreement, all time-based stock options and other stock-based awards subject to time-based vesting held by the Executive (the "Time-Based Equity Awards") shall immediately accelerate and become fully exercisable or nonforfeitable as of the later of (i) the Date of Termination or (ii) the Effective Date of the Separation Agreement and Release (the "Accelerated Vesting Date"); *provided* that any termination or forfeiture of the unvested portion of such Time-Based Equity Awards that would otherwise occur on the Date of Termination in the absence of this Agreement will be delayed until the Effective Date of the Separation Agreement and Release and will only occur if the vesting pursuant to this subsection does not occur due to the absence of the Separation Agreement and Release becoming fully effective within the time period set forth herein. Notwithstanding the foregoing, no additional vesting of the Time-Based Equity Awards shall occur during the period between the Executive's Date of Termination and the Accelerated Vesting Date; and

(iii) subject to the Executive's copayment of premium amounts at the active employees' rate and the Executive's proper election to receive benefits under COBRA, the Company shall pay the monthly employer contribution that the Company would have made to provide health insurance to the Executive if the Executive had remained employed by the Company until the earliest of (A) the twelve (12) month anniversary of the Date of Termination; (B) the Executive's eligibility for group medical plan benefits under any other employer's group medical plan; or (C) the cessation of the Executive's continuation rights under COBRA; provided, however, if the Company determines that it cannot pay such amounts without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), then the Company will convert such payments to payroll payments directly to the Executive for the time period specified above. Such payments shall be subject to tax- related deductions and withholdings and paid on the Company's regular payroll dates. For the avoidance of doubt, the taxable payments described above may be used for any purpose, including, but not limited to, continuation coverage under COBRA.

(iv) The amounts payable under this Section 6(a) shall be paid or commence to be paid within 60 days after the Date of Termination; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, such payment shall be paid or commence to be paid in the second calendar year by the last day of such 60-day period.

(b) Additional Limitation.

(i) Anything in this Agreement to the contrary notwithstanding, in the event that the amount of any compensation, payment or distribution by the Company to or for the benefit of the Executive, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise, calculated in a manner consistent with Section 280G of the Code and the applicable regulations thereunder (the "Aggregate Payments"), would be subject to the excise tax imposed by Section 4999 of the Code, then the Aggregate Payments shall be reduced (but not below zero) so that the sum of all of the Aggregate Payments shall be $1.00 less than the amount at which the Executive becomes subject to the excise tax imposed by Section 4999 of the Code; provided that such reduction shall only occur if it would result in the Executive receiving a higher After Tax Amount (as defined below) than the Executive would receive if the Aggregate Payments were not subject to such reduction. In such event, the Aggregate Payments shall be reduced in the following order, in each case, in reverse chronological order beginning with the Aggregate Payments that are to be paid the furthest in time from consummation of the transaction that is subject to Section 280G of the Code: (1) cash payments not subject to Section 409A of the Code; (2) cash payments subject to Section 409A of the Code; (3) equity- based payments and acceleration; and (4) non-cash forms of benefits; provided that in the case of all the foregoing Aggregate Payments all amounts or payments that are not subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c) shall be reduced before any amounts that are subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c).

(ii) For purposes of this Section 6(b), the "After Tax Amount" means the amount of the Aggregate Payments less all federal, state, and local income, excise and employment taxes imposed on the Executive as a result of the Executive's receipt of the Aggregate Payments. For purposes of determining the After Tax Amount, the Executive shall be deemed to pay federal income taxes at the highest marginal rate of federal income taxation applicable to individuals for the calendar year in which the determination is to be made, and state and local income taxes at the highest marginal rates of individual taxation in each applicable state and locality, net of the maximum reduction in federal income taxes which could be obtained from deduction of such state and local taxes.

(iii) The determination as to whether a reduction in the Aggregate Payments shall be made pursuant to Section 6(b)(i) shall be made by a nationally recognized accounting firm selected and paid by the Company (the "Accounting Firm"), which shall provide detailed supporting calculations both to the Company and the Executive within 15 business days of the Date of Termination, if applicable, or at such earlier time as is reasonably requested by the Company or the Executive. Any determination by the Accounting Firm shall be binding upon the Company and the Executive.

(c) Definitions. For purposes of this Section 6, the following terms shall have the following meanings:

"Change in Control" shall have the meaning of "Sale Event" as defined in the Stock Plan or any successor plan.

7. Section 409A.

(a) Anything in this Agreement to the contrary notwithstanding, if at the time of the Executive's separation from service within the meaning of Section 409A of the Code, the Company determines that the Executive is a "specified employee" within the meaning of Section 409A(a)(2)(B)(i) of the Code, then to the extent any payment or benefit that the Executive becomes entitled to under this Agreement on account of the Executive's separation from service would be considered deferred compensation otherwise subject to the 20 percent additional tax imposed pursuant to Section 409A(a) of the Code as a result of the application of Section 409A(a)(2)(B)(i) of the Code, such payment shall not be payable and such benefit shall not be provided until the date that is the earlier of (A) six months and one day after the Executive's separation from service, or (B) the Executive's death. If any such delayed cash payment is otherwise payable on an installment basis, the first payment shall include a catch-up payment covering amounts that would otherwise have been paid during the six-month period but for the application of this provision, and the balance of the installments shall be payable in accordance with the original schedule.

(b) All in-kind benefits provided and expenses eligible for reimbursement under this Agreement shall be provided by the Company or incurred by the Executive during the time periods set forth in this Agreement. All reimbursements shall be paid as soon as administratively practicable, but in no event shall any reimbursement be paid after the last day of the taxable year following the taxable year in which the expense was incurred. The amount of in-kind benefits provided, or reimbursable expenses incurred in one taxable year shall not affect the in-kind benefits to be provided or the expenses eligible for reimbursement in any other taxable year (except for any lifetime or other aggregate limitation applicable to medical expenses). Such right to reimbursement or in-kind benefits is not subject to liquidation or exchange for another benefit.

(c) To the extent that any payment or benefit described in this Agreement constitutes "non-qualified deferred compensation" under Section 409A of the Code, and to the extent that such payment or benefit is payable upon the Executive's termination of employment, then such payments or benefits shall be payable only upon the Executive's "separation from service." The determination of whether and when a separation from service has occurred shall be made in accordance with the presumptions set forth in Treasury Regulation Section 1.409A-1(h).

(d) The parties intend that this Agreement will be administered in accordance with Section 409A of the Code. To the extent that any provision of this Agreement is ambiguous as to its compliance with Section 409A of the Code, the provision shall be read in such a manner so that all payments hereunder comply with Section 409A of the Code. Each payment pursuant to this Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2). The parties agree that this Agreement may be amended, as reasonably requested by either party, and as may be necessary to fully comply with Section 409A of the Code and all related rules and regulations in order to preserve the payments and benefits provided hereunder without additional cost to either party.

(e) The Company makes no representation or warranty and shall have no liability to the Executive or any other person if any provisions of this Agreement are determined to constitute deferred compensation subject to Section 409A of the Code but do not satisfy an exemption from, or the conditions of, such Section.

8. Restrictive Covenants Agreement. The terms of the Executive's Restrictive Covenants Agreement in Section 7 of the Prior Agreement are incorporated herein by reference.

9. Litigation and Regulatory Cooperation. During and after the Executive's employment, the Executive shall reasonably cooperate fully with the Company in the defense or prosecution of any claims or actions now in existence or which may be brought in the future against or on behalf of the Company which relate to events or occurrences that transpired while the Executive was employed by the Company. The Executive's full cooperation in connection with such claims or actions shall include, but not be limited to, being available to meet with counsel to prepare for discovery or trial and to act as a witness on behalf of the Company at mutually convenient times. During and after the Executive's employment, the Executive also shall cooperate fully with the Company in connection with any investigation or review of any federal, state or local regulatory authority as any such investigation or review relates to events or occurrences that transpired while the Executive was employed by the Company. The Company shall reimburse the Executive for any reasonable out-of-pocket expenses including reasonable attorney's fees incurred by Executive in connection with the Executive's performance of obligations pursuant to this Section 9.

10. Survival. The provisions of this Agreement shall survive the termination of the Executive's employment to the extent necessary to effectuate the terms contained herein.

11. Background Check. Employment with the Company is conditioned upon successful completion of a background check, which may include background screening by a third-party contractor. The Company reserves the right to conduct such a check in accordance with controlling laws and regulations at any time.

12. Waiver. No waiver of any of Executive's obligations under this Agreement shall be effective unless made in writing by the Company. The failure of the Company to require Executive's performance of any term or obligation of this Agreement, or the waiver of any breach of this Agreement, shall not prevent the Company's subsequent enforcement of such term or obligation or be deemed a waiver of any subsequent breach.

13. Severability. In case any provisions (or portions thereof) contained in this Agreement shall, for any reason, be held invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect the other provisions of this Agreement, and this Agreement shall be construed as if such invalid, illegal or unenforceable provision had never been contained herein. If, moreover, any one or more of the provisions contained in this Agreement shall for any reason be held to be excessively broad as to duration, geographical scope, activity or subject, it shall be construed by limiting and reducing it, so as to be enforceable to the extent compatible with the applicable law as it shall then appear.

14. Choice of Law and Jurisdiction. This Agreement will be deemed to be made and entered into in the Commonwealth of Massachusetts, and will in all respects be interpreted, enforced, and governed under the laws of the Commonwealth of Massachusetts. Executive hereby consents to personal jurisdiction of the state and federal courts situated within Massachusetts for purposes of enforcing this Agreement, and waives any objection that Executive might have to personal jurisdiction or venue in those courts. **ANY ACTION, DEMAND, CLAIM OR COUNTERCLAIM ARISING UNDER OR RELATING TO THIS AGREEMENT OR THE EXECUTIVE'S EMPLOYMENT WITH THE COMPANY, INCLUDING WITHOUT LIMITATION ANY CLAIMS OF DISCRIMINATION ARISING UNDER STATE OR FEDERAL LAW, WILL BE RESOLVED BY A JUDGE ALONE AND EACH OF THE COMPANY AND THE EXECUTIVE WAIVES ANY RIGHT TO A JURY TRIAL THEREOF**.

15. Successor to the Executive. This Agreement shall inure to the benefit of and be enforceable by the Executive's personal representatives, executors, administrators, heirs, distributees, devisees and legatees. In the event of the Executive's death after termination of employment but prior to the completion by the Company of all payments due them under this Agreement, the Company shall continue such payments to the Executive's beneficiary designated in writing to the Company prior to death (or to their estate, if the Executive fails to make such designation).

16. Successor to Company. The Company shall require any successor (whether direct or indirect, by purchase, merger, consolidation or otherwise) to all or substantially all of the business or assets of the Company expressly to assume and agree to perform this Agreement to the same extent that the Company would be required to perform it if no succession had taken place. Failure of the Company to obtain an assumption of this Agreement at or prior to the effectiveness of any succession shall be a material breach of this Agreement.

17. Notices. Any notices, requests, demands and other communications provided for by this Agreement shall be sufficient if in writing and delivered in person or sent by a nationally recognized overnight courier service or by registered or certified mail, postage prepaid, return receipt requested, to the Executive at the last address the Executive has filed in writing with the Company or, in the case of the Company, at its main offices, attention of the Board.

18. Counterparts. This Agreement may be executed in any number of counterparts, each of which when so executed and delivered shall be taken to be an original; but such counterparts shall together constitute one and the same document. Delivery of an executed counterpart's signature page of this Agreement, by facsimile, electronic mail in portable document format (.pdf), or by any other electronic means intended to preserve the original graphic and pictorial appearance of a document, has the same effect as delivery of an executed original of this Agreement.

19. Gender Neutral. This Agreement uses the singular they/them/their pronoun to refer to the neutral gender, non-binary gender, the masculine gender, or the feminine gender, unless the context clearly indicates otherwise.

20. Entire Agreement; Amendment. This Agreement, the Restrictive Covenants Agreement, any applicable option agreement or other stock-based award agreement and the Stock Plan constitute the entire agreement between the Company and Executive with respect to the subject matter hereof, and supersede all prior agreements or understandings, both written and oral, between the Company and Executive with respect to the subject matter hereof, but does not in any way merge with or supersede any other confidentiality, assignment of inventions or other restrictive covenant agreement or obligation entered into by the Company and Executive, which agreements and obligations shall supplement, and shall not limit or be limited by, this Agreement. This Agreement may be amended only in a written agreement executed by a duly authorized officer of the Company and Executive.

[Remainder of page intentionally left blank]

IN WITNESS WHEREOF, the parties have executed this Agreement effective on the date and year first above written.

AXCELLA THERAPEUTICS

By: /s/ William Hinshaw

William Hinshaw

Its: President and Chief Executive Officer

EXECUTIVE

/s/ Daniel Kirby

Daniel Kirby

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 June 30, 2022 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: August 12, 2022

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

I, Robert Crane, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended June 30, 2022 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: August 12, 2022

By: /s/ Robert Crane

Robert Crane
Senior Vice President and Chief Financial Officer
(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 June 30, 2022 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 Robert Crane, Senior Vice President of Finance and Chief Financial Officer 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: August 12, 2022

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

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

Date: August 12, 2022

By: /s/ Robert Crane

Robert Crane
Senior Vice President and Chief Financial Officer
(Principal Financial Officer)