UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2024

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: 001-40558

Akili, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**92-3654772**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
71 Commercial Street, Mailbox 312 Boston, Massachusetts	**02109**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 313-8853

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common stock, $0.0001 par value per share	**AKLI**	**Nasdaq Capital Market**

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

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

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

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

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

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

As of May 7, 2024, the registrant had 78,715,885 shares of common stock, $0.0001 par value per share, outstanding.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q (this "Quarterly Report") contains statements that are forward-looking. All statements other than statements of historical facts are forward-looking statements. This includes, without limitation, statements regarding the financial position, business strategy and the plans and objectives of management for our future operations. These statements constitute projections, forecasts and forward-looking statements, and are not guarantees of performance. Such statements can be identified by the fact that they do not relate strictly to historical or current facts. When used in this Quarterly Report, words such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "strive," "would" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking.

Forward-looking statements in this Quarterly Report and in any document incorporated by reference in this Quarterly Report may include, for example, statements about:

- our ability to achieve and maintain profitability in the future;
- our financial performance and ability to respond to general economic conditions;
- our ability to manage our business in a cost-efficient manner;
- our ability to manage our business as a result of the recent workforce reduction and shift in our strategy announced in April 2024 to focus on supporting our partnership with Shionogi & Co. Ltd. ("Shionogi"), in parallel with our and our board of directors' ("Board") evaluation of potential strategic alternatives;
- our and our Board's ability to complete the evaluation of potential strategic alternatives and to identify, pursue, and complete a transaction on terms that are in the best interests of and favorable to us and our stockholders, if at all;
- our ability to access sources of capital, including debt financing and other sources of capital to finance operations and growth;
- our ability to successfully manage and execute on our transition from a prescription to a non-prescription model;
- our ability to successfully manage and execute on our ongoing efforts to obtain regulatory authorization of EndeavorOTC in adults with ADHD;
- our ability to achieve and maintain market acceptance and adoption of EndeavorRx, EndeavorOTC and any other future digital therapeutics by users;
- our ability to accurately forecast demand for EndeavorRx, EndeavorOTC and any other future products;
- our ability to obtain or maintain access for EndeavorRx, EndeavorOTC and any other future products via the Apple App Store and Google Play;
- the effect of uncertainties related to public health crises;
- our ability to maintain or obtain patent protection and/or the patent rights relating to EndeavorRx, EndeavorOTC and our other product candidates and our ability to protect our intellectual property and prevent third parties from competing against us;
- our ability to successfully manage and continue to support and make available EndeavorRx, EndeavorOTC and any other future products;
- our ability to maintain regulatory authorization for EndeavorRx in the authorized indication, to obtain and maintain regulatory authorization to convert our prescription EndeavorRx product to a non-prescription product, and to obtain and maintain regulatory authorization for EndeavorOTC and any other future products or product candidates, in the U.S. and in foreign markets, and any related restrictions or limitations of an authorized product or product candidate;
- our ability to obtain funding for our operations, including funding necessary to further develop, advance and commercialize EndeavorRx, EndeavorOTC and our other product candidates;
- our ability to retain our key executives and to attract and retain highly skilled employees;
- our ability to identify, in-license or acquire additional technology or product candidates;
- our ability to successfully protect against security breaches and other disruptions to our information technology structure;
- the impact of applicable laws and regulations, whether in the U.S. or foreign jurisdictions, and any changes thereto;

•our ability to successfully compete against other companies developing similar products to our current and potential future product offerings;

•our estimates regarding expenses, capital requirements and needs for additional financing;

•our ability to establish and maintain an effective system of internal controls over financial reporting;

•our ability to regain compliance with the continued listing requirements of the Nasdaq Capital Market ("Nasdaq") and maintain the listing of our securities on Nasdaq;

•the outcome of any legal or governmental proceedings that may be instituted against us; and

•other factors detailed under the section titled "*Risk Factors*".

These forward-looking statements are based on information available as of the date of this Quarterly Report and current expectations, forecasts and assumptions, and involve a number of judgments, risks and uncertainties. Accordingly, forward-looking statements should not be relied upon as representing our views as of any subsequent date, and we do not undertake any obligation to update forward-looking statements to reflect events or circumstances after the date they were made, whether as a result of new information, future events or otherwise, except as may be required under applicable securities laws.

As a result of a number of known and unknown risks and uncertainties, our actual results or performance may be materially different from those expressed or implied by these forward-looking statements. You should not place undue reliance on these forward-looking statements.

RISK FACTORS SUMMARY

Our business is subject to numerous risks and uncertainties, including those highlighted in the section titled "Risk Factors", which illuminate challenges that we face in connection with the successful implementation of our strategy and the growth of our business. The following considerations, among others, may offset our competitive strengths or have a negative effect on our business strategy, which could cause a decline in the price of shares of our securities and result in a loss of all or a portion of your investment:

•We are exploring strategic alternatives that could significantly impact our future operations and financial position. Any strategic alternative process may disrupt our current plans and operations, and we may be unable to recognize any benefits of the strategic alternatives process or a potential strategic transaction. We will incur significant costs related to the strategic alternatives process or a potential strategic transaction.

•We have a history of significant losses and may not be able to achieve or maintain profitability.

•The failure of our digital therapeutics to achieve and maintain market acceptance and adoption by users could have a material adverse effect on our business, prospects, results of operations and financial condition.

•The market for digital therapeutics is new, rapidly evolving, and increasingly competitive, the healthcare industry in the U.S. is undergoing significant structural change, and the demand for digital therapeutics in the U.S. and in markets outside of the U.S. is uncertain, which makes it difficult to forecast demand for our products. As a result, all prospective financial information included herein is subject to change.

•The market opportunities and revenue potential of EndeavorRx and EndeavorOTC and any potential expanded market for EndeavorRx and EndeavorOTC across additional age ranges in ADHD have not been established with precision. We have estimated the sizes and revenue potential of the market opportunities for EndeavorRx, our FDA-authorized product, and for EndeavorOTC, and these market opportunities may be smaller than we estimate.

•Our development programs represent novel and innovative potential therapeutic areas, and negative perception of any product or product candidate that we develop could adversely affect our ability to conduct our business, obtain marketing authorizations or identify alternate regulatory pathways to market for such product candidate.

•Clinical trials conducted by us or by third parties of any of our products or product candidates may fail to produce results necessary to support marketing authorization.

•We face competition, and new products may emerge that provide different or better alternatives for treatment of the conditions that EndeavorRx, EndeavorOTC, if granted marketing authorization, or our future products, if granted marketing authorization, are authorized to treat.

•If we fail to obtain and maintain clearance, de novo classification or approval to market our products and product candidates, including EndeavorRx and EndeavorOTC, or if we are delayed in obtaining such marketing authorizations, our business, prospects, results of operations and financial condition could be materially and adversely affected.

•EndeavorOTC and EndeavorRx are currently available via the Apple App Store® and on Google Play™, and each of our products is supported by third-party infrastructure. If our ability to access these markets or access necessary third-party infrastructure was stopped or otherwise restricted or limited, it could have a material adverse effect on our business, prospects, results of operations and financial condition.

•If we are not able to develop and release new products, or successful enhancements, new features, and modifications to EndeavorOTC, EndeavorRx or any future products, our business, prospects, results of operations and financial condition could be materially and adversely affected.

•We recently transitioned from a single third-party digital pharmacy for the fulfillment of prescriptions to an internally developed in-house distribution system for EndeavorRx. The limited experience we have with this new in-house distribution system may increase the risk that we could have a disruption in the fulfillment of prescriptions for EndeavorRx, which could have a material and adverse effect on our reputation, business, results of operations and financial condition.

•If we are unable to adequately protect and enforce our intellectual property and proprietary technology, obtain and maintain patent protection for our technology and products where appropriate or if the scope of the patent protection obtained is not sufficiently broad, or if we are unable to protect the confidentiality of our trade secrets and know-how, our competitors could develop and commercialize technology and products similar or identical to our products, and our ability to successfully commercialize our technology and products may be impaired.

•If we fail to comply with obligations in the agreements under which we collaborate with or license intellectual property rights from third parties, or otherwise experience disruptions to our business relationships with collaborators or licensors, we could lose rights or the potential benefits of prospective cash payments that are important to our business, such as under the Option and Collaboration Agreement dated December 19, 2018, by and between us and Shionogi, as amended (the “Amended Shionogi Agreement”).

•We will need substantial additional funding, and if we are unable to raise capital when needed or on terms favorable to us, our business, financial condition and results of operations could be materially and adversely affected.

•The amount of our future losses is uncertain and our quarterly and annual operating results may fluctuate significantly or fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

•If we fail to regain compliance with the continued listing requirements of Nasdaq, our common stock could be delisted from Nasdaq, which would adversely affect the liquidity of our common stock and our ability to raise additional capital or enter into strategic transactions.

•Our common stock has been subject to price volatility, low trading volume and large spreads in bid and ask prices quoted by market makers from time to time, which has led to significant fluctuations in the market price of our common stock. Our stockholders may not be able to readily liquidate their investment or may be forced to sell at depressed prices due to low trading volume. If a higher volume active market in our common stock does not develop, our stockholders may be unable to readily sell the shares they hold or may not be able to sell their shares at all.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

AKILI, INC.

Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)
(unaudited)

	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 63,161	$ 75,150
Restricted cash	180	305
Accounts receivable	144	300
Prepaid expenses and other current assets	1,513	2,275
Total current assets	64,998	78,030
Property and equipment, net	835	680
Operating lease right-of-use asset	1,442	1,577
Prepaid expenses and other long-term assets	90	96
Total assets	**$ 67,365**	**$ 80,383**
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	1,101	1,285
Accrued expenses and other current liabilities	1,794	3,326
Deferred revenue	38	100
Operating lease liability	779	756
Note payable, short term	7,500	7,500
Total current liabilities	11,212	12,967
Note payable, long term	1,671	3,445
Operating lease liability, net of current portion	1,528	1,730
Corporate bond, net of bond discount	2,115	2,054
Earn-out liabilities	608	1,632
Other long-term liabilities	23	23
Total liabilities	**17,157**	**21,851**
Commitments and contingencies		
Stockholders' equity		
Common stock, $0.0001 par value: 1,000,000,000 shares authorized; 78,684,864 and 78,356,527 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	8	8
Additional paid-in capital	359,744	358,305
Accumulated deficit	(309,544)	(299,781)
Total stockholders' equity	**50,208**	**58,532**
Total liabilities and stockholders' equity	**$ 67,365**	**$ 80,383**

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

AKILI, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share amounts)
(unaudited)

	Three Months Ended March 31,	
	2024	2023
Revenues	$ 383	$ 113
Cost of revenues	173	137
Gross profit (loss)	210	(24)
Operating expenses:		
Research and development	4,183	6,084
Selling, general and administrative	6,892	13,011
Total operating expenses	11,075	19,095
Operating loss	(10,865)	(19,119)
Other income (expense):		
Other income	667	1,043
Interest expense	(453)	(622)
Change in estimated fair value of earn-out liabilities	888	(2,013)
Total other income (expense)	1,102	(1,592)
Loss before income taxes	(9,763)	(20,711)
Income tax expense	-	-
Net loss	$ (9,763)	$ (20,711)
Unrealized gain on short-term investments	$ —	$ 23
Comprehensive loss	$ (9,763)	$ (20,688)
Net loss	$ (9,763)	$ (20,711)
Weighted average common stock outstanding - basic and diluted	78,526,669	78,079,013
Net loss per share - basic and diluted	$ (0.12)	$ (0.27)

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

AKILI, INC.

Condensed Consolidated Statements of Stockholders' Equity
(In thousands, except share amounts)
(unaudited)

	Three Months Ended March 31, 2024				
	Common Stock		Additional Paid-in	Accumulated	Total
	Shares	Value	Capital	Deficit	Equity
Balance at December 31, 2023	**78,356,527**	**$ 8**	**$ 358,305**	**$ (299,781)**	**$ 58,532**
Stock-based compensation expense	-	-	1,438	-	1,438
Exercise of stock options	204,053	-	1	-	1
Vesting of RSUs	124,284	-	-	-	-
Net loss	-	-	-	(9,763)	(9,763)
Balance at March 31, 2024	**78,684,864**	**$ 8**	**$ 359,744**	**$ (309,544)**	**$ 50,208**

	Three Months Ended March 31, 2023					
	Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total
	Shares	Value	Capital	Deficit	Income (Loss)	Equity
Balance at December 31, 2022	**78,022,924**	**$ 8**	**$ 350,980**	**$ (240,288)**	**$ (21)**	**$ 110,679**
Stock-based compensation expense	-	-	2,449	-	-	2,449
Exercise of stock options	16,713	-	-	-	-	-
Vesting of RSUs	78,161	-	-	-	-	-
Other comprehensive income	-	-	-	-	23	23
Net loss	-	-	-	(20,711)	-	(20,711)
Balance at March 31, 2023	**78,117,798**	**$ 8**	**$ 353,429**	**$ (260,999)**	**$ 2**	**$ 92,440**

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

AKILI, INC.

Condensed Consolidated Statements of Cash Flows
(In thousands)
(unaudited)

	Three Months Ended March 31,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (9,763)	$ (20,711)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	75	77
Reduction in the carrying amount of right-of-use assets	135	169
Stock-based compensation expense	1,302	2,759
Amortization of premium on short-term investments	-	(432)
Non cash interest expense	162	194
Change in fair value of earn-out liabilities	(888)	2,013
Changes in operating assets and liabilities:		
Accounts receivable	156	(8)
Prepaid expenses and other current assets	776	1,079
Prepaid expenses and other long-term assets	6	(1)
Accounts payable	(184)	(1,268)
Accrued expenses and other current liabilities	(1,532)	(2,788)
Operating lease liabilities	(179)	(195)
Deferred revenue	(62)	14
Net cash used in operating activities	(9,996)	(19,098)
Cash flows from investing activities:		
Acquisition of property and equipment	(3)	(3)
Capitalized software development costs	(227)	-
Purchases of short-term investments	-	(22,082)
Proceeds from maturities of short-term investments	-	75,000
Net cash provided by (used in) investing activities	(230)	52,915
Cash flows from financing activities:		
Proceeds from exercise of stock options	1	-
Taxes paid related to net share settlement of share-based awards	(14)	(45)
Repayment of principal on note payable	(1,875)	-
Net cash used in financing activities	(1,888)	(45)
Net increase (decrease) in cash, cash equivalents, and restricted cash	(12,114)	33,772
Cash, cash equivalents, and restricted cash at beginning of period	75,455	54,402
Cash, cash equivalents, and restricted cash at end of period	$ 63,341	$ 88,174
Supplementary Information:		
Cash paid for interest	$ 310	$ 422

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

1. Nature of the Business and Basis of Presentation

Organization

Akili, Inc. (collectively referred to with its wholly-owned, controlled subsidiaries, as "Akili" or the "Company") operates as one business segment and is a leading digital medicine company, pioneering the development of cognitive treatments through game-changing technologies. Akili's approach of leveraging technologies designed to directly target the physiology of the brain has established a new category of medicine—medicine that is validated through clinical trials like a drug or medical device, but experienced like entertainment. In June 2020, EndeavorRx, the first product built on Akili's platform, was granted marketing authorization and classified as a Class II medical device by the U.S. Food and Drug Administration ("FDA") through FDA's de novo process. EndeavorRx is indicated for use to improve attention function for children ages 8-17 with primarily inattentive or combined-type ADHD, who have a demonstrated attention issue, following the Company's receipt of FDA authorization in December 2023 for the expanded EndeavorRx label to include older children ages 13-17. In June 2023, the Company released EndeavorOTC, which is built on the same platform as EndeavorRx, nationwide without a prescription to improve attention function, ADHD symptoms and quality of life in adults 18 years of age and older with primarily inattentive or combined-type ADHD, under the FDA guidance entitled "*Enforcement Policy for Digital Health Devices for Treating Psychiatric Disorders During the Coronavirus Disease 2019 Public Health Emergency*" (the "COVID-19 Guidance"). The COVID-19 Guidance allows for the marketing of certain digital therapeutics without premarket clearance, de novo classification, or approval so long as certain criteria are met for the duration of the COVID-19 Guidance, which was expected to remain in effect until November 7, 2023 consistent with FDA guidance entitled "*Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency*" (the "COVID-19 Transition Guidance"). The COVID-19 Transition Guidance allows for the continued distribution of devices falling under the COVID-19 Guidance without marketing authorization so long as the manufacturer has submitted a marketing submission to FDA, the submission has been accepted by FDA prior to November 7, 2023 and FDA has not taken a final action on the marketing submission. While EndeavorOTC has not been authorized by FDA for any indications, the Company submitted a marketing submission to FDA for EndeavorOTC on October 30, 2023. Through guidance from FDA regarding the COVID-19 Transition Guidance, it was clarified that marketing submissions received by FDA on or before November 7, 2023, that pass their technical review after the deadline without being placed on submission hold will still be eligible for continued enforcement discretion. Pursuant to FDA's guidance on this topic, and given that the Company has since passed FDA's technical review and has not been placed on submission hold, the Company is continuing to distribute and make EndeavorOTC available under the COVID-19 Guidance. In April 2024, the Company announced an amended agreement with Shionogi & Co. Ltd. ("Shionogi"), as well as the Company and the Company's board of directors' (the "Board") ongoing process to evaluate potential strategic alternatives. As a result of the Company's announcements and the related workforce reduction of approximately 46% of the Company's employees, the Company's efforts are primarily focused on supporting Shionogi's regulatory and commercialization activities, continuing to support current users of its EndeavorRx and EndeavorOTC products and make its products available for purchase, and continuing to pursue regulatory authorization from FDA for EndeavorOTC in adults with ADHD. The Company is headquartered in Boston, Massachusetts.

On August 19, 2022, (the "Closing Date"), Social Capital Suvretta Holdings Corp. I ("SCS") consummated the previously announced merger pursuant to the Agreement and Plan of Merger (the "Merger Agreement"), dated January 26, 2022, by and among SCS, Akili Interactive Labs, Inc. and Karibu Merger Sub, Inc., pursuant to which Karibu Merger Sub, Inc. merged with and into Akili Interactive Labs, Inc., with Akili Interactive Labs, Inc. becoming a wholly owned subsidiary of SCS (the "Business Combination"). Upon the closing of the Business Combination (the "Closing"), SCS changed its name to Akili, Inc. Akili, Inc. (formerly SCS) is a Delaware corporation incorporated on December 1, 2020. Akili Interactive Labs, Inc. is a Delaware corporation incorporated on December 1, 2011.

Going Concern

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations and the need to obtain additional financing. The Company requires a significant amount of capital to fund its current operating requirements based on its shift in corporate strategy announced in late April 2024. The Company's efforts are primarily focused on supporting Shionogi's regulatory and commercialization activities, continuing to support current users of its EndeavorRx and EndeavorOTC products and make its products available for purchase, and continuing to pursue regulatory authorization from FDA for EndeavorOTC in adults with ADHD.

There can be no assurance that the Company's product development and substantially reduced commercialization efforts will be successful; that adequate protection for the Company's intellectual property will be obtained; that any products developed will obtain necessary government regulatory authorization; or that any products will be commercially viable. Even if the Company's product development and limited commercialization efforts are successful, it is uncertain when, if ever, the Company will generate significant

revenue from product sales. The Company operates in an environment of rapid change in technology and substantial competition from pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees and consultants.

The Company's condensed consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities in the ordinary course of business. The Company has experienced negative operating cash flows for the three months ended March 31, 2024 and had an accumulated deficit of $309,544 at March 31, 2024. The Company believes that its cash and cash equivalents at March 31, 2024 of $63,161, will be sufficient to fund the Company's planned operations and existing obligations for at least one year after the date of this Quarterly Report.

The future viability of the Company is dependent on its ability to generate cash from operating activities and manage liquidity by maintaining reduced operating expenses. The Company may also seek to raise additional capital to finance its operations. The Company's failure to generate cash from operating activities or to raise capital when needed, or on terms favorable to the Company, could have a negative impact on its financial condition and ability to execute on its shift in corporate strategy announced in late April 2024.

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") and include the accounts of the Company, after elimination of all intercompany accounts and transactions. As permitted for interim reporting, certain footnotes or other financial information that are normally required by U.S. GAAP may be condensed or omitted, unless otherwise required by U.S. GAAP or Securities and Exchange Commission ("SEC") rules and regulations. These condensed consolidated financial statements were prepared on the same basis as and should be read in conjunction with the Company's annual consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023 (the "Annual Report"). In the opinion of management, all adjustments of a normal recurring nature, considered necessary for fair presentation, have been included in these condensed consolidated financial statements. The results of operations for the three months ended March 31, 2024 are not necessarily indicative of the results to be expected for the year ending December 31, 2024 or for any other interim period or future year. The condensed consolidated balance sheet as of December 31, 2023 was derived from the audited annual consolidated financial statements but does not include all information required by U.S. GAAP for annual consolidated financial statements.

2. Summary of Significant Accounting Policies

The Company's significant accounting policies are disclosed in the audited consolidated financial statements for the year ended December 31, 2023, included in the Annual Report. There have been no material changes to the significant accounting policies during the three months ended March 31, 2024.

Earn-Out Liabilities: In connection with the Business Combination, holders of Legacy Akili common stock, Legacy Convertible Preferred Stock and warrants to purchase shares of Legacy Akili common stock ("Earn-Out Shareholders") and employees or individual service providers holding options to purchase shares of Legacy Akili common stock, in each case as designated by the Board of Akili as an earn-out service provider prior to the Closing Date ("Earn-Out Service Providers") received the contingent right to receive additional Common Stock upon the achievement of certain earn-out targets (the "Rights"). The Company concluded the issuance of Rights to Earn-Out Shareholders constitutes a deemed dividend and evaluated the Rights for classification under guidance applicable to financial instruments. In assessing classification, the Company considered ASC Subtopic 815-40 "*Contracts in Entity's Own Equity*" and determined the Rights contain settlement provisions that preclude them from being indexed to the Company's stock and accordingly liability classification is required. The Company concluded issuance of the Rights to Earn-Out Service Providers represents compensation in scope of ASC Topic 718, "*Compensation - Stock Compensation.*" In considering relevant classification guidance, the Company determined the Rights issued to Earn-Out Service Providers are liabilities because they are indexed to whether such Earn-Out Service Providers hold qualifying equity instruments when the earn-out targets are achieved. The fair value of the contingent earn-out consideration is estimated as of the Closing Date at the present value of the expected contingent earn-out consideration using a Monte Carlo Simulation Method ("MCSM"). The Company reviews the probability of achievement of the earn-out targets to determine the impact on the fair value of the earn-out consideration on a quarterly basis over the earn-out period. For Earn-Out Shareholders, the corresponding fair value was initially recorded against additional paid-in capital. Changes in the estimated fair value of the contingent earn-out consideration related to Earn-Out Shareholders are recorded in other income (expense) in the Consolidated Statements of Operations and Comprehensive Loss and are reflected in the period in which they are identified. For Earn-Out Service Providers, the corresponding fair value was initially recorded within operating expenses in the same functional category as the grantees' operating expenses. Changes in the estimated fair value of contingent earn-out consideration related to Earn-Out

(dollars in thousands, except share and per share amounts)

Service Providers is recorded as stock compensation for the period. Changes in the estimated fair value of the contingent earn-out consideration may materially impact or cause volatility in the Company's operating results.

Revenue: The Company generates revenue from contracts with caregivers and patients who purchase subscriptions to access EndeavorRx ("Clients"), the Company's FDA-authorized video game treatment. Clients are billed in advance for the entire subscription term (new subscriptions are currently for 30 days). Along with the subscription to the video game product, Clients also receive reporting metrics and technical support services. The reporting metrics rely on gameplay data being sent back from EndeavorRx, which the Company analyzes in order to provide information on daily efforts and level completion to Clients throughout the subscription term via the EndeavorRx Insight app. The subscription to the video game product, reporting metrics and technical support services are combined as a single stand-ready performance obligation because these elements are not considered distinct in the context of the contract with the customer. Accordingly, the consideration is recognized ratably on an over time basis over the subscription period which begins once the access code is inputted into the game by the Client and game play has started.

The Company generates revenue from customers who purchase EndeavorOTC subscriptions of variable term lengths (currently available as three months, six months or one year) to access the video game treatment. Customers are billed in advance for the entire applicable subscription term. Along with the subscription to the video game treatment, the customers also receive technical support services and access to software updates. The technical support services and access to software updates were determined to be immaterial in the context of the contract primarily due to the fact that the underlying selective stimulus management engine ("SSME") technology is not being updated throughout the subscription term, and therefore the primary functionality of the product is not changed during the term of the arrangement. As EndeavorOTC has significant stand-alone functionality that can be used immediately upon delivery, the performance obligation is considered complete upon delivery and all of the consideration is recognized at that point in time.

The following table presents the Company's revenue by product type:

	Three Months Ended March 31,	
	2024	2023
EndeavorOTC revenue	$254	$—
EndeavorRx revenue	129	113
Total	$383	$113

There was no collaboration revenue in either period.

As of March 31, 2024, the Company has a contract liability related to EndeavorRx product revenue, which consists of amounts that have been paid but have not been recognized as revenue. All amounts are expected to be recognized as revenue within 12 months of the balance sheet date and are classified as current deferred revenue. The Company recognized $80 of product revenue in the three months ended March 31, 2024 that was previously included in the December 31, 2023 deferred revenue balance.

Contract Liabilities	Product
Balance at December 31, 2023	$ 100
Revenue recognized	129
Revenue deferred	(191)
Balance at March 31, 2024	$ 38

Cost of revenue: Cost of revenue includes personnel and related costs, third party contractor expenses, customer support costs, royalties, amortization of capitalized software related to our two commercialized products and subscription portal, and software subscriptions related to our products and hosting fees. Sales of EndeavorOTC incur Apple App Store and Google Play fees, both of which are included in cost of revenue. As the Company controls the product until it is transferred to the customer, it is considered the principal in the arrangement and all revenue and cost of revenue is shown gross in the Condensed Consolidated Statements of Operations and Comprehensive Loss.

(dollars in thousands, except share and per share amounts)

3. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	March 31, 2024	December 31, 2023
Accrued bonus	$ 454	$ 2,355
Accrued royalties	139	150
Accrued wages and benefits	136	200
Accrued clinical study expenses	19	12
Accrued consulting service expenses	45	129
Other accrued expenses	1,001	480
Total	$ 1,794	$ 3,326

4. Corporate Bond

In March 2019, in connection with Shionogi exercising its option to enter into a collaboration agreement with the Company, the Company issued a $5,000 corporate bond to Shionogi for cash (the “Corporate Bond”). The Corporate Bond is unsecured and is subordinated to the obligations of the Company under indebtedness for borrowed money owed by the Company to any bank or other financial institution.

The Company recognized amortization expense of $61 and $54 related to the discount on the Corporate Bond as a component of interest expense in the condensed consolidated statements of operations and comprehensive loss for the three months ended March 31, 2024 and 2023, respectively.

The carrying amount of the corporate bond is as follows:

	March 31, 2024	December 31, 2023
Corporate Bond	$ 5,000	$ 5,000
Unamortized discount on Corporate Bond	(2,885)	(2,946)
Corporate Bond, net of discount	$ 2,115	$ 2,054

See Note 9 for a description of the Shionogi Amendment entered into by the Company and Shionogi effective as of April 26, 2024, pursuant to which the Corporate Bond was canceled and forgiven by Shionogi.

5. Note Payable

Amended and Restated Loan and Security Agreement

At March 31, 2024, the Company had outstanding principal of $8,750 and there is no remaining available undrawn debt. The Company recognized non-cash interest expense related to debt issuance costs of $101 and $139 for the three months ended March 31, 2024 and 2023, respectively. The Company recognized selling, general and administrative expense related to loan commitment fees of $0 and $42 for the three months ended March 31, 2024 and 2023, respectively. The interest rate in effect was 12.3% and 11.8% as of March 31, 2024 and 2023, respectively. At March 31, 2024, the carrying amount of the note payable (excluding the current portion of $7,500) is as follows:

Outstanding principal	$ 8,750
Note payable, short term	(7,500)
Final payment	750
Unamortized debt issuance costs	(329)
Note payable, long term (net of debt issuance costs)	$ 1,671

(dollars in thousands, except share and per share amounts)

Future minimum principal payments due under the Amended and Restated Loan and Security Agreement, excluding the final payment of $750 due at maturity, prepayment or termination, are as follows:

Years Ending December 31,	
Remainder of 2024	5,625
2025	3,125
Total	$ 8,750

See Note 9 for a description of the Company's May 8, 2024 repayment in full of the outstanding principal, outstanding interest, and final payment under, and full termination of, the Amended and Restated Loan and Security Agreement, including agreement to terminate the associated liens on Company assets.

6. Stock-Based Compensation

2022 Stock Option and Incentive Plan: Share-based compensation expense related to stock options, RSUs, PSUs, and the expense related to Earn-Out Service Providers, is classified in the condensed consolidated statements of operations and comprehensive loss as follows:

	Three Months Ended March 31,	
	2024	2023
Research and development	$ 670	$ 879
Selling, general and administrative	632	1,880
Total	$ 1,302	$ 2,759

Included in the three months ended March 31, 2024 and 2023 balances in the table above is $(136) and $310, respectively, of stock-based compensation related to the potential issuance of the Earn-Out Shares to Earn-Out Service Providers.

Stock Options: The following is a summary of stock option activity for the three months ended March 31, 2024:

	Number of Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance at December 31, 2023	14,591,753	$ 2.94	7.31	
Granted	66,000	$ 0.25		
Cancelled	(513,456)	$ 2.09		
Exercised	(207,238)	$ 0.01		
Balance at March 31, 2024	13,937,059	$ 3.00	7.11	$ 3
Exercisable March 31, 2024	7,738,868	$ 3.81	5.57	$ —
Options vested and expected to vest, March 31, 2024	13,937,059	$ 3.00	7.11	$ 3

The fair value of all option activity was estimated at the date of grant using a Black-Scholes model with the following weighted-average assumptions for the three months ended March 31, 2024 and 2023:

	Three Months Ended March 31,	
	2024	2023
Fair value of Common Stock	$ 0.25	$ 1.56
Expected volatility	102.89%	99.24%
Expected term (in years)	5.83	6.13
Risk-free interest rate	4.23%	3.87%
Expected dividend yield	0.00%	0.00%

(dollars in thousands, except share and per share amounts)

The weighted average grant-date fair value of stock options granted to employees during the three months ended March 31, 2024 and 2023 was $0.21 and $1.26 per share, respectively.

During the three months ended March 31, 2024 and 2023, the aggregate intrinsic value of stock option awards exercised was $54 and $26, respectively. Aggregate intrinsic value represents the difference between the exercise price and the fair value of the underlying Common Stock on the date of exercise.

As of March 31, 2024 there was $8,666 of unrecognized compensation cost related to unvested stock option grants to employees under the 2022 Plan, which is expected to be recognized over a weighted-average period of 2.0 years.

Restricted Stock Units: The following table summarizes RSU activity for the three months ended March 31, 2024:

	Number of RSUs		Weighted-Average Grant Date Fair Value
Balance at December 31, 2023	2,998,837	$	0.89
Granted	16,000	$	0.32
Vested	(129,530)	$	1.77
Forfeited	(113,917)	$	0.87
Balance at March 31, 2024	2,771,390	$	0.85

As of March 31, 2024 there was $2,096 of unrecognized compensation cost related to unvested RSUs under the 2022 Plan, which is expected to be recognized over a weighted-average period of 2.2 years.

Performance Stock Units: The following table summarizes PSU activity for the three months ended March 31, 2024:

	Number of PSUs		Weighted-Average Grant Date Fair Value
Balance at December 31, 2023	2,028,134	$	1.50
Granted	—		n/a
Vested	—		n/a
Forfeited	(284,650)	$	1.50
Balance at March 31, 2024	1,743,484	$	1.50

As of March 31, 2024, there was $1,254 of unrecognized compensation cost related to unvested PSUs, which is expected to be recognized over a weighted average period of approximately 1.4 years.

7. Fair Value of Financial Assets and Liabilities

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

	Fair Value Measurements as of March 31, 2024			
Description	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents:				
Money market funds	$ 50,252	$ -	$ -	$ 50,252
Liabilities				
Long-term liabilities:				
Earn-out liabilities	$ -	$ -	$ 608	$ 608

(dollars in thousands, except share and per share amounts)

	Fair Value Measurements as of December 31, 2023			
Description	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents:				
Money market funds	$ 61,539	$ -	$ -	$ 61,539
Liabilities				
Long-term liabilities:				
Earn-out liabilities	$ -	$ -	$ 1,632	$ 1,632

The Company evaluates transfers between levels at the end of each reporting period. There were no transfers of financial instruments between levels during the three months ended March 31, 2024.

As of March 31, 2024 and December 31, 2023, the Company's cash equivalents consisted of money market funds with original maturities of less than 90 days from the date of purchase.

Earn-out liabilities — Upon the Closing, the Earn-Out Shares were accounted for as a liability because the triggering events that determine the number of shares to be earned (the "Triggering Events") included events that were indexed to the Common Stock of the Company. The estimated fair value of the Earn-out liabilities is determined at each reporting period using a Monte Carlo Simulation Method ("MCSM").

	Earn-Out Shareholders	Earn-Out Service Providers	Total
Fair value as of December 31, 2023	$ 1,415	$ 217	$ 1,632
Change in fair value	(888)	(136)	(1,024)
Fair value as of March 31, 2024	$ 527	$ 81	$ 608

The following assumptions were used at March 31, 2024:

Price target: price target as defined in the Merger Agreement for each Triggering Event:

- Triggering Event I is $15.00 per share
- Triggering Event II is $20.00 per share
- Triggering Event III is $30.00 per share

Current stock price: the closing stock price as quoted on Nasdaq as of March 31, 2024 was $0.29.

Expected term: the expected term is 3.4 years as of March 31, 2024, which is the remaining term of the earn-out period.

Expected volatility: the volatility rate as of March 31, 2024 was 122.5%. The volatility rate was determined using an average of historical volatilities over the expected term of selected industry peers deemed comparable to the Company.

Expected dividend yield: the expected dividend yield is zero as it is not expected that the Company will declare dividends on Common Stock during the expected term.

8. Net Loss Per Share

The computation of basic net loss per share is based on the weighted-average number of our common shares outstanding. The computation of diluted net loss per share is based on the weighted-average number of our common shares outstanding and potential dilutive common shares during the period as determined by the treasury stock method. The following table summarizes the computation of basic and diluted net loss per share attributable to common stockholders of the Company:

(dollars in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2024	2023
Numerator:		
Net loss attributable to common stockholders - basic and diluted	$ (9,763)	$ (20,711)
Denominator:		
Weighted average common stock outstanding - basic and diluted	78,526,669	78,079,013
Net loss per share attributable to common stockholders - basic and diluted	$ (0.12)	$ (0.27)

The following potentially dilutive outstanding securities were excluded from the computation of diluted net loss per share attributable to common stockholders because their effect would have been anti-dilutive or issuance of such shares is contingent upon the satisfaction of certain conditions which were not satisfied by the end of the period:

	Three Months Ended March 31,	
	2024	2023
Warrants to purchase Common Stock	133,578	133,578
Stock options to purchase Common Stock	13,937,059	12,773,849
Earn-out shares	7,536,461	7,536,461
Unvested RSUs	2,771,390	1,645,948
Unvested PSUs	1,743,484	4,554,408
Total	26,121,972	26,644,244

9. Subsequent Events

Shionogi

Akili Interactive Labs, Inc., a wholly owned subsidiary of the Company (“Akili Interactive Labs”), and Shionogi previously entered into a December 2018 Option and Collaboration Agreement (as previously amended, the “Shionogi Agreement”) pursuant to which Akili Interactive Labs and Shionogi agreed to collaborate in the clinical development and commercialization of certain Company digital therapeutic products in Japan and Taiwan. On April 26, 2024, Akili Interactive Labs and Shionogi entered into a further amendment (the “Shionogi Amendment”, and such date the “Amendment Effective Date”) to the Shionogi Agreement, modifying certain payment terms and obligations.

The Shionogi Amendment modified the financial terms of the Shionogi Agreement to provide for the following:

- Shionogi will pay Akili Interactive Labs $10.5 million within 30 business days of the Amendment Effective Date, in consideration for the elimination of (i) all future royalty payments that had been provided for under the Shionogi Agreement and (ii) certain future regulatory and sales milestone payments that had been provided for under the Shionogi Agreement.

- In consideration for Akili Interactive Labs entering into the Shionogi Amendment, and effective as of the Amendment Effective Date, Shionogi and Akili Interactive Labs canceled the $5.0 million Corporate Bond previously issued by Akili Interactive Labs to Shionogi and terminated the corresponding bond subscription agreement, resulting in the elimination of all Akili Interactive Labs repayment obligations under such Corporate Bond.

- Akili Interactive Labs is entitled to receive up to a total of $3.5 million from Shionogi by the end of 2025 in consideration of certain development and support services to be performed by Akili Interactive Labs, as well as an additional $1.0 million from Shionogi payable in the event that Akili Interactive Labs delivers to Shionogi an updated version of SDT-001 within 11 months of the Amendment Effective Date. Of the above $3.5 million, at least $1.5 million shall be paid to Akili Interactive Labs within 30 business days of the Amendment Effective Date.

- Akili Interactive Labs is entitled to receive up to a total of $3.0 million from Shionogi in potential regulatory milestone payments.

Restructuring

On April 30, 2024, the Company announced a restructuring of its operations and a reduction in its workforce as part of the Company and the Board's ongoing process of evaluating potential strategic alternatives. As a result of the restructuring, the Company expects to incur a restructuring charge associated primarily with severance and other benefits related to 31 employees, representing approximately 46% of the employee base at the time of the restructuring across different areas and functions. The Company estimates the severance and restructuring-related costs associated with the restructuring will be approximately $2.3 - $2.8 million and such costs are expected to be recorded in the quarter ended June 30, 2024. The Company expects that payment of most of these costs will be paid in 2024.

SVB Debt Repayment

On May 8, 2024, the Company, Silicon Valley Bank ("SVB") and SVB Innovation Credit Fund VIII, L.P. entered into a payoff letter (the "Payoff Letter") for a voluntary prepayment with respect to the Amended and Restated Loan and Security Agreement, dated May 25, 2021 (the "SVB Loan Agreement"). Pursuant to the Payoff Letter, the Company paid a total of approximately $8.3 million to SVB, representing the outstanding principal, accrued and unpaid interest, final payment and fees due to SVB under the SVB Loan Agreement, all facilities thereunder and related loan documents, in repayment of the Company's outstanding obligations under the SVB Loan Agreement, all facilities thereunder and related loan documents, and thereby terminated the SVB Loan Agreement, all facilities thereunder and related loan documents.

Pursuant to the Payoff Letter, SVB's commitments to extend further credit to the Company terminated; SVB agreed to release and terminate all liens or security interests granted to secure the obligations under the SVB Loan Agreement and the Company was unconditionally released from its respective guaranties and obligations under the SVB Loan Agreement, all facilities thereunder and related loan documents without further action (other than with respect to customary provisions and agreements that are expressly specified to survive the termination).

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

The following discussion and analysis of the financial condition and results of operations of Akili, Inc. and its consolidated subsidiaries should be read together with Akili's unaudited condensed consolidated financial statements as of March 31, 2024 and for the three months ended March 31, 2024 and 2023, together with the related notes thereto, included elsewhere in this Quarterly Report. The discussion and analysis should also be read together with the audited consolidated financial statements as of and for the years ended December 31, 2023 and 2022 included in our Annual Report on Form 10-K for the year ended December 31, 2023 (the "Annual Report"). This discussion contains forward-looking statements and involves numerous risks and uncertainties, including, but not limited to, those described under the heading "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in this Form 10-Q. All references to years, unless otherwise noted, refer to our fiscal years, which end on December 31. Akili Interactive Labs, Inc. became a wholly owned subsidiary of Akili, Inc. on August 19, 2022. For purposes of this section, all references to "we," "us," "our," "Akili" or the "Company" refer to Akili, Inc. and its consolidated subsidiaries.

Overview

Akili is a leading digital medicine company, pioneering the development of cognitive treatments through game-changing technologies. Our approach of leveraging technologies designed to directly target the physiology of the brain has established a new category of medicine—medicine that is validated through clinical trials like a drug or medical device, but experienced like entertainment. In June 2020, EndeavorRx, the first product built on our platform, was granted marketing authorization and classified as a Class II medical device by the U.S. Food and Drug Administration ("FDA") through FDA's de novo process. EndeavorRx is indicated for use to improve attention function for children ages 8-17 with primarily inattentive or combined-type ADHD, who have a demonstrated attention issue. The indication was expanded from children ages 8-12 to include older children ages 13-17 following our receipt of FDA authorization in December 2023 for the expanded EndeavorRx label. In June 2023, we released EndeavorOTC, which is built on the same platform as EndeavorRx, nationwide without a prescription to improve attention function, ADHD symptoms and quality of life in adults 18 years of age and older with primarily inattentive or combined-type ADHD, under the FDA guidance entitled "*Enforcement Policy for Digital Health Devices for Treating Psychiatric Disorders During the Coronavirus Disease 2019 Public Health Emergency*" (the "COVID-19 Guidance"). The COVID-19 Guidance allows for the marketing of certain digital therapeutics without premarket clearance, de novo classification, or approval so long as certain criteria are met for the duration of the COVID-19 Guidance, which was expected to remain in effect until November 7, 2023 consistent with FDA guidance entitled "*Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency*" (the "COVID-19 Transition Guidance"). The COVID-19 Transition Guidance allows for the continued distribution of devices falling under the COVID-19 Guidance without marketing authorization so long as the manufacturer has submitted a marketing submission to FDA, the submission has been accepted by FDA prior to November 7, 2023 and FDA has not taken a final action on the marketing submission. While EndeavorOTC has not been authorized by FDA for any indications, we submitted a marketing submission to FDA for EndeavorOTC on October 30, 2023. Through guidance from FDA regarding the COVID-19 Transition Guidance, it was clarified that marketing submissions received by FDA on or before November 7, 2023, that pass their technical review after the deadline without being placed on submission hold are eligible for continued enforcement discretion. Pursuant to FDA's guidance on this topic, and given that we have since passed FDA's technical review and have not been placed on submission hold, we are continuing to distribute and make EndeavorOTC available under the COVID-19 Guidance. We are headquartered in Boston, Massachusetts.

Recent Developments

On April 30, 2024, we announced an amendment (the "Shionogi Amendment") to the Option and Collaboration Agreement dated December 19, 2018 with Shionogi, as amended (together with the Shionogi Amendment, the "Amended Shionogi Agreement"). Under the terms of this Amended Shionogi Agreement, Shionogi has canceled and forgiven our $5.0 million long-term debt obligation under the Corporate Bond and agreed to make certain payments for SDT-001 (the Japanese, localized version of our AKL-T01 digital treatment, marketed as EndeavorRx® in the United States). We will receive an upfront payment of $10.5 million in consideration for the elimination of future royalty payments and certain future milestone payments and will also be eligible to receive up to a total of $4.5 million from Shionogi in consideration of our development and support services, with at least $1.5 million of such services fees payable up front, and up to a total of $3.0 million from Shionogi in potential regulatory milestone payments. SDT-001 is currently under marketing approval review in Japan as a potential digital treatment for children and adolescents with ADHD.

In parallel, we announced that our Board has initiated a process that is currently ongoing to evaluate potential strategic alternatives to maximize shareholder value. As a part of this evaluation of strategic alternatives, we also announced a restructuring to lower operating expenses while focusing on supporting Shionogi's regulatory and commercialization activities. Our workforce was reduced by

approximately 46% including an elimination of the Company's marketing and medical affairs teams. In conjunction with this restructuring, we have substantially reduced promotional activity for our EndeavorRx and EndeavorOTC products.

As a result, our efforts are primarily focused on supporting Shionogi's regulatory and commercialization activities, continuing to support current users of our EndeavorRx and EndeavorOTC products and make our products available for purchase, and continuing to pursue regulatory authorization from FDA for EndeavorOTC in adults with ADHD, which remains under review, in parallel with exploration of broader strategic options. Further development of our pipeline outside of ADHD will be contingent upon a number of factors, including the outcome of our and our Board's evaluation of strategic alternatives.

On May 8, 2024, as further detailed in Part II, Item 5. of this Quarterly Report, we, Silicon Valley Bank ("SVB") and SVB Innovation Credit Fund VIII, L.P. entered into a payoff letter (the "Payoff Letter") for a voluntary prepayment with respect to the Amended and Restated Loan and Security Agreement, dated May 25, 2021 (the "SVB Loan Agreement"). Pursuant to the Payoff Letter, we paid a total of approximately $8.3 million to SVB, representing the outstanding principal, accrued and unpaid interest, final payment and fees due to SVB under the SVB Loan Agreement, all facilities thereunder and related loan documents, in repayment of the Company's outstanding obligations under the SVB Loan Agreement, all facilities thereunder and related loan documents, and thereby terminated the SVB Loan Agreement, all facilities thereunder and related loan documents.

Key Commercial Metrics for EndeavorOTC

We have historically reported certain commercial metrics for EndeavorOTC. In light of our recently announced restructuring and substantially reduced promotional activity for our products, and our and our Board's exploration of potential strategic alternatives, we no longer intend to report these metrics for EndeavorOTC as we no longer believe that they provide useful information to investors and others in understanding and evaluating our business and results of operations.

Development Pipeline and Commercial Update

Our limited development efforts and significantly reduced commercialization efforts are primarily focused on ADHD in adults and in children ages 8-17. Within ADHD, on the commercial side, in June 2023 we released EndeavorOTC in the Apple App Store in the United States and in September 2023 we released EndeavorOTC on Android devices in Google Play, in each case under the FDA's COVID-19 Guidance.

With respect to our ongoing partnership with Shionogi, in February 2024, Shionogi announced its submission of a marketing approval application for SDT-001 to Japan's Ministry of Health, Labour, and Welfare, for commercialization and sale in Japan. The submission for marketing approval in Japan is based on the results of the Phase 3 clinical trial conducted by Shionogi in Japan in pediatric ADHD patients. In addition, on April 30, 2024, we announced our entry into the Amended Shionogi Agreement, described above.

Our current pipeline of clinical development programs includes investigator-initiated studies.

Our efforts are primarily focused on supporting Shionogi's regulatory and commercialization activities, continuing to support current users of our EndeavorRx and EndeavorOTC products and making our products available for purchase, and continuing to pursue regulatory authorization from FDA for EndeavorOTC in adults with ADHD, in parallel with exploration of broader strategic options. Further development of our pipeline outside of ADHD will be contingent upon a number of factors, including the outcome of our and our Board's evaluation of strategic alternatives.

Factors Affecting Our Performance and Results of Operations

We believe that our performance and future success depend on many factors that present significant opportunities for us, but also pose risks and challenges, including those discussed below and in the "*Risk Factors*" section of this Quarterly Report.

Product Revenue

To date, we have not generated significant product revenue from the sale of EndeavorRx prescriptions and EndeavorOTC subscriptions. Revenue from sales of our products is difficult to predict and is not expected to substantially reduce Akili's continued operating losses resulting from our commercial efforts and research and development activities for the foreseeable future, particularly given the recently announced elimination of our marketing and medical affairs teams and substantial reduction in promotional activity for our EndeavorRx and EndeavorOTC products.

Product revenue from our existing products, as well as potential future product candidates, is and will be impacted by many factors, including product adoption and pricing.

Product Adoption

To grow our business, we will need to manage and execute on our transition from a prescription to a non-prescription model. We believe this new consumer-led subscription model will remove barriers to adoption, such as reliance on payers or the need for a prescription, and enable us to meet customer needs directly to grow the business. Given our substantial reduction in promotional activity, we may not be successful in demonstrating the benefits of our products and may not achieve the support of customers, and as a result, we anticipate that our sales may decline and/or we may fail to increase our revenue.

Pricing

In the future, we may decide to expand the pricing options available with offers spanning multiple tiers as well as various patient populations. In the future, our products may be subject to competition which may impact our pricing and in addition, our prescription products may be subject to legislative prescription-pricing practices.

As a result of our transition to a non-prescription model (beginning with our efforts to pursue regulatory authorization from FDA for our EndeavorOTC product for adults with ADHD) and in light of the corporate updates announced in April 2024, we do not anticipate actively pursuing conversations with commercial insurers and government payers regarding reimbursement coverage for our treatments. However, we plan to continue to support caregivers and patients interested in our EndeavorRx pediatric ADHD product. Patients may not be able to adopt or may choose not to adopt our prescription digital therapeutic if they are unable to obtain adequate third-party coverage or reimbursement.

Currently, EndeavorOTC is available through direct purchase via the Apple App Store, Google Play or our subscription portal.

Collaboration Revenue

We currently have the Amended Shionogi Agreement with Shionogi and pursuant to the Shionogi Amendment, we will receive an upfront payment of $10.5 million in consideration for the elimination of future royalty payments and certain future milestone payments. We will also be eligible to receive up to a total of $4.5 million from Shionogi in consideration of our development and support services, with at least $1.5 million of such service fees payable up front, and up to a total of $3.0 million from Shionogi in potential regulatory milestone payments.

If our development efforts for existing products or additional programs are successful and result in regulatory marketing authorization or collaboration or license agreements with third parties, we may generate revenue in the future from collaboration or license agreements that we may enter into with third parties. We cannot predict if, when or to what extent we may enter into future licensing or collaboration agreements. Further, we may never succeed in obtaining regulatory authorization for EndeavorOTC or additional indications for EndeavorRx or any of our product candidates that are currently under development or for any other future products.

Cost of Product Revenue

Cost of product revenue consists primarily of costs that are closely correlated or directly related to the delivery of our EndeavorRx and EndeavorOTC products, including personnel and related costs, third party contractor expenses, customer support costs, royalties, amortization of capitalized software related to our commercialized products and software subscriptions related to our products and hosting fees. Sales of EndeavorRx incurred pharmacy dispense fees and sales of EndeavorOTC incur Apple App Store and Google Play fees, which are also included in cost of product revenue. With the termination of our digital pharmacy agreement, effective in late October 2023, pharmacy dispense fees for EndeavorRx have ended as we have transitioned to an in-house direct distribution system for the processing and fulfillment of EndeavorRx. Fees charged by the app stores are between 15% and 30% of the sales price and are dependent on certain revenue thresholds. Accordingly, we expect the overall cost of product revenue to decrease given the recently announced elimination of our marketing and medical affairs teams and substantial reduction in promotional activity for our EndeavorRx and EndeavorOTC products.

Research and Development Expenses

Following the May 2023 announcement of topline results of the STARS-ADHD-Adult clinical trial, in June 2023 we released EndeavorOTC, which is built on the same SSME technology platform as our EndeavorRx product, nationwide without a prescription to improve attention function, ADHD symptoms and quality of life in adults 18 years of age and older with primarily inattentive or combined-type ADHD under the FDA's COVID-19 Guidance. We submitted a marketing submission to FDA for EndeavorOTC on October 30, 2023 and we plan to continue to pursue regulatory authorization from FDA for our EndeavorOTC product.

Following the June 2023 release of EndeavorOTC, in September 2023 we announced a new strategic plan to transition our business from a prescription to a non-prescription model. In April 2024, we announced a reprioritization of our efforts in connection with the Amended Shionogi Agreement, exploration of strategic alternatives, and a workforce reduction of approximately 46% of our employee population including the elimination of our marketing and medical affairs team and a substantial reduction in our promotional activity for EndeavorOTC and EndeavorRx. While our focus is primarily on supporting Shionogi, we plan to continue to

support existing customers using our EndeavorOTC product and our one FDA-authorized product, EndeavorRx, which is indicated for use to improve attention function for children ages 8-17 with primarily inattentive or combined-type ADHD who have a demonstrated attention issue, following our receipt of FDA authorization in December 2023 for the expanded EndeavorRx label to include older children ages 13-17.

Developing products requires a significant investment of resources over a prolonged period of time, and we plan to continue making investments in this area, particularly in connection with the Amended Shionogi Agreement. We have chosen to leverage our SSME technology, which is the therapeutic engine that targets and activates systems in the brain that play a key role in attention function, to focus on advancing our R&D activities on expanded patient populations within ADHD.

Our efforts are primarily focused on supporting Shionogi's regulatory and commercialization activities, continuing to support current users of our EndeavorRx and EndeavorOTC products and make our products available for purchase, and continuing to pursue regulatory authorization from FDA for EndeavorOTC in adults with ADHD, which remains under review, in parallel with exploration of broader strategic options. As a result, our R&D expenses decreased in the three months ended March 31, 2024, and we expect R&D expenses to decrease during the remainder of 2024.

R&D expenses consist of costs incurred in performing R&D activities, which include:

- personnel-related expenses, including salaries, bonuses, benefits and stock-based compensation for employees engaged in R&D functions;
- expenses incurred in connection with the development of our developmental and clinical pipeline;
- cost of clinical trials;
- cost of regulatory submissions, reviews, and associated external consultants;
- expenses incurred in connection with the discovery and development of our products, including under agreements with third parties, such as consultants;
- expenses incurred under agreements with consultants who supplement our internal capabilities, including software development; and
- facilities, depreciation and other expenses, which include direct and allocated expenses, such as rent and maintenance of facilities and other operating costs.

In addition to our ADHD programs, our R&D activities include investigator-initiated studies. Further development of our pipeline outside of ADHD will be contingent upon a number of factors, including the outcome of our and our Board's evaluation of strategic alternatives.

Development activities for our product candidates have a number of risks and uncertainties. All therapeutic development activities have risks and probabilities of success that can vary by disease indication. Each of our product candidates have technical, clinical, regulatory and commercial risk. See the section entitled "*Risk Factors—Risks Relating to our Products and Product Candidates*."

We expense R&D costs as incurred and do not track the costs at a project level. Advance payments that we make for goods or services to be received in the future for use in R&D activities are recorded as prepaid expenses. The prepaid amounts are expensed as the benefits are consumed. In the early phases of development, our R&D costs are often devoted to product platform and proof-of-concept studies that are not necessarily allocable to a specific product.

Selling, General and Administrative Expenses

Selling, general and administrative ("SG&A") expenses consist primarily of compensation for personnel, including stock-based compensation, related to commercial, marketing, executive, finance and accounting, legal, information technology, corporate and business development, human resource functions and impairments of right-of-use assets. Other SG&A expenses include marketing-related expenses (including advertising, marketing partners and materials, market research and analysis), software expenses, travel expenses, professional services fees (including legal, patent, accounting, audit, tax and consulting fees), insurance costs, amortization of issuance costs on undrawn debt, general corporate expenses and allocated certain payroll and facilities-related expenses, including payroll taxes, benefits, rent and facility maintenance.

We expect our commercialization-related expenses to continue to decrease for the remainder of 2024 due to our April 2024 announcement regarding the elimination of our marketing and medical affairs teams and the substantial reduction in promotional activity for our products. We plan to continue to support current users of our EndeavorRx and EndeavorOTC products and make our products available for purchase, and to continue to pursue regulatory authorization from FDA for EndeavorOTC in adults with ADHD.

Other income (expense)

Other income consists of interest earned on cash balances held in interest-bearing accounts. We expect that our other income will fluctuate in future periods based on the timing and ability to raise additional funds as well as the amount of expenditures on our commercial products, R&D and ongoing business operations.

Interest expense includes interest due on the note payable, accretion of the corporate bond discount and note payable debt issuance costs, which will decline given the Amended Shionogi Agreement executed on April 26, 2024 and the related cancellation and forgiveness of the Corporate Bond, as well as our full repayment and termination of our debt facility with SVB on May 8, 2024.

Change in fair value of earn-out liabilities includes the change in fair value during each period presented of the earn-out liabilities related to Earn-Out Shareholders.

Income taxes

Our income tax provision consists of an estimate for U.S. federal and state income taxes based on enacted rates, as adjusted for allowable credits, deductions, uncertain tax positions, changes in deferred tax assets and liabilities and changes in tax law. The provision for income taxes for 2024 and 2023 is immaterial because Akili has historically incurred net operating losses and maintains a full valuation allowance against its deferred tax assets.

Results of Operations

Three Months Ended March 31, 2024 and 2023

The table and discussion below present the results for the periods indicated:

	Three Months Ended March 31,			
(dollars in thousands, except percentages)	**2024**	**2023**	**$ Change**	**% Change**
Revenues	$ 383	$ 113	$ 270	239 %
Cost of revenues	173	137	36	26 %
Gross profit (loss)	210	(24)	234	*
Operating expenses:				
Research and development	4,183	6,084	(1,901)	-31 %
Selling, general and administrative	6,892	13,011	(6,119)	-47 %
Total operating expenses	11,075	19,095	(8,020)	-42 %
Operating loss	(10,865)	(19,119)	8,254	-43 %
Other income (expense):				
Other income	667	1,043	(376)	-36 %
Interest expense	(453)	(622)	169	-27 %
Change in estimated fair value of earn-out liabilities	888	(2,013)	2,901	*
Total other income (expense)	1,102	(1,592)	2,694	*
Loss before income taxes	(9,763)	(20,711)	10,948	-53 %
Income tax expense	-	-	-	*
Net loss	$ (9,763)	$ (20,711)	$ 10,948	-53 %
Unrealized gain on short-term investments	$ —	$ 23	$ (23)	-100 %
Comprehensive loss	$ (9,763)	$ (20,688)	$ 10,925	-53 %

* Percentage change not meaningful

Revenue—Revenue was $0.4 million and $0.1 million for the three months ended March 31, 2024 and 2023, respectively. There was an increase in revenue from the same period in the prior year primarily due to an increase in product revenue from sales of EndeavorOTC, which was released in June 2023.

Cost of revenue—Cost of revenue was $0.2 million and $0.1 million for the three months ended March 31, 2024 and 2023, respectively. There was an increase in product-related costs of revenue in the three months ended March 31, 2024 due to the increased sales volume.

Research and development—R&D expenses were $4.2 million and $6.1 million for the three months ended March 31, 2024 and 2023, respectively. Most expenses in the current period are related to the development of and updates to the EndeavorOTC product and most expenses in the prior period are related to the development of our SSME platform, which is the therapeutic engine that targets and activates systems in the brain that play a key role in attention function and is the underlying technology used in both our EndeavorRx and EndeavorOTC products. The decrease of $1.9 million was primarily due to the following:

- a decrease of $1.5 million of personnel-related expenses primarily due to the lower headcount from the restructurings, partially offset by severance payments, which decreased the expense from $4.9 million in the three months ended March 31, 2023 to $3.4 million in the three months ended March 31, 2024;
- a decrease of $0.4 million of clinical studies and expenses due to the timing of our clinical trials and the restructuring of our business to preserve capital and focus primarily on commercializing EndeavorOTC in ADHD, which resulted in the reprioritization of our pipeline of preclinical and clinical development programs. As a result, clinical studies and expenses decreased from $0.6 million in the three months ended March 31, 2023 to $0.2 million in the three months ended March 31, 2024;
- a decrease of $0.1 million of computer equipment and software expenses due to a decrease in software subscriptions, which decreased the expense from $0.3 million in the three months ended March 31, 2023 to $0.2 million in the three months ended March 31, 2024; and
- an increase of $0.1 million related to various other expenses such as an increase in external consulting fees related to new game features, which increased the expense from $0.3 million for the three months ended March 31, 2023 to $0.4 million for the three months ended March 31, 2024.

Selling, general and administrative—SG&A expenses were $6.9 million and $13.0 million for the three months ended March 31, 2024 and 2023, respectively. The decrease of $6.1 million was primarily due to the following:

- a decrease of $6.1 million in personnel-related costs, primarily due to the restructurings related to certain SG&A personnel resulting in a 58% decrease in headcount for the three months ended March 31, 2024 compared to the three months ended March 31, 2023;
- a decrease of $0.9 million related to various other expenses. The decrease is primarily driven by decreases in business insurance and costs associated with the sales force, which did not exist during the three months ended March 31, 2024;
- a decrease of $0.1 million in consulting, legal, accounting and other professional service costs; and
- an increase of $1.0 million in marketing and advertising costs.

Other income—Other income was $0.7 million and $1.0 million in the three months ended March 31, 2024 and 2023, respectively. The decrease was due to a decrease in the amount of cash held in an interest bearing account.

Interest expense—Interest expense was $0.5 million and $0.6 million in the three months ended March 31, 2024 and 2023, respectively. The $0.1 million decrease was primarily related to the decreasing SVB principal balance outstanding during the three months ended March 31, 2024.

Change in estimated fair value of earn-out liabilities—The Company accounts for the potential issuance of the Earn-Out Shares to Earn-Out Shareholders as a contingent consideration arrangement. The Company estimated the fair value at inception and revalued the earn-out liabilities as of each quarter end. The change in the fair value of the earn-out liabilities related to Earn-Out Shareholders is recorded in other income (expense) on the statement of operations each quarter.

Income taxes—We did not incur material income tax expenses for the three months ended March 31, 2024 or 2023. Given our lack of prior earnings history, we have a full valuation allowance primarily related to our net operating losses and R&D credit carryforwards that we do not consider more likely than not to be realized.

Liquidity and Capital Resources

Since our inception, our primary sources of capital have been proceeds from sales of convertible preferred stock, payments received in connection with the Collaboration Agreement, proceeds from borrowings under various credit facilities and proceeds from the Business Combination.

For the three months ended March 31, 2024 and 2023, we incurred net operating losses of $10.9 million and $19.1 million, respectively.

As of March 31, 2024, we had an accumulated deficit of $309.5 million. As of March 31, 2024, we had outstanding debt of $11.3 million, net of debt issuance costs and debt discount. As of March 31, 2024, we had cash and cash equivalents of $63.2 million.

Our cash flows may fluctuate and are difficult to forecast and will depend on many factors. The revenue from the sale of our EndeavorRx and EndeavorOTC products at the present time is not sufficient to cover operating costs incurred. Our ability to achieve sufficient revenue to cover our costs is highly dependent on achieving and maintaining broad market acceptance by customers of our non-prescription model, which may be particularly challenging in light of the significant reduction in promotional activity for our products. We expect to continue to generate operating losses and negative operating cash flows for the foreseeable future.

In May 2021, we entered into the SVB Loan Agreement with SVB and SVB Innovation Credit Fund VIII, L.P., (the "SVB Term Loan"). On March 10, 2023, SVB was closed by the California Department of Financial Protection and Innovation, and the FDIC was appointed as receiver. On March 13, 2023, pursuant to a joint statement released by the U.S. Department of Treasury, the U.S. Federal Reserve, and the FDIC, the U.S. government provided assurance that all depositors would be fully protected. Thereafter, the FDIC transferred all deposits of SVB to a newly created bridge bank, SVBB, which announced that it would fully honor existing credit facilities. On March 27, 2023, First Citizens BancShares, Inc. entered into an agreement with the FDIC to purchase all assets and liabilities of SVB and confirmed it would fully honor existing credit facilities. As of March 31, 2024, there was $8.8 million outstanding under the SVB Term Loan facility and there is no remaining available undrawn debt; the SVB Term Loan was repaid in full and the SVB Loan Agreement with SVB was terminated, effective May 8, 2024. Additionally, the corporate bond issued with Shionogi in March 2019 had $5.0 million outstanding as of March 31, 2024, however the balance was cancelled and forgiven by Shionogi in April 2024 as part of the Amended Shionogi Agreement.

Our primary uses of capital are, and we expect will continue to be for the near future, personnel costs, costs of product development particularly with respect to costs related to supporting the Amended Shionogi Agreement, costs related to our EndeavorOTC product, legal, patent and other regulatory expenses and general overhead costs. We may also pursue acquisitions, investments, joint ventures and other strategic transactions, and we also may incur significant additional costs in connection with the strategic alternatives process.

We may need substantial additional funding to pursue our shift in corporate strategy announced in late April 2024 and to support continuing operations. Until such time as we can generate significant revenue to fund operations, we expect to use proceeds from the Business Combination and issuance of equity, debt financings or other capital transactions. We may be unable to increase our revenue, raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our products, product candidates and other strategic initiatives. See - "*Funding Requirements*".

Cash and cash equivalents

Our cash and cash equivalents balance as of March 31, 2024 was $63.2 million. Our future capital requirements may vary from those currently planned and will depend on various factors, including the timing and extent of R&D spending, the timing and extent of spending incurred in connection with supporting the Amended Shionogi Agreement, development and commercialization of our EndeavorRx and EndeavorOTC products, and spending on other strategic business initiatives such as the strategic alternatives process.

Liquidity Risks

We expect to incur additional expenditures in the near term to support our ongoing activities, including supporting Shionogi's regulatory and commercialization activities, continuing to support current users of our EndeavorRx and EndeavorOTC products and make our products available for purchase, and continuing to pursue regulatory authorization from FDA for EndeavorOTC in adults with ADHD, which remains under review, in parallel with exploration of broader strategic alternatives, and continuing to operate as a public company. We expect to continue to incur net losses for the foreseeable future. Our ability to fund our product development and clinical operations as well as commercialization of EndeavorOTC will depend on the amount and timing of cash available to fund operations. Our future liquidity and capital funding requirements will depend on numerous factors, including:

- the outcome of and costs associated with our and our Board's evaluation of potential strategic alternatives;
- our revenue growth;
- our ability to successfully manage and execute on our strategy to advance EndeavorOTC for adults;
- our ability to obtain and maintain user adoption and retention of our products;
- the amount and timing of sales and other revenues from our products and any other future product candidates, if approved, including the sales price;

- the effectiveness of our substantially reduced promotional activity for our products;
- our R&D efforts;
- the emergence and effect of competing or complementary products;
- the outcome, timing and cost of obtaining and maintaining regulatory authorizations for any of our products or product candidates and of meeting regulatory requirements established by the FDA, or comparable foreign regulatory authorities;
- our timing and ability to fulfill the obligations under the Amended Shionogi Agreement and the timing and ability of Shionogi to achieve regulatory milestones under the Amended Shionogi Agreement;
- the progress, timing, scope and costs of our preclinical studies, clinical trials, potential future clinical trials and other related activities;
- the costs of commercialization activities for any of our products or product candidates that receive marketing authorization, including the costs and timing of establishing product sales, marketing and hosting capabilities, or entering into strategic collaborations with third parties to leverage or access these capabilities;
- the cash requirements of any future discovery of product candidates;
- our ability to retain our current employees and any future need to hire additional management and marketing, technical and medical personnel; and
- the extent to which we acquire or invest in business, products or technology.

A change in the outcome of any of these or other variables with respect to the development of any of our products or any other future product candidates could significantly change the costs and timing associated with the sale of our products or the development of any other future product candidates. Further, our operating plans may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such operating plans. See "*Risk Factors—Risks Related to our Financial Reporting and Position.*"

Because of the numerous risks and uncertainties associated with the development and commercialization of our products or any other future product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated product development and commercialization programs.

Cash Flows

The following table provides a summary of cash flow data for each applicable period:

	Three Months Ended March 31,	
	2024	2023
	(in thousands)	
Net cash used in operating activities	$ (9,996)	$ (19,098)
Net cash provided by (used in) investing activities	(230)	52,915
Net cash used in financing activities	(1,888)	(45)
Net increase (decrease) in cash	$ (12,114)	$ 33,772

Net Cash Used in Operating Activities

Three Months Ended March 31, 2024 and 2023

Net cash used in operating activities was $10.0 million for the three months ended March 31, 2024. Net cash used in operating activities consists of net loss of $9.8 million, adjusted for non-cash items and the effect of changes in working capital. Non-cash adjustments primarily include decreases related to the change in estimated fair value of earn-out liabilities of $0.9 million, offset by increases related to stock-based compensation expense of $1.3 million and non-cash interest expense of $0.2 million. There was an additional decrease to net loss of $1.0 million related to the change in operating assets and liabilities primarily due to a reduction in accrued expenses from the payout of the annual corporate bonus and decrease in accounts payable due to lower external spend, partially offset by a decrease in prepaid insurance and clinical trials.

Net cash used in operating activities was $19.1 million for the three months ended March 31, 2023. Net cash used in operating activities consists of net loss of $20.7 million, adjusted for non-cash items and the effect of changes in working capital. Non-cash adjustments primarily include a decrease related to amortization of premium on short-term investments of $0.4 million, stock-based

compensation expense of $2.8 million, change in estimated fair value of earn-out liabilities of $2.0 million, and non-cash interest expense of $0.2 million. There was an additional decrease to net loss of $3.2 million related to the change in operating assets and liabilities primarily due to an accrued bonus as of December 31, 2022 that was paid out in the three months ended March 31, 2023.

Net Cash Provided by (Used in) Investing Activities

Three Months Ended March 31, 2024 and 2023

Net cash used in investing activities was $0.2 million for the three months ended March 31, 2024. The cash was related to capitalized software development costs.

Net cash provided by investing activities was $52.9 million for the three months ended March 31, 2023. The cash was related to the proceeds from maturities of short-term investments, partially offset by cash used to purchase short-term investments.

Net Cash Used in Financing Activities

Three Months Ended March 31, 2024 and 2023

Net cash used in financing activities was $1.9 million for the three months ended March 31, 2024 and consisted of the repayment of principal on the note payable and taxes paid related to net share settlements of share-based awards.

Net cash used in financing activities was less than $0.1 million for the three months ended March 31, 2023 and consisted of taxes paid related to net share settlements of share-based awards.

Funding Requirements

We believe that our cash and cash equivalents at March 31, 2024 will be sufficient to fund our planned operations and existing obligations for at least one year after the date of this Quarterly Report. However, we have based this belief on assumptions that may prove to be wrong, and we could exhaust our capital resources sooner than we expect.

Please see the section in this Quarterly Report, titled "*Risk Factors—Risks Related to our Financial Reporting and Position—We will need substantial additional funding, and if we are unable to raise capital when needed or on terms favorable to us, our business, financial condition and results of operations could be materially and adversely affected*" for additional risks associated with our substantial capital requirements.

Corporate Bond

In March 2019, in connection with Shionogi exercising its option to enter into the Option and Collaboration Agreement (as amended, now referred to as the Amended Shionogi Agreement), we issued a $5.0 million corporate bond to Shionogi for cash. In consideration for entering into the Shionogi Amendment in April 2024, the bond subscription agreement and corporate bond were cancelled, resulting in the elimination of all Akili Interactive Labs repayment obligations under such corporate bond.

Debt Financing and Covenants

At March 31, 2024, the Company had outstanding principal of $8.8 million under the SVB Term Loan facility and there was no remaining available undrawn debt. The SVB Term Loan bears interest through maturity at a per annum rate of the greater of (a) the Wall Street Journal Prime Rate plus 3.75% and (b) 7.0%. As of March 31, 2024, the interest rate was 12.3%. We were required to make interest-only payments through May 2023, and starting in June 2023 we began to repay the outstanding principal in 24 equal monthly payments.

The SVB Term Loan facility was repaid in full and the SVB Loan Agreement with SVB was terminated, effective May 8, 2024.

See Note 10, *Note Payable,* of the notes to Akili's consolidated financial statements for the years ended December 31, 2023 and 2022, included in the Annual Report, and Note 5, *Note Payable*, of the notes to Akili's unaudited condensed consolidated financial statements for the three months ended March 31, 2024, included elsewhere in this Quarterly Report, for further information. In the future, we may seek to obtain other additional sources of financing, including incurring term debt or issuing equity or issuing debt securities.

Contractual Obligations

Akili entered into a membership agreement which provides access to office space in Boston, Massachusetts, which will expire in December 2024. Akili also leases office space in Larkspur, California, under a non-cancelable operating lease that expires in November 2026. We enter into agreements in the normal course of business with various vendors, which are generally cancelable upon notice. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including non-cancellable obligations of service providers, up to the date of cancellation.

See Note 7, Commitments and Contingencies, of the notes to Akili's consolidated financial statements for the years ended December 31, 2023 and 2022 included in the Annual Report, for further information.

During the periods presented, Akili did not have any relationships with unconsolidated organizations or financial partnerships, such as structured finance or special purpose entities, established for the purpose of facilitating off-balance sheet arrangements.

Emerging Growth Company Status (JOBS Act)

We are an "emerging growth company," or EGC as defined in the Jumpstart Our Business Startups ("JOBS") Act. Pursuant to the JOBS Act, an EGC is provided the option to adopt new or revised accounting standards that may be issued by Financial Accounting Standards Board ("FASB") or the SEC either (i) within the same periods as those otherwise applicable to non-emerging growth companies or (ii) within the same time periods as private companies. Akili has elected to take advantage of the exemption for complying with new or revised accounting standards within the same time periods as private companies. Accordingly, the information contained in our SEC filings may be different than the information you receive from other public companies.

Akili also has elected to take advantage of some of the reduced regulatory and reporting requirements applicable to EGCs pursuant to the JOBS Act so long as it qualifies as an EGC, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation and exemptions from the requirements of holding non-binding advisory votes on executive compensation and golden parachute payments.

Recent Accounting Pronouncements

See Note 2, *Summary of Significant Accounting Policies*, of the notes to Akili's consolidated financial statements for the years ended December 31, 2023 and 2022 included in the Annual Report, for more information about recent accounting pronouncements, the timing of their adoption, and our assessment, to the extent we have made one, of the potential impact on our financial condition and results of operations.

Summary of Critical Accounting Policies and Significant Judgements and Estimates

The preparation of our consolidated financial statements in conformity with United States generally accepted accounting principles ("U.S. GAAP") requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities in the consolidated financial statements and accompanying notes. We base these estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying amounts of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from these estimates. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and the related disclosure of contingent assets and liabilities. We monitor our estimates on an ongoing basis for changes in facts and circumstances, and material changes in these estimates could occur in the future. Changes in estimates are recorded in the period in which they become known. We base our estimates on historical experience and other assumptions that we believe to be reasonable under the circumstances. Actual results may differ from our estimates if past experience or other assumptions do not turn out to be substantially accurate.

We have identified the policies below as critical to our business operations and the understanding of our results of operations. The impact and any associated risks related to these policies on our business operations are discussed throughout this section captioned "*Akili's Management's Discussion and Analysis of Financial Condition and Results of Operations*" where such policies affect our reported and expected financial results. For a detailed discussion on the application of these and other accounting policies, see Note 2 to Akili's consolidated financial statements for the years ended December 31, 2023 and 2022, included in the Annual Report.

Earn-Out Liabilities

We concluded that the issuance of Rights to Earn-Out Shareholders constitutes a deemed dividend and evaluated the Rights for classification under guidance applicable to financial instruments. In assessing classification, we considered ASC Subtopic 815-40 "*Contracts in Entity's Own Equity*" and determined the Rights contain settlement provisions that preclude them from being indexed to our stock and accordingly liability classification is required. We concluded issuance of the Rights to Earn-Out Service Providers

represents compensation in scope of ASC Topic 718, "*Compensation - Stock Compensation."* In considering relevant classification guidance, we determined the Rights issued to Earn-Out Service Providers are liabilities because they are indexed to whether such Earn-Out Service Providers hold qualifying equity instruments when the earn-out targets are achieved. The fair value of the contingent earn-out consideration is estimated as of the acquisition date at the present value of the expected contingent payments using a Monte Carlo Simulation Method ("MCSM"), which uses the following assumptions: price targets, current stock price, risk-free interest rate, expected term, expected volatility, and expected dividend yield. The fair value estimates use unobservable inputs that reflect our own assumptions as to our ability to meet the earn-out targets and discount rates used in the calculations. The unobservable inputs are defined in ASC Topic 820, "*Fair Value Measurements and Disclosures*," as Level 3 inputs. We review the probabilities of achievement of the earn-out targets to determine the impact on the fair value of the earn-out consideration on a quarterly basis over the earn-out period. Changes in the estimated fair value of the contingent earn-out consideration related to Earn-Out Shareholders are recorded in other income (expense) in the Consolidated Statements of Operations and Comprehensive Loss and are reflected in the period in which they are identified. Changes in the estimated fair value of contingent earn-out consideration related to Earn-Out Service Providers is recorded as stock compensation for the period. Changes in the estimated fair value of the contingent earn-out consideration may materially impact or cause volatility in our operating results.

Revenue Recognition

We account for revenue recognition in accordance with ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

We only apply the five-step analysis to contracts when it is probable that we will collect the consideration to which we are entitled in exchange for the goods or services we transfer to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract, determine those that are performance obligations, and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

We generate EndeavorRx product revenue from contracts with caregivers and patients who purchase subscriptions to access our FDA-authorized, prescription-only video game-based digital therapeutic ("Clients"). Clients are billed in advance for the entire subscription term. Along with the subscription to the video game-based treatment, the Clients also receive reporting metrics and technical support services. The reporting metrics rely on gameplay data being sent back from EndeavorRx, which we analyze in order to provide information on daily efforts and level completion to our Clients throughout the subscription term via the EndeavorRx Insight app. The subscription to the video game-based treatment, reporting metrics and technical support services are combined as a single stand-ready performance obligation because the elements are not considered distinct in the context of the contract with the customer. Accordingly, the consideration is recognized ratably on an over time basis over the subscription period which begins once the access code is inputted into the game by the Client and game play has started.

We generate EndeavorOTC product revenue from contracts with customers who purchase subscriptions to access our over-the-counter video game-based digital therapeutic. Customers are billed in advance for the entire subscription term. Along with the subscription to the video game-based treatment, the customers also receive technical support services and access to software updates. The technical support services and access to software updates were determined to be immaterial in the context of the contract primarily due to the fact that the underlying SSME technology is not being updated throughout the subscription term, and therefore the primary functionality of the product is not changed during the term of the arrangement. As EndeavorOTC has significant stand-alone functionality that can be used immediately upon delivery, the performance obligation is considered complete upon delivery and all of the consideration is recognized at that point in time.

Under the Collaboration Agreement, we historically recognized revenue over time on an inputs-based method that uses a cost to cost measure of progress. There was no revenue recognized under the Collaboration Agreement for the three months ended March 31, 2024 or 2023.

Stock-Based Compensation

We have offered stock options, RSUs and PSUs to employees and non-employees. We measure and recognize compensation expense for all share-based awards based on estimated fair values on the date of grant. The compensation expense is recognized on a straight-line basis over the requisite service period for time-based awards with only service conditions. Share-based awards with performance conditions are expensed under the accelerated attribution method based on each vesting tranche. We recognize forfeitures as incurred

and, therefore, reverse previously recognized share-based compensation expense at the time of forfeiture. We use the Black-Scholes Option Pricing Model (the “Black-Scholes Model”) to estimate the fair value of stock options. RSUs are measured based on the fair values of our underlying common stock on the dates of grant. We estimate the grant-date fair values of PSUs utilizing a MCSM.

We classify stock-based compensation expense in our consolidated statement of operations in the same manner in which the award recipient’s payroll costs are classified or in which the award recipients’ service payments are classified.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

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

Item 4. Controls and Procedures.

Disclosure Controls and Procedures

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer, who is our principal executive officer, principal financial officer and principal accounting officer, to allow timely decisions regarding required disclosure.

Evaluation of Disclosure Controls and Procedures

As required by Rules 13a-15 and 15d-15 under the Exchange Act, our Chief Executive Officer who is our principal executive officer, principal financial officer and principal accounting officer, carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of March 31, 2024. Based upon his evaluation, our Chief Executive Officer concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes to our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) that occurred during the quarter ended March 31, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Our management, including our Chief Executive Officer who is our principal executive officer and principal 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 legal proceedings and subject to claims that arise in the ordinary course of business. As of March 31, 2024, we do not believe that the results of any such claims or litigation, individually or in the aggregate, will have a material adverse effect on our business, financial position, results of operations or cash flows.

Item 1A. Risk Factors.

In evaluating the Company and our business, 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 Securities and Exchange Commission (the "SEC"). An investment in our securities involves a high degree of risk. You should carefully consider the risks described below before making an investment decision. Our business, prospects, financial condition or operating results could be harmed by any of these risks, as well as other risks not currently known to us or that we currently consider immaterial. The trading price of our securities could decline due to any of these risks, and, as a result, you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. This Quarterly Report also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of a number of factors, including the risks described below. Certain statements in this "Risk Factors" section are forward-looking statements. See "Cautionary Statement Regarding Forward-Looking Statements".

Risks Related to Strategic Alternatives Process and Potential Strategic Transaction

We may not be successful in identifying and implementing any strategic business combination or other transaction and any strategic transactions that we may consummate in the future could have negative consequences.

In addition to our recently announced shift in business strategy, in April 2024 we announced that we and our Board are evaluating potential strategic alternatives to maximize shareholder value. However, there can be no assurance that this process will result in Akili pursuing a transaction or that any transaction, if pursued, will be completed on attractive terms, if at all. The process of continuing to evaluate these strategic options may be very costly, time-consuming and complex and we have incurred, and we may in the future incur, significant costs related to this continued evaluation, such as legal and accounting fees and expenses and other related charges. We may also incur additional unanticipated expenses in connection with this process. A considerable portion of these costs will be incurred regardless of whether any such course of action is implemented or transaction is completed. Any such expenses will decrease the remaining cash available for use in our business and may diminish or delay any future distributions to our stockholders.

In addition, any strategic business combination or other transactions that we may consummate in the future could have a variety of negative consequences and we may implement a course of action or consummate a transaction that yields unexpected results that adversely affect our business and decrease the remaining cash available for use in our business or the execution of our strategic plan. There can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated, lead to increased shareholder value, or achieve the anticipated results. Any failure of such potential transaction to achieve the anticipated results could significantly impair our ability to enter into any future strategic transactions and may significantly diminish or delay any future distributions to our stockholders.

We may not realize any additional value in a strategic transaction.

The market capitalization of our company is below the value of our cash and cash equivalents at March 31, 2024. Potential counterparties in a strategic transaction involving our company may place minimal or no value on our assets given the limited revenues generated to date by our products. Further, the development and commercialization of our products or product candidates will require substantial additional cash to fund. Consequently, any potential counterparty in a strategic transaction involving our company may choose not to spend additional resources and continue development or commercialization of our products or product candidates and may attribute little or no value, in such a transaction, to those products or product candidates.

If we are successful in completing a strategic transaction, we may be exposed to other operational and financial risks.

Although there can be no assurance that a strategic transaction will result from the process we have undertaken to identify and evaluate strategic alternatives, the negotiation and consummation of any such transaction will require significant time on the part of our management, and the diversion of management's attention may disrupt our business. The negotiation and consummation of any such transaction may also require more time or greater cash resources than we anticipate and expose us to other operational and financial risks, including:

- increased near-term and long-term expenditures;
- exposure to unknown liabilities;

- higher than expected acquisition or integration costs;
- incurrence of substantial debt or dilutive issuances of equity securities to fund future operations;
- write-down of assets or goodwill or incurrence of non-recurring, impairment, or other charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired business with our operations and personnel;
- impairment of relationships with key vendors or customers of any acquired business due to changes in management and ownership; and
- possibility of future litigation.

Any of the foregoing risks could have a material adverse effect on our business, financial condition and prospects.

If a strategic transaction is not consummated, our Board may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

There can be no assurance that a strategic transaction will be completed. If a strategic transaction is not completed, our Board may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision and, as with the passage of time the amount of cash available for distribution will be reduced as we continue to fund our operations. In addition, if our Board were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations and the timing of any such resolution is uncertain. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation. If a dissolution and liquidation were pursued, our Board, in consultation with our advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up.

Our ability to consummate a strategic transaction depends on our ability to retain our employees required to consummate such transaction.

Our ability to consummate a strategic transaction depends upon our ability to retain our employees required to consummate such a transaction, the loss of whose services may adversely impact the ability to consummate such transaction. In April 2024, we announced an organizational restructuring to lower operating expenses while focused on supporting Shionogi, and this restructuring reduced our workforce by approximately 46%, including the elimination of our marketing and medical affairs teams. Our cash conservation activities may yield unintended consequences, such as attrition beyond our planned reduction in workforce and reduced employee morale, which may cause remaining employees to seek alternative employment. Our ability to successfully complete a strategic transaction depends in large part on our ability to retain certain of our remaining personnel. If we are unable to successfully retain our remaining personnel, we are at risk of a disruption to our exploration and consummation of a strategic alternative as well as to our business operations.

Our most recent corporate restructuring and the associated headcount reduction may not result in anticipated savings, could result in total costs and expenses that are greater than expected, and could disrupt our business.

In April 2024, we undertook an organizational restructuring that significantly reduced our workforce. We may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from the restructuring, our operating results and financial condition would be adversely affected. Furthermore, our restructuring plan may be disruptive to our operations. For example, our headcount reductions could yield unanticipated consequences, such as increased difficulties in implementing our shift in business strategy, including the loss of institutional knowledge and expertise, attrition beyond the intended number of employees, decreased morale among our remaining employees, and the risk that we may not achieve the anticipated benefits of the reduction in force. In addition, while certain positions have been eliminated, certain functions necessary to our operations remain, and we may be unsuccessful in distributing the duties and obligations of departed employees among our remaining employees, including relevant duties and obligations related to the Amended Shionogi Agreement. The reduction in workforce could also make it difficult for us to pursue, or prevent us from pursuing, new opportunities and initiatives due to insufficient personnel, or require us to incur additional and unanticipated costs to hire new personnel to pursue such opportunities or initiatives. If we are unable to realize the anticipated benefits from the reduction in force, or if we experience significant adverse consequences from the reduction in force, our business, financial condition, and results of operations may be materially adversely affected. In addition, employee litigation related to the headcount reduction could be costly and prevent management from fully concentrating on the business.

Any future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. We may not be able to effectively manage our operations or recruit and retain qualified personnel, which may result in weaknesses in our infrastructure and operations, risks that we may not be able to comply with legal and regulatory requirements and contractual obligations to, for example, Shionogi and our product subscribers, and loss of employees and reduced productivity among remaining employees. Our future financial performance will depend, in part, on our ability to effectively manage any future growth or restructuring, as the case may be. In addition, given the substantial restructuring of our operations, it may be difficult to evaluate our current business and future prospects on the basis of historical operating performance.

We may become involved in securities class action litigation that could divert management's attention and harm our business, and insurance coverage may not be sufficient to cover all costs and damages.

In the past, securities class action litigation has often followed certain significant business transactions, such as the sale of a company or announcement of any other strategic transaction, or the announcement of negative events. These events may also result in investigations by the SEC. We may be exposed to such litigation or investigation even if no wrongdoing occurred. Litigation and investigations are usually expensive and divert management's attention and resources, which could adversely affect our business and cash resources and our ability to consummate a potential strategic transaction or could adversely effect the ultimate value our stockholders receive in any such transaction.

Risks Related to our Business and Industry

We are a technology company with a limited operating history that is focused on the delivery of digital therapeutics. We have a history of significant losses, and we may not be able to achieve or maintain profitability.

We are a technology company with a limited operating history. Like biopharmaceutical product development, digital therapeutic product development is a highly speculative undertaking and involves a substantial degree of risk. Since Akili's inception in December 2011, we have focused substantially all of our efforts and financial resources on developing our computational platform, building our research and development capabilities, and sourcing, researching, licensing in key assets and developing our products. In September 2023, we announced a strategic plan to transition from a prescription to a non-prescription business model, including our plans to pursue regulatory authorization for over-the-counter labeling of our products. In April 2024, we announced several corporate updates, and our efforts are primarily focused on supporting Shionogi's regulatory and commercialization activities pursuant to the Amended Shionogi Agreement, continuing to support current users of our EndeavorRx and EndeavorOTC products and make our products available for purchase, and continuing to pursue regulatory authorization from FDA for EndeavorOTC in adults with ADHD, which remains under review, in parallel with exploration of broader strategic options. We have generated limited revenue from product sales, and we do not expect to generate significant revenue from product sales in the foreseeable future particularly in light of our April 2024 announcement regarding the elimination of our marketing and medical affairs teams and a substantial reduction in promotional activity for our EndeavorRx and EndeavorOTC products.

We offer EndeavorRx, a prescription video game treatment indicated for use to improve attention function for children ages 8-17 years old with primarily inattentive or combined-type ADHD, who have a demonstrated attention issue and EndeavorOTC, an over-the-counter product that does not require a prescription to improve attention function, ADHD symptoms and quality of life in adults 18 years of age and older with primarily inattentive or combined-type ADHD. We have only obtained marketing authorizations to commercialize EndeavorRx in the U.S. and the European Economic Area, but have not received regulatory authorization to market it anywhere else in the world. In June 2023, EndeavorOTC, which is built on the same platform as EndeavorRx, was made available nationwide without a prescription to improve attention function, ADHD symptoms and quality of life in adults 18 years of age and older with primarily inattentive or combined-type ADHD, under the FDA guidance entitled "*Enforcement Policy for Digital Health Devices for Treating Psychiatric Disorders During the Coronavirus Disease 2019 Public Health Emergency*" (the "COVID-19 Guidance"). The COVID-19 Guidance allows for the marketing of certain digital therapeutics without premarket clearance, de novo classification, or approval so long as certain criteria are met for the duration of the COVID-19 Guidance, which was expected to remain in effect until November 7, 2023 consistent with FDA guidance entitled "*Transition Plan for Medical Devices That Fall Within Enforcement Policies Issued During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency*" (the "COVID-19 Transition Guidance"). The COVID-19 Transition Guidance allows for the continued distribution of devices falling under the COVID-19 Guidance without marketing authorization so long as the manufacturer has submitted a marketing submission to FDA, the submission has been accepted by FDA prior to November 7, 2023 and FDA has not taken a final action on the marketing submission. While EndeavorOTC has not been authorized by FDA for any indications, we submitted a marketing submission to FDA for EndeavorOTC on October 30, 2023, and EndeavorOTC remains under review with FDA. Through communications with FDA regarding the COVID-19 Transition Guidance, it was clarified that marketing submissions received by FDA on or before November 7, 2023, that pass their technical review after the deadline without being placed on submission hold will still be eligible for continued enforcement discretion. Pursuant to FDA's guidance on this topic, and given that we have since passed FDA's technical review and have not been placed on submission hold, we are continuing to commercialize, distribute, and market EndeavorOTC under the COVID-19 Guidance, however as announced in April 2024 we have significantly reduced promotional activity for our products. There can be no assurance that our submission will be accepted by FDA or that in the future we will obtain marketing authorization from

FDA or other regulators to market and sell EndeavorOTC or any other future products in the U.S. or anywhere else in the world. FDA has broad authority to change its enforcement discretion at any time. If our submission is not accepted or not ultimately authorized, FDA may not continue to provide enforcement discretion and our financials and ability to achieve profitability would be adversely affected.

We have incurred net losses and negative operating cash flows in each year since our inception. Our net loss was $9.8 million and $20.7 million for the three months ended March 31, 2024 and 2023 respectively, and we had an accumulated deficit of $309.5 million as of March 31, 2024. Our net cash used in operating activities was $10.0 million and $19.1 million for the three months ended March 31, 2024 and 2023, respectively. Substantially all of our operating losses and negative operating cash flows have resulted from costs incurred in connection with developing our technology, research and development efforts, advancing our research stage and clinical programs, building our clinical operations group, facilities costs, depreciation and amortization and general and administrative expenses. Our current efforts are primarily focused on supporting Shionogi's regulatory and commercialization activities pursuant to the Amended Shionogi Agreement, continuing to support current users of our EndeavorRx and EndeavorOTC products and make our products available for purchase, and continuing to pursue regulatory authorization from FDA for EndeavorOTC in adults with ADHD, which remains under review, in parallel with exploration of broader strategic options. Further development of our programs outside of ADHD will be contingent upon a number of factors, including the outcome of our and our Board's evaluation of strategic alternatives. We will continue to incur costs associated with operating as a public company and expect to incur significant costs associated with our strategic alternatives process. As a result, we expect to continue to incur significant operating and negative operating cash flows losses for the foreseeable future. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' deficit and working capital. Because of the numerous risks and uncertainties associated with developing and commercializing new technologies, such as EndeavorOTC and EndeavorRx, our digital therapeutics products, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis.

The failure of our digital therapeutics to achieve and maintain market acceptance and adoption, particularly by customers, could have a material adverse effect on our business, prospects, results of operations and financial condition.

Our new non-prescription business model is highly dependent on our digital therapeutics, achieving and maintaining broad market acceptance and adoption, particularly by customers. Market acceptance and adoption of our digital therapeutics depends primarily on educating our potential customers or other entities making the buying decision, as well as healthcare providers, as to the distinct features, therapeutic benefits, cost savings, and other advantages of our digital therapeutics as compared to competitive products or other currently available methodologies, the success of our commercial strategy, including direct-to-consumer marketing efforts, and our ability to respond to customer needs and have our customers recommend or promote our product. In April 2024, we announced the elimination of our marketing and medical affairs teams and a substantial reduction in promotional activity for our EndeavorRx and EndeavorOTC products, which is expected to have a material adverse effect on the adoption and awareness of our products. If we are not successful in demonstrating to existing or potential customers the benefits of our products, or if we are not able to achieve the support of customers who use our products, we may not achieve sales in line with our forecasts.

Achieving and maintaining market acceptance of our products could be negatively impacted by many factors, including:

- the failure of EndeavorOTC to achieve wide acceptance and adoption by customers;
- the failure of EndeavorRx to achieve wide acceptance among patients, self-insured employers, commercial and government payers, health plans, physicians and other government entities, and key opinion leaders in the treatment community;
- lack of additional evidence of peer-reviewed publication of clinical or real world evidence supporting the effectiveness, safety, cost-savings or other advantages of our products over competitive products or other currently available methodologies;
- perceived risks associated with the use of our digital therapeutics or similar products or technologies generally;
- our ability to maintain the FDA marketing authorization and other marketing authorizations for EndeavorRx;
- our ability to obtain and maintain marketing authorizations for EndeavorRx and for EndeavorOTC, including through label expansion;
- our ability to secure and maintain other regulatory clearance, authorization or approval for AKL-T01 for expanded indications and our other product candidates;
- the introduction of competitive products and the rate of acceptance of those products as compared to our products; and
- results of clinical, real world and health economics and outcomes research studies relating to chronic condition products or similar competitive products.

In addition, our products may be perceived by customers and healthcare providers to be more complicated or less effective than traditional approaches, and people may be unwilling to change their current health regimens. Moreover, we believe that healthcare providers tend to be slow to change their medical treatment practices because of perceived liability risks arising from the use of new products and the uncertainty of third-party reimbursement. Accordingly, healthcare providers may not recommend our products until there is sufficient evidence to convince them to alter their current approach.

Our success will depend, in part, on whether we can successfully commercialize and achieve adoption and awareness of our products.

Our overall success will depend, in part, on the commercial success of EndeavorOTC and EndeavorRx. Failure to successfully commercialize our products or to achieve adoption and awareness would likely have a material impact on our business. There are numerous examples of failures to meet high expectations of market potential for product releases in the healthcare space, including by pharmaceutical companies with more experience and resources than us. If the commercialization of our products is unsuccessful or perceived as disappointing, our stock price could decline significantly. Although our current and former employees may have previously marketed, commercialized and sold other healthcare-related products while employed at other companies, we have limited experience selling and marketing our products. And as announced in April 2024, we have eliminated our marketing and medical affairs teams and have substantially reduced promotional activity for our EndeavorRx and EndeavorOTC products, which is expected to have a material adverse effect on the adoption and awareness of our products. Any failure or delay in the timely development of our internal commercialization capabilities could adversely impact the potential for commercial success of our products.

We believe that much of our customer base and potential user populations for our products are active on social media, and we have previously engaged those platforms in an effort to elevate our national marketing presence in direct-to consumer marketing. Social media practices are evolving, which creates uncertainty and risk of noncompliance with regulations applicable to our business. For example, users of our products may use social media platforms to comment on the effectiveness of, or adverse experiences with, our products, which could result in regulatory reporting obligations or the need for us to conduct an investigation. The use of influencers and product ambassadors to promote our products also may be subject to federal truth-in-advertising laws enforced by the Federal Trade Commission (FTC), as well as comparable state consumer protection laws, and we are responsible for training those influencers on the compliant messages they can deliver to consumers. Any actual or perceived non-compliance by our influencers and patient ambassadors with those requirements could lead to an investigation by the FTC or a comparable state agency or could lead to allegations of misleading advertising.

If customers and/or healthcare providers are not willing to change current practices to adopt EndeavorOTC and/or EndeavorRx, or if EndeavorOTC and/or EndeavorRx fail to gain increased market acceptance, our ability to execute our strategy will be impaired, and our business, prospects, results of operations and financial condition could be materially adversely affected.

Our shift in strategy announced in April 2024 is no longer focused on growing our product revenue. Our current efforts are primarily focused on supporting Shionogi's regulatory and commercialization activities pursuant to the Amended Shionogi Agreement, continuing to support current users of our EndeavorRx and EndeavorOTC products and make our products available for purchase, and continuing to pursue regulatory authorization from FDA for EndeavorOTC in adults with ADHD, which remains under review, in parallel with exploration of broader strategic alternatives. Given this shift in strategy and substantially reduced promotional activity for our products, we anticipate that our product revenue may decline. Customers or the medical community may choose not to adopt our digital therapeutic products for a number of reasons, including:

- lack of comfort with or understanding of video-game based products;
- lack of comfort with EndeavorOTC or EndeavorRx video game or user interface;
- unwillingness or inability to pay for EndeavorOTC or EndeavorRx;
- lack of availability of adequate third-party payer coverage or reimbursement;
- lack of experience with our products;
- significantly reduced promotional activity for our EndeavorOTC and EndeavorRx products;
- our inability to convince key opinion leaders to recommend our products;
- perceived inadequacy of evidence supporting clinical benefits, safety or cost-effectiveness of our products;
- liability risks generally associated with the use of new products; and
- the training required to use new products.

Primary care physicians and physicians from other disciplines, as well as other medical professionals, such as psychiatrists and therapists, are often the initial point of contact for patients with ADHD. While we believe that educating physicians in these

disciplines and other medical professionals about the clinical merits, patient benefits and safety profile of our digital therapeutic products is an element of increasing product adoption, we announced in April 2024 that we have eliminated our medical affairs team and we do not plan to invest our limited resources on these efforts.

In addition, patients may not be able to adopt or may choose not to adopt our digital therapeutic if, among other potential reasons, they are worried about potential adverse effects of use of our digital therapeutic or they are unable to obtain adequate third-party coverage or reimbursement. If additional primary care physicians or other medical professionals do not appreciate and recommend the benefits of our digital therapeutics for any reason, or users choose not to adopt EndeavorOTC or patients choose not to adopt EndeavorRx, our ability to execute our strategy will be impaired, and our business, prospects, results of operations and financial condition could be materially adversely affected.

The market for digital therapeutics is new, rapidly evolving, and increasingly competitive, the healthcare industry in the U.S. is undergoing significant structural change, and the demand for digital therapeutics in markets outside of the U.S. is uncertain, which makes it difficult to forecast demand for our products. As a result, all prospective financial information included herein are subject to change.

The market for our EndeavorRx and EndeavorOTC products is new and rapidly evolving, and it is uncertain whether it will achieve and sustain high levels of demand and market adoption, particularly in light of significantly reduced promotional activity for our products. Our future financial performance will depend, in part, on growth in this market and on our ability to adapt to emerging demands of our customers. It is difficult to predict the future growth rate and size of our target market.

The healthcare industry in the U.S. is undergoing significant structural change and is rapidly evolving. We believe demand for our products has been driven in large part by rapidly growing costs in the traditional healthcare system, the movement toward patient-centricity and personalized healthcare, and advances in technology. Widespread acceptance of personalized healthcare is critical to our future growth and success. A reduction in the growth of personalized healthcare could reduce the demand for our products and result in a lower revenue growth rate or decreased revenue.

If our assumptions regarding these uncertainties are incorrect or change in reaction to changes in our markets, or if we do not manage or address these risks successfully, our results of operations could differ materially from our expectations, and our business could suffer.

The market opportunities and revenue potential of EndeavorRx and EndeavorOTC and any potential expanded market for EndeavorRx and EndeavorOTC across additional age ranges in ADHD have not been established with precision. Any estimated size and revenue potential or other estimates of the market opportunities for EndeavorRx, our FDA-authorized product, and for EndeavorOTC, may be smaller than estimated.

The precise incidence and prevalence for ADHD are unknown. Our projections of both the number of people who have this disorder, as well as the people with ADHD who have the potential to benefit from treatment with EndeavorRx or EndeavorOTC, are based on estimates and assumptions, which are inherently uncertain. The potential revenue opportunity in ADHD for EndeavorRx and EndeavorOTC will ultimately depend upon, among other things, feedback from our market testing efforts including various pricing and distribution strategies, the regulatory and commercial strategy, the diagnosis criteria included in the final label for our current and future products for sale for this indication, acceptance by customers and the medical community, and pricing. The number of potential customers in our targeted commercial markets and elsewhere may turn out to be lower than expected, our expected duration of therapy or treatment may turn out to be lower than expected, customers may not be otherwise amenable to treatment with our FDA-authorized product, our over-the-counter product or any other future product candidates, or new customers may become increasingly difficult to identify or gain access to, all of which would adversely affect our revenue potential, results of operations and our business. If we are not successful in achieving regulatory authorizations for our products or demonstrating the benefits of our products or do not achieve the support of these customer groups, our sales may decline, or we may fail to increase our revenue.

Our development programs represent novel and innovative potential therapeutic areas, and negative perception of any product or product candidate that we develop could adversely affect our ability to conduct our business, obtain marketing authorizations or identify alternate regulatory pathways to market for such product candidate.

Our EndeavorRx and EndeavorOTC products are considered relatively new and novel therapeutic approaches. Our success will depend, in part, upon market acceptance and adoption of our products by customers as well as upon healthcare providers who specialize in the treatment of diseases targeted by our products recommending potential treatments that involve the use of our products in lieu of, or in addition to, existing treatments with which they are more familiar and for which greater clinical data may be available. In addition, responses by the U.S., state or foreign governments to negative public perception or ethical concerns may result in new legislation or regulations that could limit our or third parties' ability to develop or commercialize any of our products or product candidates, obtain or maintain marketing authorization, identify alternate regulatory pathways to market or otherwise achieve profitability.

For example, in the U.S., EndeavorRx is the first and only video game-based prescription digital therapeutic that has been granted marketing authorization by the FDA for children ages 8-17 years old with primarily inattentive or combined-type ADHD who have a

demonstrated attention issue. We have developed a therapeutic technology for the treatment of attention-related cognitive impairments associated with ADHD and the potential treatment of, e.g., ASD, COVID fog, MS, major depressive disorder and acute cognitive dysfunction. The FDA or other regulatory authorities may lack experience in evaluating the safety and efficacy of products or product candidates based on such technology, which could result in a longer than expected regulatory review process, increase expected development costs and delay or prevent potential commercialization of products or product candidates.

Negative publicity concerning our products or the digital therapeutics market as a whole could limit market acceptance of our products. If customers and healthcare providers have a negative perception of digital therapeutics, then a market for our products may not develop at all, or it may develop more slowly than we expect. Our success will depend to a substantial extent on the willingness of healthcare providers to recommend our products, and our ability to demonstrate the value of our products to existing and potential customers as well as healthcare providers. Similarly, negative publicity regarding patient confidentiality and privacy in the context of technology-enabled healthcare or concerns experienced by our competitors could limit market acceptance of digital therapeutics.

Clinical trials conducted by us or by third parties of any of our products or product candidates may fail to produce results necessary to support marketing authorization.

We have incurred substantial expense for and devoted significant time to, and may in the future incur substantial additional expense for and devote significant additional time to, clinical trials but cannot be certain that the trials will ever result in commercial gains. We may experience significant setbacks in clinical trials, even after earlier clinical trials showed promising results, and failure can occur at any time during the clinical development process. Any of our products or product candidates may malfunction or may produce undesirable adverse effects that could cause us, institutional review boards ("IRBs") or regulatory authorities to interrupt, delay or halt clinical trials. We, IRBs, the FDA, or another regulatory authority may suspend or terminate clinical trials at any time to avoid exposing trial participants to unacceptable health risks. Clinical trials conducted by us or by third parties of any of our products or product candidates may produce negative or inconclusive results or may demonstrate a lack of effect of our products or product candidates. Additionally, the FDA or other regulatory authorities may disagree with our interpretation of the data from our pilot studies and clinical trials, or may find the clinical trial design, conduct or results inadequate to demonstrate safety or effectiveness, and may require us to pursue additional clinical trials, which could further delay the authorization of our products or product candidates. If we are unable to demonstrate the safety and effectiveness of our products or product candidates in clinical trials, we will be unable to obtain and maintain the marketing authorizations we need to commercialize our products.

In addition, to the extent that additional information regarding our products or product candidates being studied in clinical trials could translate to currently authorized products, such as information on new side effects, those results may impact existing authorizations, and required contraindications, warnings or precautions in product labeling.

Enrollment and retention of patients in clinical trials conducted by us or by third parties of our products or product candidates is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside of our control. If we or third parties experience delays or difficulties in the enrollment or retention of patients in clinical trials, our ability to obtain necessary marketing authorizations for our product candidates could be delayed or prevented.

We may encounter delays or difficulties in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials on our current timelines, or at all, and even once enrolled, we may be unable to retain a sufficient number of patients to complete any of our trials. Slow enrollment in our clinical trials may lead to delays in our development timelines and milestones.

Patient enrollment in clinical trials and completion of patient follow-up depend on many factors, including the size of the patient population, the nature of the trial protocol, the ability of patients to continue to receive medical care, the eligibility criteria for the clinical trial, patient compliance, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product or product candidate being studied in relation to other available therapies, including any new treatments that may obtain marketing authorization for the indications we are investigating. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and efficacy of a product candidate, or they may be persuaded to participate in contemporaneous clinical trials of a competitor's product candidate. In addition, patients participating in our clinical trials may drop out before completion of the trial or experience adverse medical events unrelated to our products or product candidates. Disruptions caused by the effect of uncertainties related to public health have in the past and may in the future increase the likelihood that we or third parties encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may delay commencement or completion of the clinical trial, cause an increase in the costs of the clinical trial and delays, make our data more difficult to interpret, affect the powering of our trial, or result in the failure of the clinical trial.

Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our product candidates, or could render further development impossible. In addition, we rely on clinical trial sites to ensure timely conduct of our clinical trials and, while we have entered into agreements governing their services, we are limited in our ability to compel their actual performance.

Interim, "topline" and preliminary data from clinical trials of our products or product candidates may change as more patient data become available and are subject to confirmation, audit, and verification procedures that could result in material changes in the final data.

From time to time, we or our partners may publicly disclose preliminary or topline data from our or our partners' pilot studies and clinical trials of our product candidates, products, or technology, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations, and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline or preliminary results that we or our partners report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline 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, topline data should be viewed with caution until the final data are available. Interim or preliminary data from clinical trials are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment and treatment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or our partners, or by our competitors, could result in volatility in the price of our common stock.

Further, third parties, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the potential of the particular program, the likelihood of marketing authorization or commercialization of the particular product candidate, the commercial success of any product for which we may have already obtained authorization, and our company in general. In addition, the information we or our partners choose to publicly disclose regarding a particular study or clinical trial is derived from information that is typically extensive, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the interim, topline, or preliminary data that we or our partners report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our or our partners' ability to obtain marketing authorization and commercialize our product candidates or products may be harmed, which could harm our business, operating results, prospects or financial condition.

Due to the significant resources required for the development of our pipeline, and depending on our ability to access capital, we must prioritize certain development programs over others. We may fail to expend our limited resources on certain development programs that may have been more profitable or for which there is a greater likelihood of success.

We currently have one prescription-only product, EndeavorRx, that has been granted marketing authorization in the U.S. and the European Economic Area, one over-the-counter product, EndeavorOTC, that has not yet received regulatory marketing authorizations from FDA or other regulators and other product candidates outside of ADHD that are at various stages of development but for which further development will be contingent upon a number of factors, including the outcome of our and our Board's evaluation of strategic alternatives. We are currently focused primarily on supporting Shionogi's regulatory and commercialization activities pursuant to the Amended Shionogi Agreement, continuing to support current users of our EndeavorRx and EndeavorOTC products and make our products available for purchase, and continuing to pursue regulatory authorization from FDA for EndeavorOTC in adults with ADHD, which remains under review, in parallel with exploration of broader strategic options. There can be no assurance that we have prioritized optimally, that our non-prescription model or more recent shift in business strategy will be successful or that we will be successful in the programs and business model we choose to advance.

Due to the significant resources required for the advancement of our development programs, we must decide which products, product candidates and indications to pursue and advance and the amount of resources to allocate to each. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of any viable commercial products and may divert resources away from better opportunities. If we make incorrect determinations regarding the viability or market potential of any of our product candidates or misread trends in the healthcare and biotechnology industry, in particular for ADHD and other diseases or disorders resulting in cognitive impairment, our business, financial condition, and results of operations could be materially adversely affected. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other development programs that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to our product candidates through collaboration, licensing, or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights.

We are party to and may, in the future, enter collaborations, in-licensing arrangements, joint ventures, or strategic alliances with third parties that may not result in the development of commercially viable products or the generation of significant or any future revenues.

In the ordinary course of our business, we have and may continue to enter into collaborations, in-licensing arrangements, joint ventures, or strategic alliances to develop and/or commercialize digital therapeutics and/or to pursue new markets. Proposing, negotiating, and implementing collaborations, in-licensing arrangements, joint ventures, and strategic alliances is often a lengthy and complex process. These transactions may entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention in order to manage any such transaction or develop acquired products, product candidates or technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected transaction, acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses, and difficulty and cost in facilitating the transaction or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers or customers. Other companies, including those with substantially greater financial, marketing, sales, technology or other business resources, may compete with us for these opportunities or arrangements. We may not identify, secure or complete any such transactions or arrangements in a timely manner, on a cost-effective basis, on acceptable terms, or at all. We have limited institutional knowledge and experience with respect to these business development activities, and we may also not realize the anticipated benefits of any such transaction or arrangement. In particular, these collaborations may not result in the development of products that achieve commercial success or result in significant revenues and could be terminated prior to developing any products.

Additionally, we may not be in a position to exercise sole decision-making authority regarding the transaction or arrangement, which could create the potential risk of creating impasses on decisions, and our collaborators may have economic or business interests or goals that are, or that may become, inconsistent with our business interests or goals. It is possible that conflicts may arise with our collaborators, such as conflicts concerning the achievement of performance milestones, or the interpretation of significant terms under any agreement, such as those related to financial obligations or the ownership or control of intellectual property developed during the collaboration. If any conflicts arise with our current or future collaborators, they may act in their self-interest, which may be adverse to our best interest, and they may breach their obligations to us. In addition, we have limited control over the amount and timing of resources that our current collaborators or any future collaborators choose to devote or are able to devote to our collaborators' or our future products. For example, our plan to initiate a clinical trial of technology exclusively licensed from TALi Digital in children ages 3-8 with ADHD was previously delayed, and in October 2023 the parties mutually agreed to terminate the License, Development and Commercialization Agreement. Disputes between us and our collaborators may result in litigation or arbitration which would increase our expenses and divert the attention of our management. Further, these transactions and arrangements are contractual in nature and may be terminated or dissolved under the terms of the applicable agreements and, in such event, we may not continue to have rights to the products relating to such transaction or arrangement or may need to purchase such rights at a premium.

We depend on our senior management team, and the loss of one or more of our executive officers or key employees or an inability to attract and retain highly skilled employees could adversely affect our business.

Our success depends largely upon the continued services of our key executive officers and key employees. These executive officers are at-will employees and therefore they may terminate employment with us at any time with no advance notice. We rely on our broader leadership team in the areas of operations, clinical and software development, information security, marketing, compliance and general and administrative functions. For example, in connection with our shift in business strategy to focus our efforts in significant part on supporting Shionogi, we will rely on key employees to execute on this strategy. There can be no assurance that we will be successful in motivating and retaining such employees as needed. . From time to time, there may be changes in our executive management team resulting from the hiring or departure of executives or key employees, which could disrupt our business. The loss of one or more of the members of our senior management team, or other key employees, could harm our business. The replacement of one or more of our executive officers or other key employees would likely involve significant time and costs and may significantly delay or prevent the achievement of our business objectives. For example, on October 6, 2023, we announced a leadership transition where our co-founder and Chief Executive Officer, Edward Martucci II, Ph.D., resigned from his role as Chief Executive Officer and was appointed to a new role as Chair of the Board and Matthew Franklin, our President and Chief Operating Officer, was appointed to the role of President and Chief Executive Officer. In addition, Santosh Shanbhag resigned from his role as Chief Financial Officer, treasurer, principal financial officer and principal accounting officer, in each case effective January 12, 2024 and Matthew Franklin, our President, Chief Executive Officer and Chief Operating Officer assumed the duties of principal financial officer and principal accounting officer.

To continue to execute our strategy, we also must attract and retain highly skilled personnel. Competition is intense for qualified professionals. We may not be successful in continuing to attract and retain qualified personnel. We have from time to time in the past experienced, and we expect to continue to experience in the future, difficulty in hiring and retaining highly skilled personnel with appropriate qualifications. The pool of qualified personnel with experience working in the healthcare market is limited overall. In addition, many of the companies with which we compete for experienced personnel have greater resources than we have.

Additionally, our success is dependent on our ability to evolve our culture, align our talent with our business needs, engage our employees and inspire our employees to be open to change and innovate. Our business would be adversely affected if we fail to adequately plan for succession of our executives and senior management, or if we fail to effectively recruit, integrate, retain and develop key talent and/or align our talent with our business needs, in light of the current rapidly changing environment and our change

in strategy. For example, in January 2023, September 2023, and April 2024 we introduced cost reduction efforts, including reductions in our workforce to better align our workforce with our cost reduction efforts and a change in strategy. Such cost reduction efforts have in the past and may in the future adversely affect our ability to attract and retain employees, and may adversely affect our culture and impact our ability to effectively pursue our business strategy.

We face competition, and new products may emerge that provide different or better alternatives for treatment of the conditions that EndeavorRx, EndeavorOTC, if granted marketing authorization, or our future products, if granted marketing authorization, are authorized to treat. Many of our current and future competitors have or will have significantly more resources than us.

Our ability to achieve our strategic objectives will depend, among other things, on our ability to develop and commercialize products for the treatment of chronic conditions that are effective and safe, offer distinct features, are easy-to-use, provide measurable and meaningful cost savings to payers, and are more appealing than available alternatives. Our competitors, as well as a number of other companies, within and outside the healthcare industry, are pursuing new delivery devices, delivery technologies, sensing technologies, procedures, drugs, and other therapies for the monitoring and treatment of chronic conditions. Any technological breakthroughs in monitoring, treatment or prevention could reduce the potential market for our products, which would significantly reduce our sales.

The introduction by competitors of products that are or claim to be superior to our products may create market confusion, which may make it difficult for potential customers to differentiate the benefits of our products over competitive products. In addition, the entry of new digital therapeutics to the market which treat the same or similar chronic conditions as our products may lead some of our competitors to employ pricing strategies that could materially and adversely affect the pricing of our products. If a competitor develops a product that competes with or is perceived to be superior to our products, or if a competitor employs strategies that place downward pressure on pricing within our industry, our sales may decline significantly or may not increase in line with our forecasts, either of which would materially and adversely affect our business, financial condition and results of operations.

While our market is in an early stage of development, it is evolving rapidly and becoming increasingly competitive, and we expect it to attract increased competition. We currently face competition from a range of companies. Our competitors include both enterprise companies who are focused on or may enter the healthcare industry, including initiatives and partnerships launched by these large companies, and from private companies that offer solutions for specific chronic conditions. We compete with companies that are developing treatments for cognitive impairment associated with ADHD and other diseases and disorders resulting in cognitive impairment, including Shire (Takeda), Eli Lilly & Company, Novartis, Pfizer, Highland/Ironshore Therapeutics, Otsuka, Cingulate and others. While pharmaceutical and biotechnology companies have increased their focus on digital treatment in general, we are unaware of any pharmaceutical or biotechnology companies currently pursuing digital treatments for ADHD.

In the digital health space, we compete with several companies that are developing products that may eventually seek regulatory authorization or approval for treatment of ADHD, including Revibe Technologies, Lumos Labs, and Sky Therapeutics. There are also other companies working on potentially regulated products to treat cognition outside of ADHD, including Click Therapeutics in partnership with several pharmaceutical companies (Otsuka, Boehringer-Ingelheim).

We also compete with companies that have created non-regulated products to treat cognitive impairment in ADHD and other diseases and disorders resulting in cognitive impairment such as Cogstate, C8 Sciences, Cogmed, MindMaze, Thynk and Posit Science. These include educational products that are aimed at improving attention, which are not regulated by authorities like the FDA for children with ADHD, such as ACTIVATE by C8 Sciences, Skylar's Run by Thynk and BrainHQ by Posit Science, the latter of which is available via the Apple App Store and on Google Play. These companies, which may offer their solutions at lower prices, are continuing to develop additional products and becoming more sophisticated and effective. Competition from wellness apps, which are not authorized by the FDA but may attract customers for other reasons, and from other parties will result in continued pricing pressures, which are likely to lead to price declines in certain product segments, which could negatively impact our sales, profitability and market share. Additionally, if such unregulated products are allowed to compete with our products, we will face increased competition from parties who have fewer barriers to enter our industry. This increased competition could have a material adverse effect on our business, prospects, results of operations and financial condition.

Our ability to compete effectively depends on our ability to distinguish our company and our solutions from our competitors and their products.

Some of our competitors may have, or new competitors or alliances may emerge that have, greater name and brand recognition, greater market share, a larger customer base, more widely adopted proprietary technologies, greater marketing expertise, larger sales forces, or significantly greater resources than we do and may be able to offer solutions competitive with ours at a more attractive price than we can. Further, our current or potential competitors may be acquired by third parties with greater available resources. As a result, our competitors may be able to respond more quickly and effectively than we can to new or changing opportunities, technologies, standards or customer requirements and may have the ability to initiate or withstand substantial price competition. In addition, our competitors may in the future establish cooperative relationships with vendors of complementary products, technologies or services to increase the availability of their solutions in the marketplace. Our competitors could also be better positioned to serve certain segments of our market, which could create additional price pressure. In light of these factors, even if our products are more effective than those of our competitors, current or potential customers may accept competitive products in lieu of purchasing our

products. If we are unable to successfully compete, our business, financial condition, and results of operations could be materially and adversely affected.

If we cannot maintain our corporate culture, we could lose the innovation, collaboration and focus on the mission that contributes to our business.

We believe our corporate culture has been a critical contributor to our success and our ability to attract highly skilled personnel. If we do not continue to develop our corporate culture or maintain and preserve our core values as we evolve in the U.S. and internationally, which can be made more challenging following the announcement of actions like the workforce reductions announced in January 2023, September 2023, and April 2024, we may be unable to foster the innovation, curiosity, creativity, focus on execution, teamwork and the facilitation of critical knowledge transfer and knowledge sharing we believe we need to support our business strategy. Moreover, liquidity available to our employee equity holders could lead to disparities of wealth among our employees, which could adversely impact relations among employees and our culture in general. Changes in our headcount, changes in our leadership team, and our status as a public company may result in a change to our corporate culture, which could harm our business.

We have experienced significant fluctuations in headcount since inception, including significant reductions in our employee headcount more recently. We cannot assure you that our reduced headcount will be adequate to manage our business and if in the future we continue to significantly reduce our employee headcount, we may not be able to manage that reduction effectively.

Since EndeavorRx was granted marketing authorization and classified as a Class II medical device by the FDA in June 2020 and we became a public company in August 2022, we have experienced significant operational fluctuations in our headcount. For example, our full-time employee headcount was reduced by approximately 30% as part of a workforce reduction in January 2023. In September 2023, in connection with our announced planned change in business strategy to transition to a non-prescription model, we also announced a further workforce reduction of approximately 40% of our then-current workforce. In April 2024, we announced a further workforce reduction of approximately 46% of our then-current workforce. Following the completion of this most recent reduction, we expect to have approximately 36 full-time employees.

From time to time, we have taken steps to implement organizational changes to pursue greater efficiency and realign our business and strategic priorities. For example, in 2023 and 2024, we have implemented internal restructurings and reorganizations designed to reduce the size and cost of our operations and improve operational efficiencies. On January 12, 2023, September 13, 2023, and April 30, 2024, we announced restructurings of our operations and reductions in our workforce. We may take similar steps in the future as we seek to realize operating synergies, optimize our operations to achieve our target operating model and profitability objectives, respond to market forces or better reflect changes in the strategic direction of our business. Taking these actions has in the past and may in the future also result in significant expense for us, including with respect to workforce reductions, disruptions to our business as well as decreased productivity due to employee distraction and unanticipated employee turnover. For example, we could face delays or challenges with product development or other business and strategic initiatives, as well as other disruptions to our operations. In addition, if there are unforeseen expenses associated with such realignments in our business strategies, and we incur unanticipated charges or liabilities, then we may not be able to effectively realize the expected cost savings or other benefits of such actions which could have an adverse effect on our business, operating results and financial condition. In addition, as our organization continues to evolve, and we are required to implement and adapt complex organizational management structures, we may find it difficult to maintain the benefits of our corporate culture, including our ability to develop and commercialize innovative products. Any of these developments could negatively affect our business, reputation, or financial results.

While we do not currently have plans to expand our workforce, to attract top talent, we have had to offer, and believe in the future we will need to continue to offer, highly competitive compensation packages before we can validate the productivity of those employees. In addition, significant fluctuations in employee headcount and in the price of our common stock makes it more difficult or costly to use equity compensation to motivate, incentivize and retain our employees. We face significant competition for talent from other healthcare, technology and high-growth companies, which include both large enterprises and privately-held companies. If we were to seek to expand our workforce in the future, we may not be able to hire new employees quickly enough to meet our needs. If we fail to effectively manage our hiring needs and successfully integrate our new hires, our efficiency and ability to meet our forecasts and our employee morale, productivity and retention could suffer, and our business, results of operations and financial condition could be materially and adversely affected.

Changes in funding or disruption at the FDA, the SEC and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new or modified products from being developed, reviewed or commercialized in a timely manner or at all, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and grant marketing authorization for new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at FDA 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 digital therapeutics to be reviewed and/or granted marketing authorization by necessary government agencies, which would adversely affect our business. For example, in recent years, including for 35 days beginning on December 22, 2018, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities.

If a prolonged government shutdown occurs, or if global health concerns or other events continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, 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. Further, in our operations as a public company, future government shutdowns or delays could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

We will incur increased costs and demands upon management as a result of complying with the laws and regulations affecting public companies, which could adversely affect our business, results of operations, and financial condition.

We are a public company, and are subject to the reporting requirements of the Exchange Act, the listing standards of Nasdaq and other applicable securities rules and regulations. We expect that the requirements of these rules and regulations will continue to increase our legal, accounting and financial compliance costs, make some activities more difficult, time-consuming and costly, and place significant strain on our personnel, systems and resources. For example, the Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and results of operations. As a result of the complexity involved in complying with the rules and regulations applicable to public companies, our management's attention may be diverted from other business concerns, which could harm our business, results of operations and financial condition.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs, and making some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest substantial resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from business operations to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Being a public company subject to these rules and regulations effectively requires us to maintain director and officer liability insurance, which is expensive, and we may be required to accept reduced coverage or incur substantially higher costs to maintain coverage. These factors could also make it more difficult for us to attract and retain qualified members of the Board, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

As a result of disclosure of information in the Annual Report and in filings required of a public company, we may be subject to an increased risk of threatened or actual litigation, including by competitors and other third parties. If such claims are successful, our business and results of operations could be harmed, and even if the claims do not result in litigation or are resolved in our favor, these claims, and the time and resources necessary to resolve them, could divert the resources of our management and harm our business, results of operations, and financial condition.

Any failure to offer high-quality customer support may adversely affect our relationships with our existing and prospective patients and users of our products, and in turn our business, results of operations and financial condition.

In implementing and using our products, our customers will depend on our support to resolve issues in a timely manner. We may be unable to respond quickly enough to accommodate short-term increases in demand for support, particularly in light of our workforce reduction announced in late April 2024. Increased demand for support could increase costs and adversely affect our results of operations and financial condition. Any failure to maintain high-quality support, or a market perception that we do not maintain high-quality support, could adversely affect customer satisfaction or the willingness of physicians to prescribe our prescription-only product or recommend our over-the-counter product, or any such future products, and in turn our business, results of operations, and financial condition.

Acquisitions and strategic alliances could distract management and expose us to financial, execution and operational risks that could have a detrimental effect on our business.

We may pursue acquisitions or licenses of technology to, among other things, expand the number of products we provide as well as the features within those products. We cannot guarantee that we will identify suitable candidates for acquisition or licensing, that the transactions will be completed on acceptable terms, or at all, or that we will be able to integrate newly acquired or licensed technology

into our existing business. The acquisition and integration of another technology would divert management attention from other business activities, including our core business. This diversion, together with other difficulties we may incur in integrating newly acquired or licensed technology, could have a material adverse effect on our business, financial condition and results of operations. In addition, we may borrow money or issue capital stock to finance such transactions. Such borrowings might not be available on terms as favorable to us as our current borrowing terms and may increase our leverage, and the issuance of capital stock (or securities exchangeable therefore) could dilute the interests of our stockholders.

Risks Relating to our Products and Product Candidates

Even though we have received marketing authorizations in the U.S. and European Economic Area for EndeavorRx and may receive U.S. and foreign marketing authorizations for other products or product candidates in the future, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expenses.

While we have received U.S. and European Economic Area marketing authorization for EndeavorRx for an initial indication, FDA or comparable foreign regulatory authorities may grant marketing authorization for any of our other indications or product candidates, including those derived from our most advanced therapeutic engine, SSME technology. In addition, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the FDA or comparable foreign regulatory authority approved products and product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and listing, compliance with FDA labeling requirements, including unique device identification requirements, as well as continued compliance with Good Manufacturing Practices (cGMPs) or similar foreign requirements and Good Clinical Practices (GCPs) for any post-marketing clinical trials that we conduct post-approval. Any marketing authorizations that we receive for our product candidates may also be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing studies, and surveillance to monitor the safety and efficacy of the product. Later discovery of previously unknown problems with a product, 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, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- clinical trial holds;
- fines, warning letters or other regulatory enforcement action;
- refusal by the FDA or comparable foreign regulatory authorities to authorize or approve pending submissions filed by us or our partners;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

FDA's and comparable foreign regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay marketing authorization of our product candidates. For example, on February 2, 2024, the FDA published a final rule to amend its Quality System Regulation ("QSR") requirements to align more closely with the international consensus standards for medical devices by converging with quality management system ("QMS") requirements used by other regulatory authorities from other countries. Specifically, the final rule does so primarily by incorporating by reference the 2016 edition of the International Organization of Standardization ("ISO"), ISO 13485 standard. The amended regulation is referred to as the Quality Management System Regulation ("QMSR") and is effective February 2, 2026. 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 authorization that we may have obtained, which could have a material adverse effect on our business, prospects, results of operations, financial condition and our ability to achieve or sustain profitability.

Our current products and product candidates are in various stages of development. Our products or product candidates may fail in development or suffer delays that adversely affect their commercial viability. If we fail to maintain clearance, de novo classification or approval to market our products and product candidates, including EndeavorRx and EndeavorOTC for expanded indications, or if we are delayed in obtaining such marketing authorizations, our business, prospects, results of operations and financial condition could be materially and adversely affected.

The process of seeking FDA marketing authorization is expensive and time consuming. There can be no assurance that marketing authorization will be granted. If we are not successful in obtaining timely clearance, de novo classification or approval of our product candidates, we may never be able to generate significant revenue and may be forced to cease operations. Although our current efforts are primarily focused on supporting Shionogi's regulatory and commercialization activities pursuant to the Amended Shionogi Agreement, continuing to support current users of our EndeavorRx and EndeavorOTC products and make our products available for

purchase, and continuing to pursue regulatory authorization from FDA for EndeavorOTC in adults with ADHD, which remains under review, in parallel with exploration of broader strategic options, we have in the past and may in the future resume development of our programs outside of ADHD. Further development of and such programs will be contingent upon a number of factors, including the outcome of our and our Board's evaluation of strategic alternatives. The FDA can delay, limit or deny marketing authorizations for many reasons, including:

- we may not be able to demonstrate to the FDA's satisfaction that our products or product candidates meet the applicable regulatory standards for clearance, de novo classification, or approval, as applicable;
- the FDA may disagree that our clinical data supports the label and use that we are seeking; and
- the FDA may disagree that the data from our preclinical or pilot studies and clinical trials is sufficient to support marketing authorization.

Obtaining marketing authorization from the FDA or any foreign regulatory authority could result in unexpected and significant costs for us and consume management's time and other resources. The FDA could ask us to supplement our submissions, collect additional nonclinical data, conduct additional clinical trials, prepare additional manufacturing data or information or engage in other time-consuming actions, or it could simply deny our requests. In addition, if granted marketing authorization, we will be required to obtain additional FDA authorizations prior to making certain modifications to our devices. Further, FDA may impose other restrictions on our marketing authorizations, or we may lose marketing authorization, if post-market data demonstrates safety issues or lack of efficacy. If we are unable to obtain and maintain the necessary marketing authorizations to market our products, our financial condition may be adversely affected, and our ability to grow domestically and internationally would likely be limited. Additionally, even if granted marketing authorization, our products, including EndeavorRx and EndeavorOTC, may not receive marketing authorization for the indications that are necessary or desirable for successful commercialization or profitability. This could have a material adverse effect on our business, prospects, results of operations and financial condition.

EndeavorOTC and EndeavorRx are currently available via the Apple App Store® and on Google Play™, and each of our products is supported by third-party infrastructure. If our ability to access these markets or access necessary third-party infrastructure was stopped or otherwise restricted or limited, it could have a material adverse effect on our business, prospects, results of operations and financial condition.

Our EndeavorOTC product and our EndeavorRx product are exclusively accessed through and depend on the Apple App Store and Google Play. Both Apple and Google have broad discretion to make changes to their operating systems or payment services or change the manner in which their mobile operating systems function and their respective terms and conditions applicable to the distribution of our digital therapeutics, and to interpret their respective terms and conditions in ways that may limit, eliminate or otherwise interfere with our products, our ability to distribute our products through their stores, our ability to update our products, including to make bug fixes or other feature updates or upgrades, the features we provide, the manner in which we market our products and our ability to access native functionality or other aspects of mobile devices. To the extent either or both of them do so, our business, prospects, results of operations and financial condition could be materially and adversely affected.

There is no guarantee that the third-party infrastructure that currently supports our digital therapeutics will continue to support them or, if it does not, that other alternatives will be available or that they will be available on terms that are commercially acceptable to us. We will continue to be dependent on third-party mobile operating systems, technologies, networks and standards that we do not control, such as the Android and iOS operating systems, and any changes, bugs, technical or regulatory issues in such systems, our current relationships with carriers or future relationships with mobile manufacturers, or in their terms of service or policies that degrade our digital therapeutics' functionality, reduce or eliminate our ability to distribute our digital therapeutics, limit our ability to deliver high quality digital therapeutics, or impose fees or other charges related to delivering our offerings, could adversely affect our product usage and revenue.

We rely upon third party providers of cloud-based infrastructure to host our platform. Any disruption in the operations of these third-party providers, limitations on capacity or interference with our use could have a material adverse effect on our business, prospects, results of operations and financial condition.

Our platform's technological infrastructure is implemented using third-party hosting services, such as Amazon Web Services. We have no control over any of these third parties, and we cannot guarantee that such third-party providers will not experience system interruptions, outages or delays, or deterioration in their performance. We need to be able to access our computational platform at any time, without interruption or degradation of performance. Our hosted platform depends on protecting the virtual cloud infrastructure hosted by third-party hosting services by maintaining our configuration, architecture, features, and interconnection specifications, as well as protecting the information stored in these virtual data centers, which is transmitted by third-party Internet service providers. We have experienced, and expect that in the future we may again experience, interruptions, delays and outages in service and availability from time to time due to a variety of factors, including infrastructure changes, human or software errors, hosting disruptions and capacity constraints. Any limitation on the capacity of our third-party hosting services could adversely affect our business, financial condition, and results of operations. In addition, any incident affecting our third-party hosting services'

infrastructure, which may be caused by cyber-attacks, natural disasters, fire, flood, severe storm, earthquake, power loss, telecommunications failures, terrorist or other attacks, and other disruptive events beyond our control, could negatively affect our cloud-based solutions. A prolonged service disruption affecting our cloud-based solutions could damage our reputation or otherwise harm our business. We may also incur significant costs for using alternative equipment or taking other actions in preparation for, or in reaction to, events that damage the third-party hosting services we use.

In the event that our service agreements with our third-party hosting services are terminated, or there is a lapse of service, elimination of services or features that we utilize, interruption of Internet service provider connectivity, or damage to such facilities, we could experience interruptions in access to our platform as well as significant delays and additional expense in arranging or creating new facilities and services and/or re-architecting our hosted software solutions for deployment on a different cloud infrastructure service provider, which could have a material adverse effect on our business, prospects, results of operations and financial condition.

If we are not able to develop and release new products, or successful enhancements, new features, and modifications to EndeavorRx, EndeavorOTC or any future products, our business, prospects, results of operations and financial condition could be materially and adversely affected.

We expect that the digital therapeutics market, as with many technology markets, will be characterized by rapid technological change, frequent new product and service introductions and enhancements, changing customer demands, and evolving industry standards. As an initial matter, a significant portion of our market may not have access to smartphones or other technology necessary to utilize our digital therapeutics. In addition, the introduction of products and services embodying new technologies could quickly make existing products and services obsolete and unmarketable. Additionally, changes in laws and regulations could impact the usefulness of our products and could necessitate changes or modifications to our products to accommodate such changes. We invest resources in researching and developing new products and enhancing our existing products by incorporating additional features, improving functionality, and adding other improvements to meet our patients' and users' evolving needs. The success of any enhancements or improvements to our products or any new products depends on several factors, including regulatory review timelines, timely completion, competitive pricing, adequate quality testing, integration with new and existing technologies in our products and third-party collaborators' technologies and overall market acceptance. We may not succeed in developing, marketing and delivering on a timely and cost-effective basis enhancements or improvements to our products or any new products that respond to continued changes in market demands or new customer requirements, and any enhancements or improvements to our products or any new products may not achieve market acceptance. Since developing our products is complex, the timetable for the release of new products and enhancements to existing products is difficult to predict, and we may not offer new products and updates as rapidly as our patients and users require or expect. Any new products that we develop or acquire may not be introduced in a timely or cost-effective manner, may contain errors or defects, or may not achieve the broad market acceptance necessary to generate significant or any revenue.

The introduction of new products and products by competitors, the development of entirely new technologies to replace existing offerings or shifts in healthcare benefits trends could make our products obsolete or materially and adversely affect our business, financial condition and results of operations. We may experience difficulties with software development, industry standards, design or marketing that could delay or prevent our development, introduction or implementation of new products, enhancements, additional features or capabilities. If users, patients and healthcare providers do not widely adopt our products, we may not be able to realize a return on our investment. If we do not accurately anticipate user demand and patient demand or we are unable to develop, license or acquire new features and capabilities on a timely and cost-effective basis, or if such enhancements do not achieve market acceptance, it could result in adverse publicity, loss of revenue or market acceptance or claims by users, patients or healthcare providers brought against us, each of which could have a material adverse effect on our reputation, business, prospects, results of operations and financial condition.

In addition, the markets in which we compete are characterized by rapidly changing technology, evolving industry standards, frequent introductions and enhancements, and changing consumer demands and preferences. For example, generally technology focused companies are increasingly integrating artificial intelligence into their operations. Any use of artificial intelligence in our business presents risks and challenges, including that algorithms may be flawed, datasets may be insufficient, erroneous, stale, or contain biased information, or content chosen for display to consumers by artificial intelligence systems may be discriminatory, offensive, illegal, or otherwise harmful. These deficiencies and other failures of artificial intelligence systems could subject us to competitive harm, regulatory action, legal liability, and brand or reputational harm. In addition, there is no guarantee that our use of third party artificial intelligence tools or other artificial intelligence focused initiatives will be competitive or attract more consumers to our platform.

Security breaches, loss of data and other disruptions could compromise sensitive information related to our patients, users or business or prevent us from accessing critical information and expose us to liability, which could have a material adverse effect on our reputation, business, prospects, results of operations and financial condition.

In the ordinary course of our business, we access, generate, process, and store sensitive data, including research data, clinical trial data, real-world data, patient data, user data, intellectual property and proprietary business information owned or controlled by ourselves or our employees, partners and other parties. We manage and maintain our applications and data utilizing a combination of

on-site systems and cloud-based data centers and third party services. We utilize third party vendors to manage parts of our code, infrastructure, application and services. These applications and data encompass a wide variety of business-critical information, including confidential, sensitive or personal information regarding our users, patients, clinical trial subjects, vendors, customers, employees and others, as well as research and development information, commercial information, and business and financial information. We face a number of risks relative to protecting this critical information, including loss of access risk, inappropriate use or disclosure, accidental exposure, unauthorized access, inappropriate modification, and the risk of our being unable to adequately monitor, audit and modify our controls over our critical information. This risk extends to the third party vendors and subcontractors we use to manage this sensitive data or otherwise process on our behalf.

In addition, we and our third party vendors are at constant risk of cyber-attacks or cyber intrusions via viruses, worms, break-ins, malware, ransomware, phishing attacks, hacking, theft of resources, denial-of-service attacks or other attacks and similar disruptions from the unauthorized use of or access to computer systems (including from internal and external sources) that attack our products or systems or those of our third party vendors, or attempt to fraudulently induce our employees, consumers, third party vendors or others to disclose passwords or other sensitive information or unwittingly provide access to our systems or data. These types of incidents continue to be prevalent and pervasive across industries, including in our industry, and such attacks on our systems have occurred in the past and are expected to occur in the future. In addition, we expect the amount and sophistication of the perpetrators of these attacks to continue to expand, which could include nation-state actors. Any such incident could lead to interruptions, delays or product outages, causing loss of critical data or the unauthorized disclosure or use of personally identifiable or other confidential information. There are no assurances that our programs and actions taken to protect against security breaches or to investigate and address problems related to cyber or other security problems will be sufficient to prevent or limit the impact of any cyber intrusion or related attack.

Further, to the extent our employees are working remotely whether at home or elsewhere, additional risks may arise. The secure processing, storage, maintenance and transmission of this critical information are vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take reasonable measures to protect sensitive data from unauthorized access, use or disclosure, no security measures can be perfect and our third-party vendors' and subcontractors' information technology and infrastructure may be vulnerable to attacks by hackers or infections by viruses or other malware or breached due to erroneous actions or inactions by our employees or contractors, malfeasance or other malicious or inadvertent disruptions. Any such breach or interruption could compromise our systems and the information stored there could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Any such access, breach, or other loss of information could result in legal claims or proceedings. Unauthorized access, loss or dissemination could also disrupt our operations, result in a material disruption of our development programs and damage our reputation, any of which could adversely affect our business. For example, the loss, corruption, unavailability of, or damage to our computational models would interfere with and undermine the insights we draw from our platform, which could result in the waste of resources on insights based on flawed premises. In addition, the loss or corruption of, or other damage to, clinical trial data from ongoing or future clinical trials could result in delays in our efforts to obtain marketing authorizations and significantly increase our costs to recover or reproduce the data.

Additionally, although we maintain cybersecurity insurance coverage, we cannot be certain that such coverage will be adequate for data security liabilities actually incurred, will cover any indemnification claims against us relating to any incident, will continue to be available to us on economically reasonable terms, or at all, or that any insurer will not deny coverage as to any future claim. The successful assertion of one or more large claims against us that exceed available insurance coverage, or the occurrence of changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, could have a material adverse effect on our reputation, business, prospects, results of operations and financial condition.

We recently transitioned from a single third party digital pharmacy for the fulfillment of prescriptions for EndeavorRx to an internally developed in-house distribution system for EndeavorRx. This new in-house distribution system may increase the risk that we could have a disruption in the transition, fulfillment and renewal of prescriptions for EndeavorRx, which could have a material and adverse effect on our reputation, business, results of operations and financial condition.

We recently transitioned from a single third party digital pharmacy for the fulfillment of prescriptions for EndeavorRx and currently rely on an internally developed in-house distribution system for EndeavorRx. Prior to this transition, we had no experience as a company in operating an in-house distribution system and may not be successful in doing so. Our lack of experience with this new in-house distribution system may increase the risk that our system could have or develop technical issues, bugs or other problems that we are unable to resolve in a timely manner or at all and could have a disruption in the fulfillment of prescriptions for EndeavorRx which could delay, prevent or impair the distribution and sale of EndeavorRx. In addition, we may lose customers who access EndeavorRx through our legacy third party digital pharmacy and choose not to transition, fulfill, or renew their prescriptions on our in-house distribution system.

Pharmacies and distributors of digital therapeutics are subject to state and federal laws and regulations, and we are now fully responsible for compliance with federal and state law and regulations, to the extent they apply, and for maintaining adequate quality control, quality assurance and qualified personnel. If our in-house distribution system fails to maintain regulatory compliance or adequate quality control and quality assurance, we may need to find alternatives with the capability to dispense prescriptions for

prescription digital therapeutics (PDTs). As part of the transition to an in-house distribution system, there can be no assurance that positions we have taken or may take in the future with respect to the potential applicability or inapplicability of certain laws and regulations will be viewed as adequate or sufficient now or in the future. If a regulatory authority finds deficiencies with or withdraws required licenses in the future, we may be subject to significant fines or penalties, or potentially other civil or even criminal penalties or disruption in the supply of our products or other significant impacts on our business. In addition, we may need to find alternatives with the capability to fulfill prescriptions for PDTs, which could significantly impact our ability to fulfill, distribute and sell EndeavorRx. There are a limited number of third parties that could do so, and we may be unable to establish any agreements with other third party alternatives or to do so on acceptable terms.

Any performance failure on the part of our in-house distribution system or our employees could disrupt the distribution and sale of EndeavorRx. If our in-house distribution cannot perform as anticipated, we may be required to replace such system. We may incur added costs and delays in identifying and qualifying any such replacement, and there can be no assurance that an alternative distributor would be available. The aforementioned risks with our in-house distribution system could have a material adverse effect on our business, prospects, results of operations and financial condition.

Notwithstanding the transition to an in-house distribution system, we still rely on certain third parties, for example, for database and software products and support of our system. Our current and anticipated future dependence upon others for the fulfillment of prescriptions for our product candidates or products may adversely affect our future profit margins and our ability to distribute any products that receive marketing authorization on a timely and competitive basis.

Our products or product candidates may cause undesirable side effects or have other properties that could limit their commercial potential.

If we or others identify undesirable side effects directly or indirectly caused by our products or product candidates, a number of potentially significant negative consequences could result, including:

- we may lose marketing authorization of such product;
- regulatory authorities may require additional warnings on the product's label;
- we may be required to issue safety communications to patients or healthcare providers that outline the risks of such side effects;
- we could be sued and held liable for harm caused to users or patients; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product or product candidate and, as a result of negative impacts to our reputation, our other products or product candidates and could have a material adverse effect on our business, prospects, results of operations and financial condition.

The misuse or off-label use of our products may harm our reputation in the marketplace, result in injuries that lead to product liability or other suits or result in costly investigations, fines, or sanctions by regulatory bodies.

Although our products, if granted marketing authorization, are marketed for the specific therapeutic uses for which the devices were designed and our personnel will be trained to not promote our products for uses outside of the FDA-authorized indications for use, known as "off-label uses," we cannot, however, prevent a physician from using our products in ways, when in the physician's independent professional medical judgment, he or she deems it appropriate. There may be increased risk of injury to users or patients if primary care physicians attempt to use our products off-label. Furthermore, the use of our products for off-label uses may not effectively treat such conditions, which could harm our reputation in the marketplace among primary care physicians, patients and users.

If following authorization of any other products or product candidates we may commercialize, or with respect to EndeavorRx or EndeavorOTC, the FDA or any foreign regulatory body determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of an untitled letter or warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action under other regulatory authority, such as false claims laws for any products for which we obtain government reimbursement, if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations.

In addition, physicians may misuse our products with their patients if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our products are misused, we may become subject to costly litigation by our patients or their

patients. As described below, product liability claims could divert management's attention from our core business, be expensive to defend and result in sizeable damage awards against us that may not be covered by insurance.

Our products may be subject to product recalls. A recall of our products, either voluntarily or at the direction of the FDA or another governmental authority, or the discovery of serious safety issues with our products, could have a material adverse effect on our business, prospects, results of operations and financial condition.

The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products, such as in the event of material deficiencies or defects in their design or manufacture or in the event that a product poses an unacceptable risk to health.

The FDA's authority to require a recall for medical devices must be based on a finding that there is reasonable probability that the device would cause serious injury or death. We may also decide to voluntarily recall our products. A government-mandated or voluntary recall could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and could materially and adversely affect our reputation and business, which could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. We may also be subject to liability claims, be required to bear other costs, or take other actions that could have a material adverse effect on our business, prospects, results of operations and financial condition.

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. We may initiate voluntary recalls or corrections for our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls and we may be subject to enforcement action.

We face potential product liability exposure, and, if claims brought against us are successful, we could incur substantial liabilities.

Our business exposes us to potential product liability claims that are inherent in the design, manufacture, testing and sale of medical devices. We could become the subject of product liability lawsuits alleging that component failures, manufacturing flaws, design defects or inadequate disclosure of product-related risks or product-related information resulted in an unsafe condition, injury or death to patients or users. In addition, the misuse of our products, or the failure of patients or users to adhere to operating guidelines, could cause significant harm to patients or users which could result in product liability claims. Product liability lawsuits and claims, safety alerts or product recalls, with or without merit, could cause us to incur substantial costs, and could place a significant strain on our financial resources, divert the attention of management from our core business, harm our reputation and materially and adversely affect our ability to attract and retain patients or users, any of which could have a material adverse effect on our business, prospects, results of operations and financial condition.

Although we maintain third-party product liability insurance coverage, it is possible that claims against us may exceed the coverage limits of our insurance policies. Even if any product liability loss is covered by an insurance policy, these policies typically have substantial deductibles for which we are responsible. Product liability claims in excess of applicable insurance coverage could have a material adverse effect on our business, prospects, results of operations and financial condition. In addition, any product liability claim brought against us, with or without merit, could result in an increase of our product liability insurance premiums. Insurance coverage varies in cost and can be difficult to obtain, and we cannot guarantee that we will be able to obtain insurance coverage in the future on terms acceptable to us or at all.

Additionally, from time to time we may enter into agreements pursuant to which we indemnify third parties for certain claims relating to our products. These indemnification obligations may require us to pay significant sums of money for claims that are covered by these indemnification obligations. We are not currently subject to any product liability claims; however, any future product liability claims against us, regardless of their merit, may result in negative publicity about us that could ultimately harm our reputation and could have a material adverse effect on our business, prospects, results of operations and financial condition.

We are required to report certain malfunctions, deaths and serious injuries associated with our products, which can result in voluntary corrective action or agency enforcement action.

Under the FDA's medical device reporting regulations, we are required to report to the FDA when information from any source suggests that any of our products may have caused or contributed to a death or serious injury or that any of our products has malfunctioned and, if the malfunction were to recur, would likely cause or contribute to death or serious injury. If we fail to report these events to the FDA within the required timeframes, or at all, the FDA could take enforcement action against us.

Any adverse event involving our products, whether in the U.S. or abroad, could result in future voluntary corrective actions, such as recalls, including corrections or customer notifications, or agency action, such as inspection or enforcement actions. If malfunctions do occur, we may be unable to correct the malfunctions adequately or prevent further malfunctions, in which case we may need to cease manufacture and distribution of the affected products, initiate voluntary recalls, and redesign the products. Regulatory authorities may also take actions against us, such as ordering recalls, imposing fines, or seizing the affected products. Any corrective

action, whether voluntary or involuntary, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

Risks Related to our Regulatory Compliance and Legal Matters

We operate in a highly regulated industry and are subject to a wide range of federal, state, and local laws, rules, and regulations, including FDA regulatory requirements and laws pertaining to fraud and abuse in healthcare, that affect nearly all aspects of our operations. Failure to comply with these laws, rules, and regulations, or to obtain and maintain required licenses, could subject us to enforcement actions, including substantial civil and criminal penalties, and might require us to recall or withdraw a product from the market or cease operations. Any of the foregoing could have a material adverse effect on our business, prospects, results of operations and financial condition.

We and our products are subject to extensive regulation in the U.S., including by the FDA. The regulations to which we are subject are complex. The FDA regulates, among other things, with respect to medical devices: design, development and manufacturing; testing, labeling, content and language of instructions for use; clinical trials; product safety; medical device cybersecurity; premarket clearance, de novo classification, and approval; establishment registration and device listing; marketing, sales and distribution; complaint handling; record keeping procedures; advertising and promotion; recalls and field safety corrective actions; post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; post-market studies; and product import and export. The FDA monitors compliance with these applicable regulatory requirements through periodic unannounced inspections as well as various other channels, such as reviewing post-market surveillance and recall reports, monitoring advertising and promotional practices on-line and at trade shows, and reviewing trade complaints submitted by competitors or other third parties. We do not know whether we will pass any future inspections for FDA compliance, or whether the FDA might identify compliance concern(s) through other channels of information. Failure to comply with applicable regulations could jeopardize our ability to sell our products and result in enforcement-related actions such as: FDA Form 483s; untitled or warning letters; clinical holds on research; fines; injunctions; civil penalties; termination of distribution; recalls or seizures of products; delays in the introduction of products into the market; total or partial suspension of production; refusal to grant future clearances, de novo classifications, or approvals; withdrawals of current marketing authorizations, resulting in prohibitions on the sale and distribution of our products; and in the most serious cases, criminal penalties. Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and could have a material adverse effect on our business, prospects, results of operations and financial condition.

The FDA and the Federal Trade Commission (the “FTC”) also regulate the advertising and promotion of our products to ensure that the claims we make are consistent with our regulatory authorizations, that there is adequate and reasonable data to substantiate the claims and that our promotional labeling and advertising is neither false nor misleading. If the FDA or FTC determines that any of our advertising or promotional claims are false, misleading, not substantiated or not permissible, we may be subject to enforcement actions, including untitled or warning letters, and we may be required to revise our promotional claims and make other corrections or restitutions. We also may be subject to fines, or other regulatory, civil, or criminal sanctions.

We are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business and may constrain the financial arrangements and relationships through which we research, as well as, sell, market and distribute any products for which we obtain marketing authorization. Such laws include, without limitation, federal and state anti-kickback, fraud and abuse, false claims, data privacy and security and physician and other healthcare provider payment transparency laws and regulations. If their operations are found to be in violation of any of such laws or any other governmental regulations that apply, they may be subject to significant penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, the curtailment or restructuring of operations, integrity oversight and reporting obligations, exclusion from participation in federal and state healthcare programs and imprisonment.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including our relationships with physicians and other healthcare providers, some of whom may be compensated in the form of stock or stock options for services provided to us and may be in the position to influence the ordering of or use of our products or product candidates, if approved, may not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non-compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly, time-consuming and may require significant personnel

resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

Our employees, consultants and commercial collaborators may engage in misconduct or other improper activities, including non-compliance with such regulatory standards and requirements.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of our activities could be subject to challenge under one or more of such laws. Any action brought against us for violations of these laws or regulations, even if successfully defended, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. We may be subject to private "qui tam" actions brought by individual whistleblowers on behalf of the federal or state governments, with potential liability under the federal False Claims Act including mandatory treble damages and significant per-claim penalties.

Although we have adopted policies and procedures designed to comply with these laws and regulations and conduct internal reviews of our compliance with these laws, our compliance is also subject to governmental review. The growth of our business and sales organization including future expansion outside of the U.S. may increase the potential of violating these laws or our internal policies and procedures. The risk of our being found in violation of these or other laws and regulations is further increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the federal, state and foreign laws described above or any other current or future fraud and abuse or other healthcare laws and regulations that apply to us, we may be subject to penalties, including significant criminal, civil and administrative penalties, damages and fines, disgorgement, 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, imprisonment for individuals and exclusion from participation in government programs, such as Medicare and Medicaid, as well as contractual damages and reputational harm. We could also be required to curtail or cease our operations. Any of the foregoing consequences could have a material adverse effect on our business, prospects, results of operations and financial condition.

The regulatory framework for digital health products is constantly evolving. Increasingly stringent regulatory requirements could create barriers to our development and introduction of new products. Conversely, in the event regulatory requirements are lowered, competitors could potentially enter the prescription digital therapeutic market and compete against us more easily.

Our digital therapeutics are novel and represent a new category of therapeutics for which the regulatory framework continues to evolve. Our ability to develop and introduce new products will depend, in part, on our ability to comply with these complex requirements, which include regulations related to product design, development and manufacturing; testing, labeling, content and language of instructions for use; clinical trials; product safety; premarket clearance, de novo classification, and approval; establishment registration and device listing; and marketing, sales and distribution. If, however, the regulatory framework for digital health products simplifies and the requirements that we and others are required to comply with are lowered, it could result in the increased competition and the introduction by competitors of products that are or claim to be superior to our products. For example, we have made our EndeavorOTC product available under the FDA-issued COVID-19 Guidance which allows for the marketing of certain digital therapeutics without premarket clearance, de novo classification, or approval so long as certain criteria are met for the duration of the COVID-19 Guidance, which was expected to remain in effect until November 7, 2023 consistent with the FDA-issued COVID-19 Transition Guidance. The COVID-19 Transition Guidance allows for the continued distribution of devices falling under the COVID-19 Guidance without marketing authorization so long as the manufacturer has submitted a marketing submission to FDA, the submission has been accepted by FDA prior to November 7, 2023 and FDA has not taken a final action on the marketing submission. While EndeavorOTC has not been authorized by FDA for any indications, we submitted a marketing submission to FDA for EndeavorOTC on October 30, 2023, and EndeavorOTC remains under review with FDA. Through communications with FDA regarding the COVID-19 Transition Guidance, it was clarified that marketing submissions received by FDA on or before November 7, 2023, that pass their technical review after the deadline without being placed on submission hold will still be eligible for continued enforcement discretion. Pursuant to FDA's guidance on this topic, we are continuing to commercialize, distribute, and market EndeavorOTC under the COVID-19 Guidance, however as announced in April 2024 we have significantly reduced promotional activity for our products. There can be no assurance that our submission will be accepted by FDA or that in the future we will obtain marketing authorizations from FDA or other regulators to market and sell EndeavorOTC or any other future products in the U.S. or anywhere else in the world. FDA has broad authority to change its enforcement discretion at any time. If our submission is not accepted or not ultimately authorized, FDA may not continue to provide enforcement discretion.

In addition, we submitted a filing to FDA seeking label expansion for EndeavorRx to include adolescents ages 13-17 with ADHD; this label expansion filing was accepted by FDA in May 2023 and was authorized by FDA in December 2023. However, there can be no assurance that we will be successful in maintaining this marketing authorization or in obtaining authorization from FDA to convert our EndeavorRx prescription product to over-the-counter labeling for any current or future indication.

Additionally, competitors using our products as predicates for 510(k)s may successfully argue that they should be required to submit substantially less data to support clearance of their product than was required for our products based on FDA's growing familiarity with the technology. As a result, we are subject to risks related to the developing regulatory landscape applicable to our digital therapeutics that could have a material adverse effect on our business, prospects, results of operations and financial condition.

Material modifications to our devices may require new 510(k) clearance, de novo classification, premarket approval, or supplement premarket approval, or may require us to cease marketing or recall the modified devices until clearances, authorizations, or approvals are obtained.

Material modifications to the intended use or technological characteristics of our devices may require new 510(k) clearance, de novo classification, Premarket Approval ("PMA"), or PMA supplement approval, or may require us to cease marketing or recall the modified devices until clearances, de novo classifications, or approvals are obtained. Any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design, or manufacture, requires a new 510(k) clearance or, possibly, a de novo or a PMA. The FDA requires every manufacturer to make and document this determination in the first instance. A manufacturer may determine that a modification could not significantly affect safety or effectiveness and does not represent a major change in its intended use, so that no new 510(k) clearance is necessary. The FDA may review any manufacturer's decision and may not agree with our decisions regarding whether new clearances, de novo classifications, or approvals are necessary. The FDA may also on its own initiative determine that a marketing authorization is required.

Additionally, we may determine that our devices may be marketed without marketing authorization under an FDA enforcement policy. If the FDA disagrees with (i) any determination we may make regarding whether a modification requires a new marketing authorization and requires us to obtain marketing authorization for a modified device for which we concluded that such authorization is unnecessary or (ii) any determination we may make to market a device without marketing authorization under an FDA enforcement policy, we may be required to cease marketing or to recall the device until we obtain marketing authorization. In these circumstances, we may also be subject to significant enforcement actions, regulatory fines or penalties, which could harm our operating results.

Obtaining and maintaining marketing authorization of our products or product candidates in one jurisdiction does not mean that we will be successful in obtaining marketing authorization of our products or product candidates in other jurisdictions.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the U.S. have requirements for marketing authorization of products or product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign marketing authorizations 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 and/or receive applicable marketing authorizations, our target market will be reduced and our ability to realize the full market potential of our products or product candidates will be harmed.

Obtaining and maintaining marketing authorization of our products or product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain marketing authorization in any other jurisdiction, while a failure or delay in obtaining marketing authorization in one jurisdiction may have a negative effect on the marketing authorization process in others. For example, even if the FDA grants marketing authorization of a product or product candidate, comparable regulatory authorities in foreign jurisdictions must also grant marketing authorization for the manufacturing, marketing and promotion of the product or product candidate in those countries. Marketing authorization procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the U.S., including additional nonclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In short, the foreign marketing authorization process involves all of the risks associated with FDA marketing authorization. In many jurisdictions outside the U.S., a product or product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we may intend to charge for our products will also be subject to approval.

Our commercialization efforts to date have focused almost exclusively on the U.S. Our ability to enter other foreign markets will depend, among other things, on our ability to navigate various regulatory regimes with which we do not have experience, which could delay or prevent the growth of our operations outside of the U.S.

To date, our commercialization efforts have focused almost exclusively on the U.S.. Expanding our business to attract customers in countries other than the U.S. is an element of our long-term business strategy. Our ability to continue to expand our business and to attract talented employees, customers and partners in various international markets will require considerable management attention and resources and is subject to the particular challenges of supporting a rapidly growing business in an environment of multiple languages, cultures, customs, legal systems, alternative dispute resolution systems, regulatory systems and commercial infrastructures. Entering new international markets will be expensive, our ability to successfully gain market acceptance in any particular market is uncertain and the distraction of our senior management team could harm our business, financial condition and results of operation.

Sales of our products outside of the U.S. are subject to foreign regulatory requirements that vary widely from country to country. In addition, the FDA regulates exports of medical devices from the U.S.. While the regulations of some countries may not impose

barriers to marketing and selling our products or only require notification, others require that we obtain the marketing authorization of a specified regulatory body. Complying with foreign regulatory requirements, including obtaining registrations or marketing authorizations, can be expensive and time-consuming, and we may not receive marketing authorizations in each country in which we may plan to market our products or we may be unable to do so on a timely basis. The time required to obtain registrations or marketing authorizations, if required by other countries, may be longer than that required for FDA clearance, de novo classification, or approval, and requirements for such registrations and marketing authorizations may significantly differ from FDA requirements. If we modify our products, we may need to apply for additional regulatory authorizations before we are permitted to sell the modified product. In addition, we may not continue to meet the quality and safety standards required to maintain the authorizations that we have received. If we are unable to maintain our authorizations in a particular country, we will no longer be able to sell the applicable product in that country. Marketing authorization by the FDA does not ensure registration or marketing authorization by regulatory authorities in other countries, and registration or marketing authorization by one or more foreign regulatory authorities does not ensure registration or marketing authorization by regulatory authorities in other foreign countries or by the FDA. A failure or delay in obtaining registration or marketing authorization in one country may have a negative effect on the regulatory process in others.

Doing business internationally involves a number of additional risks, including:

- multiple, conflicting and changing laws and regulations such as tax laws, privacy and data protection laws and regulations, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- requirements to maintain data and the processing of that data on servers located within the United States or in such countries;
- protecting and enforcing our intellectual property rights;
- converting our products as well as the accompanying instructional and marketing materials to conform to the language and customs of different countries;
- complexities associated with managing multiple payer reimbursement regimes, and government payers;
- competition from companies with significant market share in our market and with a better understanding of user preferences;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the effect of local and regional financial pressures on demand and payment for our products and services and exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism, political unrest, outbreak of disease (including the recent coronavirus outbreak), boycotts, curtailment of trade, and other market restrictions; and
- regulatory and compliance risks that relate to maintaining accurate information and control over activities subject to regulation under the U.S. Foreign Corrupt Practices Act (the “FCPA”), and comparable laws and regulations in other countries.

These risks and uncertainties may impact the Company’s ability to enter foreign markets, which could delay or prevent the growth of the Company’s operations outside of the U.S., and have a material adverse effect on our business, prospects, results of operations and financial condition.

The insurance coverage and reimbursement status of products that recently obtained marketing authorization or may in the future obtain marketing authorization is uncertain. Failure by us or our partners to obtain or maintain adequate coverage and reimbursement for any of our products or product candidates, particularly outside of the U.S., if granted marketing authorization, could limit our or our partners’ ability to market those products and materially and adversely affect our ability to generate revenue.

In some foreign countries, the proposed pricing for a prescription device must be approved before it may be lawfully marketed. The requirements governing medical product pricing, coverage, and reimbursement vary widely from country to country. For example, the European Union provides options for its member states 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 products 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 pharmaceuticals or medical devices will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the U.S. and generally prices tend to be significantly lower. We previously announced our transition from a prescription to a non-prescription business model and while we are not currently marketing or selling

our products in any country other than the U.S., including the European Union or any of its member states, in the event that we or our partners choose to do so in the future, we and our partners will need to comply with such requirements. For more information, see *"Business - Government Regulation - Coverage and Reimbursement"* in the Annual Report.

We may be subject to governmental investigation, litigation, and other proceedings, which are costly to defend and could have a material adverse effect on our business, prospects, results of operations and financial condition.

We may be party to government investigations, lawsuits and legal proceedings in the normal course of business. These matters are often expensive and disruptive to normal business operations. We may face allegations, lawsuits and regulatory inquiries, audits and investigations regarding data privacy, security, labor and employment, consumer protection and intellectual property infringement, including claims related to privacy, patents, publicity, trademarks, copyrights and other rights. A portion of the technologies we use incorporates open source software, and we may face claims claiming ownership of open source software or patents related to that software, rights to our intellectual property or breach of open source license terms, including a demand to release material portions of our source code or otherwise seeking to enforce the terms of the applicable open source license. We may also face allegations or litigation related to our acquisitions, securities issuances or business practices, including public disclosures about our business. Litigation and regulatory proceedings, and particularly the patent infringement and class action matters we could face, may be protracted and expensive, and the results are difficult to predict. Certain of these matters may include speculative claims for substantial or indeterminate amounts of damages and include claims for injunctive relief. Additionally, our litigation costs could be significant. Adverse outcomes with respect to litigation or any of these legal proceedings may result in significant settlement costs or judgments, penalties and fines, or require us to modify our solution or require us to stop offering certain features, all of which could have a material adverse effect on our business, prospects, results of operations and financial condition. We may also become subject to periodic audits, which would likely increase our regulatory compliance costs and may require us to change our business practices, which could have a material adverse effect on our business, prospects, results of operations and financial condition. Managing legal proceedings, litigation and audits, even if we achieve favorable outcomes, is time-consuming and diverts management's attention from our business.

The results of regulatory proceedings, litigation, claims, and audits cannot be predicted with certainty, and determining reserves for pending litigation and other legal, regulatory and audit matters requires significant judgment. There can be no assurance that our expectations will prove correct, and even if these matters are resolved in our favor or without significant cash settlements, these matters, and the time and resources necessary to litigate or resolve them, could have a material adverse effect on our business, prospects, results of operations, financial condition and the market price of our common stock.

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

We currently engage in certain activities supporting our product and platform development activities that occur outside the U.S., and for these activities we must dedicate additional resources to comply with numerous laws and regulations in each such jurisdiction. Additionally, the FCPA prohibits any U.S. individual or business from paying, offering, 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 U.S. 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 with 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 U.S., or the sharing with certain non-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 activities outside of the U.S., 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 U.S., 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.

Healthcare reform and other governmental and private payer initiatives may have an adverse effect upon, and could prevent, our products' or product candidates' commercial success.

In the U.S. and in certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could impact our ability to sell our products profitably, such as the ACA. For more information, see "*Business – Government Regulation – Healthcare Reform*" in the Annual Report.

There has been increasing legislative and enforcement interest in the U.S. with respect to prescription-pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed 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. The HHS has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. It is unclear what effect such legislative and enforcement interest may have on prescription devices.

We expect that these and other healthcare reform measures that 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 cleared, de novo classified, or approved device, which could have an adverse effect on patients for our products or product candidates. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payers.

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.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels in the U.S. directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. 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. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain marketing authorization and that may affect our overall financial condition and ability to develop product candidates. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our current or any future product candidates we may develop may lose any marketing authorization that may have been obtained and we may not achieve or sustain profitability.

If we fail to comply with the FDA's QSR or any applicable foreign equivalent, our operations could be interrupted, and our potential product sales and operating results could suffer.

We are required to comply with the FDA's QSR, which delineates, among other things, the design controls, document controls, purchasing controls, identification and traceability, production and process controls, acceptance activities, nonconforming product requirements, corrective and preventive action requirements, labeling and packaging controls, handling, storage, distribution and installation requirements, complaint handling, records requirements, servicing requirements, and statistical techniques potentially applicable to the production of our medical devices. We are also subject to the regulations of foreign jurisdictions if we market products overseas.

The FDA enforces the QSR through periodic and announced or unannounced inspections of manufacturing facilities. If our facilities or processes are found to be in non-compliance or fail to take satisfactory corrective action in response to adverse QSR inspectional findings, the FDA could take legal or regulatory enforcement actions against us and/or our products, including but not limited to the cessation of sales or the initiation of a recall of distributed products, which could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. We may also be required to bear other costs or take other actions that may have a negative impact on our future sales and our ability to generate profits.

The FDA's and other comparable non-U.S. regulatory agencies' statutes, regulations, policies or interpretations may change, and additional government regulation or statutes may be enacted, which could increase regulatory requirements, or delay, suspend, prevent marketing of any cleared, de novo classified, or approved products or necessitate the recall of distributed products. For example, on February 2, 2024, the FDA published a final rule to amend its QSR requirements to align more closely with the international consensus standards for medical devices by converging with QMS requirements used by other regulatory authorities from other countries. Specifically, the final rule does so primarily by incorporating by reference the ISO, ISO 13485 standard. The amended

regulation is referred to as the QMSR and is effective February 2, 2026. 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 authorization that we may have obtained, which could have a material adverse effect on our business, prospects, results of operations, financial condition and our ability to achieve or sustain profitability. Further, we cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the U.S. or abroad.

The medical device industry has been under heightened FDA scrutiny as the subject of government investigations and enforcement actions. If our operations and activities are found to be in violation of any FDA laws or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and other legal and/or agency enforcement actions. Any penalties, damages, fines, or curtailment or restructuring of our operations or activities could materially and adversely affect our ability to operate our business and our financial results. The risk of us being found in violation of FDA laws is increased by the fact that many of these laws are broad and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend ourselves against that action and its underlying allegations, could cause us to incur significant legal expenses and divert management's attention from the operation of our business. Where there is a dispute with a federal or state governmental agency that cannot be resolved to the mutual satisfaction of all relevant parties, we may determine that the costs, both real and contingent, are not justified by the commercial returns to us from maintaining the dispute or the product.

Various claims, design features, or performance characteristics of our medical devices that we regarded as permitted by the FDA without new marketing authorization may be challenged by the FDA or state or foreign regulators. The FDA or state or foreign regulatory authorities may find that certain claims, design features, or performance characteristics, in order to be made or included in the products, may have to be supported by further clinical studies and authorizations, which could be lengthy, costly, and possibly unobtainable.

We are subject to data privacy and security laws and regulations governing our collection, use, disclosure or storage of personally identifiable information, including protected health information and payment card data, which may impose restrictions on us and our operations. Any actual or perceived noncompliance with such laws and regulations may result in penalties, regulatory action, loss of business or unfavorable publicity.

Numerous federal and state laws and regulations govern the collection, use, disclosure, storage and transmission of personally identifiable information ("PII") including protected health information ("PHI") and information related to treatment for ADHD and other diseases and disorders resulting in cognitive impairment. These laws and regulations, including their interpretation by governmental agencies, are subject to frequent change and could have a negative impact on our business. In addition, in the future, industry requirements or guidance, contractual obligations, and/or legislation at both the federal and the state level may limit, forbid or regulate the use or transmission of health information outside of the U.S.

These varying interpretations can create complex compliance issues for us and our partners and potentially expose us to additional expense, adverse publicity and liability, any of which could have a material adverse effect on our business, prospects, results of operations and financial condition.

Federal and state consumer protection laws are increasingly being applied by the FTC and states' attorneys general to regulate the collection, use, storage and disclosure of PII, through websites or otherwise, and to regulate the presentation of website content.

The security measures that we and our third-party vendors and subcontractors have in place to ensure compliance with privacy and data protection laws may not protect our facilities and systems from security breaches, acts of vandalism or theft, computer viruses, misplaced or lost data, programming and human errors or other similar events. Even though we provide for protections through our agreements with our third-party vendors, we still have limited control over their actions and practices. A breach of privacy or security of PII or PHI may result in an enforcement action, including criminal and civil liability, against us. We are not able to predict the extent of the impact such incidents may have on our business. Enforcement actions against us could be costly and could interrupt regular operations, which could have a material adverse effect on our business, prospects, results of operations and financial condition. Even if it is determined that there was no violation of laws, enforcement actions against us could be costly, generate negative publicity and could interrupt regular operations, which could have a material adverse effect on our business, prospects, results of operations and financial condition. While we have not received any notices of violation of the applicable privacy and data protection laws and believe we are in compliance with such laws, there can be no assurance that we will not receive such notices in the future.

There is ongoing concern from privacy advocates, regulators and others regarding data privacy and security issues, and the number of jurisdictions with data privacy and security laws has been increasing. Also, there are ongoing public policy discussions regarding whether the standards for de-identification, anonymization or pseudonymization of health information are sufficient, and the risk of re-identification sufficiently small, to adequately protect patient privacy. We expect there will continue to be new proposed and amended laws, regulations and industry standards concerning privacy, data protection and information security in the U.S., such as the CCPA. In addition, New York's Stop Hacks and Improve Electronic Data Security Act, the SHIELD Act, requires any person or business owning or licensing computerized data that includes the private information of a resident of New York to implement and maintain reasonable safeguards to protect the security, confidentiality and integrity of the private information. Other U.S. states also are considering omnibus privacy legislation and industry organizations regularly adopt and advocate for new standards in these areas.

While the CCPA contains exceptions for certain activities involving PHI under the Health Insurance Portability Administration and Accountability Act of 1996, as amended ("HIPAA"), we cannot yet determine the impact that existing comprehensive state privacy laws or other such future laws, regulations and standards may have on our business.

A number of other states have proposed new privacy laws, some of which are similar to the above discussed recently passed laws. Such proposed legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and/or changes in business practices and policies. Furthermore, in addition to comprehensive privacy laws, certain states have enacted laws to focus on particular more limited privacy laws. For example, the state of Washington has passed a law to protect medical and health information not subject to HIPAA and a small number of states have passed laws that regulate biometric information. The existence of comprehensive privacy laws in different states in the country would make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance.

Future laws, regulations, standards, obligations, amendments, and changes in the interpretation of existing laws, regulations, standards and obligations could impair our or our customers' ability to collect, use or disclose information relating to users, including information derived therefrom, which could decrease demand for our products, increase our costs and impair our ability to maintain and grow our customer base and increase our revenue. Accordingly, we may find it necessary or desirable to fundamentally change our business activities and practices or to expend significant resources to modify our software or platform and otherwise adapt to these changes.

Further, our patients and users may expect us to comply with more stringent privacy and data security requirements than those imposed by laws, regulations or self-regulatory requirements, and we may be obligated contractually to comply with additional or different standards relating to our handling or protection of data. If we, or any third parties we or our partners use to process PII on our behalf, are unable to properly protect the privacy and security of personal information, including protected health information, we and they could be found to have breached our and their contracts with certain third parties.

Any failure or perceived failure by us to comply with federal or state laws or regulations, industry standards or other legal obligations, or any actual or suspected privacy or security incident, whether or not resulting in unauthorized access to, or acquisition, release or transfer of PII or other data, may result in governmental enforcement actions and prosecutions, private litigation, fines and penalties or adverse publicity and could cause our customers to lose trust in us, which could have a material adverse effect on our reputation, business, prospects, results of operations and financial condition. We may be unable to make such changes and modifications in a commercially reasonable manner or at all, and our ability to develop new products could be limited. Any of these developments could harm our business, financial condition and results of operations. Privacy and data security concerns, whether valid or not valid, may inhibit retention of our products by existing customers or adoption of our products by new customers.

Around the world, data collection and use are governed by laws and regulations governing the use, processing and cross-border transfer of personal information.

In the event we decide to conduct clinical trials or engage in other human data collection, we may be subject to additional privacy restrictions. Many foreign jurisdictions, including, without limitation, member states of the European Union (the "EU"), and the United Kingdom, Canada, Israel, Australia, New Zealand, Japan and many other countries have adopted legislation that increase or change the requirements governing the collection, distribution, use, storage, disclosure, or other processing, and/or security of personal information and other data in these jurisdictions. If our privacy or data security measures fail to comply with current or future laws and regulations, we may be subject to litigation, regulatory investigations or other liabilities, or our customers may terminate their relationships with us.

Personal privacy and data security have become significant issues in the U.S., Europe, and in many other jurisdictions. The regulatory framework for privacy and security issues worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Many federal, state, and foreign government bodies and agencies have adopted, or are considering adopting, laws and regulations regarding the collection, use, and disclosure of personal information, including protected health information. These laws and regulations, including their interpretation by governmental agencies, are subject to frequent change and could have a negative impact on Akili's business. In addition, in the future, industry requirements or guidance, contractual obligations, and/or legislation at both the federal and the state level may limit, forbid or regulate the use or transmission of health information outside of the U.S..

These varying interpretations can create complex compliance issues for us and our partners and potentially expose us to additional expense, adverse publicity and liability, any of which could adversely affect our business.
Federal and state consumer protection laws are increasingly being applied by the FTC and states' attorneys general to regulate the collection, use, storage and disclosure of personal or personally identifiable information, through websites or otherwise, and to regulate the presentation of website content.

The security measures that we and our third-party vendors and subcontractors have in place to ensure compliance with privacy and data protection laws may not protect our facilities and systems from security breaches, acts of vandalism or theft, computer viruses,

misplaced or lost data, programming and human errors or other similar events. Even though we provide for appropriate protections through our agreements with our third-party vendors, we still have limited control over their actions and practices. A breach of privacy or security of personally identifiable health information may result in an enforcement action, including criminal and civil liability, against us. We are not able to predict the extent of the impact such incidents may have on our business. Enforcement actions against us could be costly and could interrupt regular operations, which may adversely affect our business. While we have not received any notices of violation of the applicable privacy and data protection laws and believe we are in compliance with such laws, there can be no assurance that we will not receive such notices in the future.

Our international operations are subject to international laws and regulations, regulatory guidance, and industry standards relating to data protection, privacy, and information security. For EU and UK future operations, if any, this would include the GDPR and the UK GDPR. The GDPR and the UK GDPR are currently still aligned but there may be further divergence in the future, including with regard to administrative burdens. The UK has announced plans to reform the country's data protection legal framework in its Data Reform Bill, which will introduce changes to the UK GDPR. This may lead to additional compliance costs and could increase our overall risk exposure as we may no longer be able to take a unified approach across the EU and the UK.

The GDPR and UK GDPR are wide-ranging in scope and impose numerous additional requirements on companies that process personal data, including requirements relating to having a legal basis for processing personal data, stricter requirements relating to the processing of sensitive data (such as health data), requiring that consent of individuals to whom the personal data relates is obtained in certain circumstances, requiring disclosures to individuals regarding data processing activities, requiring that safeguards are implemented to protect the security and confidentiality of personal data, creating mandatory data breach notification requirements in certain circumstances, requiring data protection impact assessments for high-risk processing and requiring that certain measures (including contractual requirements) are put in place when engaging third-party processors. The GDPR and the UK GDPR also provide individuals with various rights in respect of their personal data, including rights of access, erasure, portability, rectification, restriction and objection. The GDPR and UK GDPR define personal data to include pseudonymized or coded data and requires different informed consent practices and more detailed notices for clinical trial participants and investigators than apply to clinical trials conducted in the U.S. We are required to apply GDPR and UK GDPR standards to any clinical trials that our EU and UK established businesses carry out anywhere in the world.

The GDPR and UK GDPR impose strict rules on the transfer of personal data to countries outside the EU, including the U.S. The UK and Switzerland have adopted similar restrictions. Although the UK is regarded as a third country under the GDPR, EC has now issued a decision recognizing the UK as providing adequate protection under the GDPR and, therefore, transfers of personal data originating in the EU to the UK remain unrestricted. Like the GDPR, the UK GDPR restricts personal data transfers outside the UK to countries not regarded by the UK as providing adequate protection. The UK government has confirmed that personal data transfers from the UK to the EU remain free flowing.

To enable the transfer of personal data outside of the EU or the UK, adequate safeguards must be implemented in compliance with European and UK data protection laws. On June 4, 2021, the EC issued new forms of standard contractual clauses for data transfers from controllers or processors in the EU (or otherwise subject to the GDPR) to controllers or processors established outside the EU (and not subject to the GDPR). The new standard contractual clauses require exporters to assess the risk of a data transfer on a case-by-case basis, including an analysis of the laws in the destination country. The UK is not subject to the EC's new standard contractual clauses but has published a UK-specific transfer mechanism, which enables transfers from the UK. The UK-specific mechanism, the "International Data Transfer Agreement", requires a similar risk assessment of the transfer as the standard contractual clauses. Further, the EU and United States have adopted its adequacy decision for the EU-U.S. Data Privacy Framework ("Framework"), which entered into force on July 11, 2023. This Framework provides that the protection of personal data transferred between the EU and the U.S. is comparable to that offered in the EU. This provides a further avenue to ensuring transfers to the United States are carried out in line with GDPR. There has been an extension to the Framework to cover UK transfers to the United States. The Framework could be challenged like its predecessor frameworks. We are required to implement these new safeguards when conducting restricted data transfers under GDPR and UK GDPR and doing so requires significant effort and cost.

The GDPR and UK GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR and UK GDPR. Implementing legislation in applicable EU member states and the UK, including by seeking to establish appropriate lawful bases for the various processing activities we carry out as a controller or joint controller, reviewing security procedures and those of our vendors and collaborators, and entering into data processing agreements with relevant vendors and collaborators, we cannot be certain that our efforts to achieve and remain in compliance have been, and/or will continue to be, fully successful. Given the breadth and depth of changes in data protection obligations, preparing for and complying with the GDPR and UK GDPR and similar laws' requirements are rigorous and time intensive and require significant resources and a review of our technologies, systems and practices, as well as those of any third-party collaborators, service providers, contractors or consultants that process or transfer personal data.

Other countries around the world in which we conduct trials or otherwise do business have also enacted strict privacy and data protection laws. For example, the Act on the Protection of Personal Information ("APPI") of Japan regulates privacy protection issues in Japan. The APPI shares similarities with the GDPR, including extraterritorial application and obligations to provide certain notices

and rights to citizens of Japan. We may be required to modify our policies, procedures, and data processing measures in order to address requirements under these or other privacy, data protection, or cyber security regimes, and may face claims, litigation, investigations, or other proceedings regarding them and may incur related liabilities, expenses, costs, and operational losses.

In addition to general privacy and data protection requirements, many jurisdictions around the world have adopted legislation that regulates how businesses operate online and enforces information security, including measures relating to privacy, data security and data breaches. Many of these laws require businesses to notify data breaches to the regulators and/or to data subjects. These laws are not consistent, and compliance in the event of a widespread data breach is costly and burdensome.

In many jurisdictions, enforcement actions and consequences for non-compliance with protection, privacy and information security laws and regulations are rising. In the EU and the UK, data protection authorities may impose large penalties for violations of the data protection laws, including potential fines of up to €20 million (£17.5 million in the UK) or 4% of annual global revenue, whichever is greater. The authorities have shown a willingness to impose significant fines and issue orders preventing the processing of personal data on non-compliant businesses. Data subjects also have a private right of action, as do consumer associations, to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of applicable data protection laws. The APPI allows for fines of up to ¥100 million for violations of the law. In the U.S., possible consequences for non-compliance include enforcement actions in response to rules and regulations promulgated under the authority of federal agencies and state attorneys general and legislatures and consumer protection agencies.

In addition, privacy advocates and industry groups have regularly proposed, and may propose in the future, self-regulatory standards that may legally or contractually apply to us. If we fail to follow these security standards, even if no customer information is compromised, we may incur significant fines or experience a significant increase in costs.

The risk of our being found in violation of these laws is increased by the fact that the interpretation and enforcement of such laws is not entirely clear. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

Compliance with 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. It could also require us to change our business practices and put in place additional compliance mechanisms, may interrupt or delay our development, regulatory and commercialization activities and increase our cost of doing business. Failure by us or our collaborators and third-party providers to comply with data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties and orders preventing us from processing personal data), private litigation and result in significant fines and penalties against us. Moreover, clinical trial participants about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to 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, could result in adverse publicity and could have a material adverse effect on our business, financial condition, results of operations and prospects.

We provide patient and user services using text and voice calls to communicate with healthcare providers, patients, users and prospective patients, and we are subject to various marketing and advertising laws including the Telephone Consumer Protection Act (the "TCPA"). If we fail to comply with applicable laws, including the TCPA, we may be subject to significant liabilities.

Our patient service center uses short message service ("SMS") text messages and telephone calls to communicate with healthcare providers, patients and prospective patients. We also may use SMS, text messages and telephone calls for marketing purposes with the recipient's advance consent. The actual or perceived improper sending of text messages or the making of telephone calls may subject us to potential risks, including liabilities or claims relating to consumer protection laws. Numerous class-action suits under federal and state laws have been filed in recent years against companies who conduct SMS texting programs or make unwanted telephone calls, with many resulting in multi-million-dollar settlements to the plaintiffs. Any future such litigation against us could be costly and time-consuming to defend. For example, the Telephone Consumer Protections Act of 1991, the TCPA, is a federal statute that protects consumers from unwanted telephone calls, faxes, and text messages, and restricts telemarketing and the use of automated SMS text messages without proper consent. Additionally, state regulators may determine that telephone calls to our patients or users are subject to state telemarketing regulations. Federal or state regulatory authorities or private litigants may claim that the notices and disclosures we provide, form of consents we obtain, or our SMS texting practices are not adequate or violate applicable law. This may in the future result in civil claims against us. The scope and interpretation of the laws that are or may be applicable to the delivery of text messages are continuously evolving and developing. If we do not comply with these laws or regulations or if we become liable under these laws or regulations, we could face direct liability, could be required to change some portions of our business model, could face negative publicity, and our business, prospects, results of operations and financial condition could be materially and adversely

affected. Even an unsuccessful challenge of our SMS texting or telephone calling practices by our customers, regulatory authorities, or other third parties could result in negative publicity and could require a costly response from and defense by us.

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. Our relationships with customers and third-party payers 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, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.

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 herein as "Trade Laws"), prohibit companies and their employees, agents, clinical research organizations, 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 expect our non-U.S. activities may increase in time. If our non-U.S. activities were to increase in the future, we plan to engage third parties for clinical trials and/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. Any of these consequences could have a material adverse effect on our business, prospects, results of operations and financial condition.

Our employees, independent contractors, consultants, commercial collaborators, principal investigators, vendors and other agents may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, vendors and other agents may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or disclosure of unauthorized activities to us that violates applicable regulations, including those laws requiring the reporting of true, complete and accurate information to regulatory agencies, manufacturing standards and U.S. federal and state healthcare laws and regulations. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. We could face liability under the U.S. federal Anti-Kickback Statute and similar U.S. state laws. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, referrals, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in significant regulatory sanctions and serious harm to our reputation. Further, should violations include promotion of unapproved (off-label) uses of one or more of our products, we could face significant regulatory sanctions for unlawful promotion, as well as substantial penalties under applicable federal or state laws. Similar concerns could exist in jurisdictions outside of the U.S. as well. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. For more information, see "*Business – Government Regulation – Health Care Laws and Regulations"* in the Annual Report.

It is possible that we may make grants to independent charitable foundations that help financially needy patients with their premium, co-pay, and co-insurance obligations. If we choose to do so, and if we or our vendors or donation recipients are deemed to fail to comply with relevant laws, regulations or evolving government guidance in the operation of these programs, we could be subject to damages, fines, penalties, or other criminal, civil, or administrative sanctions or enforcement actions. We cannot ensure that our compliance controls, policies, and procedures will be sufficient to protect against acts of our employees, business partners, or vendors that may violate the laws or regulations of the jurisdictions in which we operate. Regardless of whether we have complied with the law, a government investigation could impact our business practices, harm our reputation, divert the attention of management, increase our expenses, and reduce the availability of foundation support for our patients who need assistance.

The precautions we take to detect and prevent misconduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or 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, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, 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, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could have a material adverse effect on our business, prospects, results of operations and financial condition.

Federal, state and local employment-related laws and regulations could increase our cost of doing business and subject us to fines and lawsuits.

Our operations are subject to a variety of federal, state and local employment-related laws and regulations, including, but not limited to, the U.S. Fair Labor Standards Act, which governs such matters as minimum wages, the Family Medical Leave Act, overtime pay, compensable time, recordkeeping and other working conditions, Title VII of the Civil Rights Act, the Employee Retirement Income Security Act, the Americans with Disabilities Act, the National Labor Relations Act, regulations of the Equal Employment Opportunity Commission, regulations of the Office of Civil Rights, regulations of the Department of Labor (DOL), regulations of state attorneys general, federal and state wage and hour laws, and a variety of similar laws enacted by the federal and state governments that govern these and other employment-related matters. As our employees are located in a number of states, compliance with these evolving federal, state and local laws and regulations could substantially increase our cost of doing business while failure to do so could subject us to fines and lawsuits.

Risks Related to our Intellectual Property and Technology

If we are unable to adequately protect and enforce our intellectual property and proprietary technology, obtain and maintain patent protection for our technology and products where appropriate or if the scope of the patent protection obtained is not sufficiently broad, or if we are unable to protect the confidentiality of our trade secrets and know-how, our competitors could develop and commercialize technology and products similar or identical to our products, and our ability to successfully commercialize our technology and products may be impaired.

Our commercial success will depend in part on our ability to obtain, maintain, protect and enforce our proprietary and intellectual property rights in the U.S. and other countries for our products and product candidates, and our core technologies, including EndeavorRx, EndeavorOTC, preclinical and clinical assets, methods of use patents and related know-how. We seek to protect our proprietary and intellectual property position by, among other methods, filing patent applications in the U.S. and abroad related to our proprietary technology, inventions and improvements that are important to the development and implementation of our business. However, the patent process is expensive, time consuming and complex, and we may not be able to apply for patents on certain aspects of our technology and products in a timely fashion, at a reasonable cost, in all jurisdictions or at all, and any potential patent coverage we obtain may not be sufficient to prevent substantial competition. In some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain, enforce and defend the patents, covering technology that we may exclusively license from third parties. Further, we can provide no assurance that any of our current or future patent applications will result in issued patents or that any issued patents will provide us with any competitive advantage. In addition, we also rely on trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary and intellectual property position that we seek to protect, in part, through confidentiality agreements with employees, consultants and others. We cannot assure you, however, that our proprietary information will not be shared or accessed without authorization, that our confidentiality agreements will not be breached, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise become known to or independently developed by competitors. Further, if any collaboration partner or licensor is unable to obtain or maintain patent or trade secret protection with respect to product candidates that we or they currently are or may in the future develop, or if the scope of the protection secured is not sufficiently broad, third parties could develop and commercialize products similar or identical to ours and our ability to commercialize any product candidates we may develop may be adversely affected. Our inability to maintain and protect our proprietary information and trade secrets could have a material adverse effect on our business, prospects, results of operations and financial conditions.

We may become involved in litigation to protect or enforce our patents and other intellectual property rights, which could be expensive, time consuming and unsuccessful. We may not be able to effectively prosecute and enforce our intellectual property rights throughout the world. Failure to protect or enforce intellectual property rights could have a material adverse effect on our business, prospects, results of operations and financial condition.

Competitors and other third parties may infringe, misappropriate or otherwise violate our patents and other intellectual property rights. To counter infringement or unauthorized use, we may be required to file infringement claims. A court may disagree with our allegations, however, and may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover it. Further, such third parties could counterclaim that we infringe their intellectual property or that a patent we have asserted against them is invalid or unenforceable. In patent litigation in the U.S., defendant counterclaims, post-grant review, and *inter partes* reviews challenging the validity, enforceability or scope of asserted patents are commonplace. In addition, third parties may initiate legal proceedings against us to assert such challenges to our intellectual property rights. The outcome of any such proceeding is generally unpredictable. 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. Patents may be unenforceable if someone connected with prosecution of the patent withheld relevant information from the U.S. Patent and Trademark Office (the “USPTO”) or made a misleading statement during prosecution. It is possible that prior art of which we and the patent examiner were unaware during prosecution exists, which could render any patents that may issue invalid. Moreover, it is also possible that prior art may exist that we are aware of but do not believe is relevant to our future patents, should they issue, but that could nevertheless be determined to render our patents invalid.

An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. If a defendant were to prevail on a legal assertion of invalidity or unenforceability of our patents covering one of our products or product candidates, we would lose at least part, and perhaps all, of the patent protection covering such product, product candidate or technology. Competing products may also be sold in other countries in which our patent coverage might not exist or be as strong. Any litigation or other proceedings to enforce our intellectual property rights may fail and, even if successful, may result in substantial costs and distract our management and other personnel. Any of the foregoing could have a material adverse effect on our business, prospects, results of operations and financial condition.

Accusations of infringement of third-party intellectual property rights could have a material adverse effect on our business, prospects, results of operations and financial condition.

There has been substantial litigation in the healthcare industry regarding intellectual property rights, and we may be sued for infringement from time to time in the future. Also, in some instances, we have agreed to indemnify third parties for expenses and liability resulting from claimed intellectual property infringement. From time to time, we may receive requests for indemnification in connection with allegations of intellectual property infringement and we may choose, or be required, to assume the defense and/or reimburse third parties for their expenses, settlement and/or liability. We cannot assure you that we will be able to settle any future claims or, if we are able to settle any such claims, that the settlement will be on terms favorable to us. Our broad range of technology may increase the likelihood that third parties will claim that we infringe their intellectual property rights.

We may in the future receive notices of allegations of infringement, misappropriation or misuse of other parties' proprietary rights. Furthermore, regardless of their merits, accusations and litigation of this nature may require significant time and expense to defend, may negatively affect customer relationships, may divert management's attention away from other aspects of our operations and, upon resolution, could have a material adverse effect on our business, prospects, results of operations and financial condition.

Certain technology necessary for us to provide our solutions may, in fact, be patented by other parties either now or in the future. If such technology were validly patented by a third party, we may have to negotiate a license for the use of that technology. We may not be able to negotiate such a license at a price that is acceptable to us or at all. The existence of such a patent, or our inability to negotiate a license for any such technology on acceptable terms, could force us to cease using the technology and cease offering products incorporating the technology, which could have a material adverse effect on our business, prospects, results of operations and financial condition.

If we, or any of our products or product candidates, were found to be infringing on the intellectual property rights of any third party, we could be subject to liability for such infringement, which could be material. We could also be prohibited from using or selling certain products or product candidates, prohibited from using certain processes, or required to redesign certain products or product candidates, each of which could have a material adverse effect on our business, prospects, results of operations and financial condition.

These and other outcomes may result in the loss of a substantial number of existing customers or prohibit the acquisition of new customers; cause us to pay license fees for intellectual property we are deemed to have infringed; cause us to incur costs and devote valuable technical resources to redesigning our products or product candidates; cause our cost of revenues to increase; cause us to accelerate expenditures to preserve existing revenues; materially and adversely affect our brand in the marketplace and cause a substantial loss of goodwill; cause us to change our business methods or products or product candidates; and require us to cease certain business operations or offering certain products or features.

If we fail to comply with obligations in the agreements under which we collaborate with or license intellectual property rights from third parties, or otherwise experience disruptions to our business relationships with collaborators or licensors, we could lose rights that are important to our business.

We license certain intellectual property that is important to our business, including from the University of California San Francisco, and in the future we may enter into additional agreements that provide us with licenses to valuable intellectual property or technology. Some of our current license agreements impose various development, diligence, commercialization or sublicensing, and other obligations, including payments in connection with the achievement of specified milestones, on us in order to maintain the licenses. In spite of our efforts, a current or future licensor might conclude that we have materially breached our obligations under such license agreements and seek to terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patent rights licensed thereunder fail to provide the intended exclusivity, competitors or other third parties would have the freedom to seek marketing authorization of, and to market, products identical to ours and we may be required to cease our development and commercialization of certain of our product candidates. Any of the foregoing could have a material adverse effect on our business, prospects, results of operations and financial condition.

Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;

- the extent to which our technology and processing infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

The agreements under which we may license intellectual property or technology from third parties may be complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, prospects, results of operations and financial condition. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, prospects, results of operations and financial condition.

Confidentiality and intellectual property assignment agreements that we have with our employees and other parties may not adequately prevent disclosure of trade secrets and other proprietary information.

We depend heavily upon confidentiality agreements with our officers, employees, consultants and subcontractors to maintain the proprietary nature of our technology. These measures may not afford us complete or even sufficient protection, and may not afford an adequate remedy in the event of an unauthorized disclosure of confidential information. If we fail to protect and/or maintain our intellectual property, third parties may be able to compete more effectively against us, we may lose our technological or competitive advantage, and/or we may incur substantial litigation costs in our attempts to recover or restrict use of our intellectual property. In addition, others may independently develop technology similar to ours, otherwise avoiding the confidentiality agreements, or produce patents that would materially and adversely affect our business, prospects, financial condition and results of operations. A third party may also attempt to reverse engineer or otherwise obtain and use our proprietary technology without our consent which could have a material adverse effect on our business, prospects, results of operations and financial condition.

Some of our solutions utilize third-party open-source data and software, and any failure to comply with the terms of one or more of these open-source software licenses could have a material adverse effect on our business, prospects, results of operations and financial condition, subject us to litigation, or create potential liability.

Our solutions include software and data licensed from third parties under any one or more open source licenses, and we expect to continue to incorporate open source software in our solutions in the future. Moreover, we cannot ensure that we have effectively monitored our use of open source software, or validated the quality or source of such software, or that we are in compliance with the terms of the applicable open source licenses or our current policies and procedures. There have been claims against companies that use open source software in their products and services asserting that the use of such open source software infringes the claimants' intellectual property rights. As a result, we could be subject to suits by third parties claiming that what we believe to be licensed open source software infringes such third parties' intellectual property rights. Additionally, if an author or other third party that distributes such open source software were to allege that we had not complied with the conditions of one or more of these licenses, we could be required to incur significant legal expenses defending against such allegations and could be subject to significant damages and required to comply with onerous conditions or restrictions on these solutions, which could disrupt the distribution and sale of these solutions. Litigation could be costly for us to defend, have a material adverse effect on our business, prospects, results of operations and financial condition, or require us to devote additional research and development resources to change our solutions. Furthermore, these third-party open source providers could experience service outages, data loss, privacy breaches, cyber-attacks, and other events relating to the applications and services they provide that could diminish the utility of these services and which could harm our business as a result.

Use of open source software may entail greater risks than use of third-party commercial software, as open source licensors generally do not provide warranties or other contractual protections regarding infringement claims or the quality of the code, including with respect to security vulnerabilities where open source software may be more susceptible. In addition, certain open source licenses require that source code for software programs that interact with such open source software be made available to the public at no cost and that any modifications or derivative works to such open source software continue to be licensed under the same terms as the open source software license. The terms of various open source licenses to which we are subject have not been interpreted by courts in the relevant jurisdictions, and there is a risk that such licenses could be construed in a manner that imposes unanticipated conditions or restrictions on our ability to market or provide our software and data. By the terms of certain open source licenses, we could be required to release the source code of our proprietary software, and to make our proprietary software available under open source licenses, if we combine our proprietary software with open source software in a certain manner. In the event that portions of our

proprietary software are determined to be subject to an open source license, we could be required to publicly release the affected portions of our source code, re-engineer all or a portion of our solutions, or otherwise be limited in the licensing of our solutions, each of which could reduce or eliminate the value of our solutions. Disclosing our proprietary source code could allow our competitors to create similar products with lower development effort and time and ultimately could result in a loss of sales. Furthermore, any such re-engineering or other remedial efforts could require significant additional research and development resources, and we may not be able to successfully complete any such re-engineering or other remedial efforts. Any of these events could create liability for us and damage our reputation, which could have a material adverse effect on our business, prospects, results of operations, financial condition and the market price of our shares.

Changes to the patent law in the U.S. and other jurisdictions could diminish the value of patents in general and may impact the validity, scope or enforceability of our patent rights, thereby impairing our ability to protect our products or product candidates.

As is the case with other digital therapeutic companies, our success is dependent on intellectual property, particularly patents and trade secrets. Obtaining and enforcing patents in the digital therapeutic industry involve both technological and legal complexity and are therefore costly, time consuming, and inherently uncertain. Our patent rights, their associated costs, and the enforcement or defense of such patent rights may be affected by developments or uncertainty in the patent statute, patent case law or USPTO rules and regulations. Changes in either the patent laws or interpretation of the patent laws could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of our issued patents.

For example, in March 2013, under the Leahy-Smith America Invents Act (the "America Invents Act"), the U.S. transitioned from a "first to invent" to a "first-to-file" patent system. Under a "first-to-file" system, assuming that other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on an invention regardless of whether another inventor had made the invention earlier. A third party that files a patent application in the USPTO after March 2013, but before us, could therefore 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 U.S. and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either file any patent application related to our technology or product candidates or invent any of the inventions claimed in our or our licensor's patents or patent applications. The America Invents Act also includes a number of other significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted, allowing third party submission of prior art and establishing a new post-grant review system 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 U.S. 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. The effects of these changes are currently unclear as the USPTO continues to promulgate new regulations and procedures in connection with the America Invents Act and many of the substantive changes to patent law, including the "first-to-file" provisions, only became effective in March 2013. In addition, the courts have yet to address many of these provisions and the applicability of the act and new regulations on the specific patents discussed in this filing have not been determined and would need to be reviewed. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Additionally, there have been recent proposals for additional changes to the patent laws of the U.S. and other countries that, if adopted, could impact our ability to obtain patent protection for our proprietary technology or our ability to enforce rights in our proprietary technology. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce any patents that we may obtain in the future.

In addition, it is uncertain whether the World Trade Organization (the "WTO") will waive certain intellectual property protections now or in the future on certain technologies. It is unknown if such a waiver would be limited to patents, or would include other forms of intellectual property including trade secrets and confidential know-how. We cannot be certain that any of our current or future product candidates or technologies would not be subject to an intellectual property waiver by the WTO. We also cannot be certain that any of our current or future intellectual property rights, whether patents, trade secrets, or confidential know-how would be eliminated, narrowed, or weakened by such a waiver. Given the uncertain future actions by the WTO and other countries and jurisdictions around the world, including the U.S., it is unpredictable how our current or future intellectual property rights or how our current or future business would be impacted.

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 collaborators or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other 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. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and trade names by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, know-how, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could have a material adverse effect on our business, prospects, results of operations and financial condition.

We in-license patents and content from third parties to develop our products and product candidates. If we fail to obtain or maintain such licenses, or have a dispute with a third-party licensor, it could materially and adversely affect our ability to commercialize the product or product candidates affected by the dispute.

Licensing intellectual property involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- amount of royalty payments under the license agreement;
- whether and to what extent our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patent and other rights to collaborators and other third parties;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our products, and what activities satisfy those diligence obligations; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our collaborators.

We use the patented or proprietary technology of third parties to commercialize our products. If we are not able to maintain such licenses, or fail to obtain any future necessary licenses on commercially reasonable terms or with sufficient breadth to cover the intended use of third-party intellectual property, our business could be materially harmed.

If disputes over licensed intellectual property prevent or impair our ability to maintain the licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product, or the dispute may have an adverse effect on our results of operation.

Risks Related to our Financial Reporting and Position

We will need substantial additional funding, and if we are unable to raise capital when needed or on terms favorable to us, our business, financial condition and results of operations could be materially and adversely affected.

We have consumed substantial amounts of capital to date, and we expect to incur net losses over the next several years as we continue to develop our business, make our products available for purchase and make investments in our human capital. While further development of Akili's programs outside of the ADHD space will be contingent upon a number of factors, including the outcome of our and our Board's evaluation of strategic alternatives, we expect to continue to spend substantial amounts to manage and execute on our shift in strategy where our current efforts are primarily focused on supporting Shionogi's regulatory and commercialization activities pursuant to the Amended Shionogi Agreement, continuing to support current users of our EndeavorRx and EndeavorOTC products and make our products available for purchase, and continuing to pursue regulatory authorization from FDA for EndeavorOTC in adults with ADHD, which remains under review, in parallel with exploration of broader strategic options. Other unanticipated costs may arise in the course of these efforts. We cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any product or product candidate we develop and may need substantial additional funding to complete the development and commercialization of our existing and any future products or product candidates. Our future need for additional funding depends on many factors, including:

- the scope, progress, results and costs of researching and developing our current product candidates, as well as other additional product candidates we may develop and pursue in the future;

•the timing of, and the costs involved in, obtaining marketing authorization for EndeavorOTC, marketing authorization for label expansion and authorization of conversion of our EndeavorRx prescription product to over-the-counter labeling, and for any other additional product candidates we may develop and pursue in the future;

•the number of future product candidates that we may pursue and their development requirements;

•the costs of commercialization activities for EndeavorOTC and for our product candidates, including the costs and timing of establishing product sales, marketing, and distribution capabilities (should we decide in the future to increase investment in promotional activity for our products or reestablish sales or marketing efforts);

•the costs of activities required as we continue to support caregivers and patients interested in our EndeavorRx pediatric ADHD product;

•revenue received from commercial sales of EndeavorOTC, EndeavorRx and, subject to receipt of authorization, revenue, if any, received from commercial sales of our product candidates;

•the extent to which we in-license or acquire rights to other products, product candidates or technologies;

•our investment in our human capital required to grow the business and any associated costs we may incur if we decide to expand our research and development or further build out a commercial infrastructure;

•the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property-related claims; and

•the costs of operating a public company.

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, reduce or terminate our product development programs or plans for commercialization. Further, if we raise additional capital in the form of capital stock (or securities exchangeable therefore), such issuances could dilute the interests of our stockholders.

We do not currently have any commitments for future funding. We believes that our cash and cash equivalents at March 31, 2024 will be sufficient to fund our planned operations and existing obligations for at least one year after the date of this Quarterly Report. Our estimates may prove to be wrong, and we could use our available capital resources sooner than expected. Further, changing circumstances, some of which are beyond our control, could cause us to consume capital significantly faster than anticipated, and we may need to seek additional funds sooner than planned. If adequate funds are not available on acceptable terms, we may not be able to successfully execute our business plan or continue our business.

The amount of our future losses is uncertain and our quarterly and annual operating results may fluctuate significantly or fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

Our quarterly and annual operating results may fluctuate significantly in the future due to a variety of factors, many of which are outside of our control and may be difficult to predict, including the following:

•the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;

•our ability to successfully recruit and retain subjects for clinical trials, and any delays caused by difficulties in such efforts;

•our ability to obtain and maintain marketing authorization for our products, product candidates and the timing and scope of any such marketing authorizations we may receive;

•the timing and cost of, and level of investment in, research and development activities relating to our products or product candidates, which may change from time to time;

•our ability to attract, hire and retain qualified personnel;

•expenditures that we will or may incur to develop additional product candidates;

•the level of demand for EndeavorRx and for EndeavorOTC and our other product candidates should such products or product candidates receive marketing authorizations, which may vary significantly;

•the risk/benefit profile, cost and reimbursement policies with respect to EndeavorRx and our other products or product candidates, if granted marketing authorization, and existing and potential future therapeutics that compete with our products or product candidates;

•the changing and volatile U.S. and global economic environments including global inflationary pressures; and

•future accounting pronouncements or changes in our accounting policies.

The cumulative effects 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. 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 operating results or revenue 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 guidance we may provide.

If we fail to regain compliance with the continued listing requirements on Nasdaq, our common stock could be delisted from Nasdaq, which would adversely affect the liquidity of our common stock and our ability to raise additional capital or enter into strategic transactions.

On April 23, 2024, we received a letter from the Listing Qualifications Staff (the "Nasdaq Staff") of The Nasdaq Stock Market LLC ("Nasdaq") notifying us that we has been granted an additional 180-day compliance period, or until October 21, 2024 (the "Extension Notice"), to regain compliance with Nasdaq's minimum closing bid price rule required by the continued listing requirements of Nasdaq Listing Rule 5550(a)(2) (the "Bid Price Requirement"). Nasdaq's determination follows our recent request for such additional compliance period and is based, in part, on our written notice to the Nasdaq Staff of its intention to cure the deficiency during the additional compliance period and if necessary, by effecting a reverse stock split.

Previously, on October 24, 2023, we received a written notification from Nasdaq notifying us that the bid price of our common stock had closed below $1.00 per share for 30 consecutive business days and that we therefore were not in compliance with the Bid Price Requirement.

The Extension Notice has no immediate effect on the listing of our common stock on the Nasdaq Capital Market, which will continue to be listed and traded on the Nasdaq Capital Market subject to the listing rules. To regain compliance, the closing bid price of the our common stock must be at least $1.00 per share for a minimum of 10 consecutive business days before October 21, 2024. If we do not regain compliance during the additional compliance period, then Nasdaq will notify us of its determination to delist our common stock, at which point we would have an opportunity to appeal the delisting determination to a hearings panel. There can be no assurance that we will be successful in regaining compliance with the Nasdaq listing rules or in maintaining the listing of our common stock on the Nasdaq Capital Market. We intend to actively monitor the closing bid price of our common stock and will evaluate available options to resolve the deficiency and regain compliance with the Bid Price Requirement.

There are many factors that may adversely affect our minimum bid price, including those described in the Risk Factors section of this Quarterly Report. Many of these factors are outside of our control. As a result, we may not be able to sustain compliance with the Bid Price Requirement in the long term.

Any potential delisting of our common stock from Nasdaq would likely result in decreased liquidity and increased volatility for our common stock and would adversely affect our ability to raise additional capital or to enter into strategic transactions. Any potential delisting of our common stock from Nasdaq would also make it more difficult for our stockholders to sell our common stock.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, investors may lose confidence in the accuracy of our financial reports, which would harm our business and the trading price of our common stock. Our management is required to evaluate the effectiveness of our internal control over financial reporting.

As a public reporting company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), the Dodd-Frank Wall Street Reform and Consumer Protection Act and the rules and regulations established by the SEC and Nasdaq. These rules and regulations require, among other things, that we establish and periodically evaluate procedures with respect to our internal control over financial reporting. Reporting obligations as a public company are likely to place a considerable strain on our financial and management systems, processes and controls, as well as on our personnel, including senior management. In addition, as a public company, we are required to document and test our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act so that our management can certify as to the effectiveness of our internal control over financial reporting.

In support of such certifications, we are required to document and make significant changes and enhancements, including potentially hiring additional personnel, to our internal control over financial reporting. Likewise, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting until our first annual report is required to be filed with the SEC following the date we are no longer an emerging growth company.

To achieve compliance with Section 404 within the prescribed period, we need to continue to dedicate internal resources, including hiring additional financial and accounting personnel and potentially engaging outside consultants. During our evaluation of our

internal control, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective.

We rely on assumptions, estimates, internally developed software and data from third parties to deliver timely and accurate information in order to accurately report our financial results in the timeframe and manner required by law.

Certain of our performance indicators and other business metrics are calculated using third-party applications or internal company data that have not been independently verified. While these numbers are based on what we believe to be reasonable calculations for the applicable period of measurement, there are inherent challenges in measuring such information. In addition, our measurement of certain metrics may differ from estimates published by third parties or from similarly-titled metrics of our competitors due to differences in methodology and as a result our results may not be comparable to our competitors.

We could be subject to additional tax liabilities and our ability to use our net operating loss carryforwards and other tax attributes may be limited.

We have incurred net operating losses ("NOLs") since our inception and may never achieve or sustain profitability. Generally, for U.S. federal income tax purposes, NOLs incurred will carry forward. However, NOL carryforwards generated prior to January 1, 2018, are subject to expiration for U.S. federal income tax purposes. As of December 31, 2023, we had federal NOL carryforwards of approximately $275.5 million, of which $31.2 million will begin to expire in 2031. As of December 31, 2023, we had state NOL carryforwards of approximately $163.0 million which will begin to expire in 2031. As of December 31, 2023, we also had federal research and development tax credits of $6.3 million, which may be available to offset future income tax liabilities. The federal research and development tax credit carryforwards would begin to expire in 2039. As of December 31, 2023, we also had state research and development tax credits of $2.9 million, which may be available to offset future income tax liabilities.

In general, under Sections 382 and 383 of the Code, a corporation that undergoes an "ownership change," generally defined as a greater than 50% change by value in our equity ownership by certain stockholders over a three-year period, the corporation's ability to use its pre-ownership change NOLs, carryforwards and other pre-ownership change tax attributes, such as research tax credits, to offset its post-ownership change income or taxes may be limited. Similar provisions of state tax law may also apply to limit the use of our state NOL carryforwards and other state tax attributes. We have not performed an analysis to determine whether our past issuances of stock and other changes in our stock ownership may have resulted in one or more ownership changes. In addition, future changes in our stock ownership, which may be outside of our control, may materially limit our ability to utilize our NOL carryforwards and other tax attributes. As a result, even if we earn net taxable income in the future, we may be unable to use a material portion of our NOL carryforwards and other tax attributes, which could materially and adversely affect our future cash flows. There is also a risk that regulatory changes, such as suspensions on the use of NOL or other unforeseen reasons, may result in our existing NOL carryforwards expiring or otherwise becoming unavailable to offset future taxable income. For these reasons, we may not be able to utilize a material portion of our NOL carryforwards and other tax attributes, even if we attain profitability. A temporary suspension of the use of certain net operating losses and tax credits has been enacted in California, and other states may enact suspensions as well. If we are limited in our ability to use our NOLs in future years in which we have taxable income, we will pay more taxes than if we were able to fully utilize our NOLs. This could have a material adverse effect on our business, prospects, results of operations and financial condition.

Risks Related to the Business Combination

As a former shell company, we face certain disadvantages relative to companies that pursued a traditional initial public offering.

SCS was a special purpose acquisition company, a form of shell company under the rules of the SEC. Shell companies are more highly regulated than non-shell operating companies and face significant additional restrictions on their activities under federal securities laws. As a result of the Business Combination, we ceased to be a shell company. However, companies that were formerly shell companies continue to face disadvantages under SEC rules, including (a) the inability to use Form S-3 until at least one year after the filing of information equivalent to that required by Form 10 after ceasing to be a shell company, (b) the inability to qualify as a "well-known seasoned issuer" and file automatically effective registration statements for three years after ceasing to be a shell company, (c) the inability to "incorporate by reference" information in certain registration statements filed under the Securities Act of 1933, as amended (the "Securities Act") for a period of three years after ceasing to be a shell company, (d) the inability to use most free writing prospectuses until at least three years after a qualifying business combination, (e) the inability to use Form S-8 to register shares issuable in connection with certain compensatory plans and arrangements until 60 days after the filing of information equivalent to that required by Form 10, (f) the inability of stockholders to rely on Rule 144 for resales of securities until at least one year after the filing of information equivalent to that required by Form 10 and the provision of current public information, and (g) exclusion from certain safe harbors for offering-related communications under the Securities Act for three years after ceasing to be a shell company, including for research reports and certain communications in connection with business combinations. We expect that these disadvantages will make it more challenging and expensive, and create greater risks and delays, for both us and our stockholders to offer securities. These challenges may make our securities less attractive than those of companies that are not former shell companies and may raise our relative cost of capital.

Certain members of our Board and their affiliated companies have been, and may from time to time be, associated with negative media coverage or public actions or become involved in legal proceedings or governmental investigations unrelated to our business.

Current and former members of our Board have been involved in a wide variety of businesses. Such involvement has, and may lead to, media coverage and public awareness. As a result of such involvement, certain current or former members of our Board and their affiliated companies have also been, and may from time to time be, involved in legal proceedings or governmental investigations unrelated to our business, and may be exposed to reputational risks resulting from other events such as allegations of misconduct or other negative publicity or press speculation. For example, in February 2021, Clover Health, which merged with Social Capital Hedosophia Holdings Corp. III, IPOC, received a letter from the SEC indicating that it is conducting an investigation and requesting document and data preservation from January 1, 2020 relating to certain matters that were referenced in an article by Hindenburg Research, and certain shareholders of Clover Health have also brought civil suits against Mr. Palihapitiya (a former member and chair of our Board) in his capacity as Chairman and Chief Executive Officer of IPOC for alleged breaches of fiduciary duty, unjust enrichment, corporate waste and violations of federal securities laws, in connection with IPOC's business combination with Clover Health. Any such media coverage, public action, legal proceedings or investigations may be detrimental to our reputation, and may have an adverse effect on the price of our securities or on our business, financial condition, results of operations and prospects.

Changes in laws or regulations or how such laws or regulations are interpreted or applied, or a failure to comply with any laws or regulations, may adversely affect our business and results of operations.

We are subject to laws and regulations enacted by national, regional and local governments. In particular, we are required to comply with certain SEC and other legal requirements. We may be subject to additional laws and regulations. Compliance with, and monitoring of, applicable laws and regulations may be difficult, time consuming and costly. A failure to comply with applicable laws or regulations, as interpreted and applied, could have a material adverse effect on our business and results of operations. In addition, those laws and regulations and their interpretation and application may change from time to time, including as a result of changes in economic, political, social and government policies, and those changes could have a material adverse effect on our business and results of operations.

Delaware law contain certain provisions, including anti-takeover provisions that limit the ability of stockholders to take certain actions and could delay or discourage takeover attempts that stockholders may consider favorable.

The Delaware General Corporation Law (the "DGCL") contain provisions that could have the effect of rendering more difficult, delaying, or preventing an acquisition that stockholders may consider favorable, including transactions in which stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, and therefore depress the trading price of our common stock. These provisions could also make it difficult for stockholders to take certain actions, including electing directors who are not nominated by the current members of our Board or taking other corporate actions, including effecting changes in our management. These provisions could delay or prevent hostile takeovers and changes in control or changes in our Board or management.

The provisions of the Bylaws requiring exclusive forum in the Court of Chancery of the State of Delaware and the federal district courts of the U.S. for certain types of lawsuits may have the effect of discouraging lawsuits against our directors and officers.

The Bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, in the event that such court does not have, or declines to accept, jurisdiction, another state court located within the State of Delaware) will be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of us, (ii) any action asserting a claim for or based on a breach of a fiduciary duty owed by any current or former director, officer or other employee of us to us or our stockholders including a claim alleging the aiding and abetting of such a breach of fiduciary duty, (iii) any action asserting a claim against us or any current or former director, officer or other employee of us arising pursuant to any provision of the DGCL or our certificate of incorporation or bylaws (as may be amended from time to time) (including the interpretation, validity or enforceability thereof), (iv) any action asserting a claim related to or involving us that is governed by the internal affairs doctrine, or (v) any action asserting an "internal corporate claim" as that term is defined in Section 115 of the DGCL (the "Delaware Forum Provision"). The Delaware Forum Provision, however, does not apply to any causes of actions arising under the Securities Act or the Exchange Act or to any claim for which the federal courts have exclusive jurisdiction. The Bylaws also provide that, unless we consent in writing to the selection of an alternate forum, the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act, and the rules and regulations promulgated thereunder, will be the federal district courts of the U.S. (the "Federal Forum Provision"). Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. The Delaware Forum Provision and the Federal Forum Provision will not relieve our duties to comply with the federal securities laws and the rules and regulations thereunder, and our stockholders will not be deemed to have waived our compliance with these laws, rules and regulations.

These provisions may have the effect of discouraging lawsuits against the directors and officers of us. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation or bylaws has been challenged in legal proceedings, and it is possible that, in connection with any applicable action brought against us, a court could find the choice of forum provisions contained in the Bylaws to be inapplicable or unenforceable in such action.

Risks Related to our Common Stock

The market price of our common stock could be volatile, and you could lose all or part of your investment.

The price of our common stock may fluctuate due to a variety of factors, including, without limitation:

- risks associated with the potential delisting of our common stock on Nasdaq should we not be able to maintain or regain compliance with the continued listing rules of Nasdaq;
- changes in the industries in which we and our customers operate;
- developments involving our competitors;
- developments involving our collaborators or other third parties with which we do business;
- changes in laws and regulations affecting our business;
- changes in our business strategy;
- variations in our operating performance and the performance of our competitors in general;
- actual or anticipated fluctuations in our quarterly or annual operating results;
- publication of research reports by securities analysts about our or our competitors or our industry;
- the public's reaction to our press releases, our other public announcements and our filings with the SEC;
- actions by stockholders, including the sale of shares of our common stock by the third-party investors ("PIPE Investors") that purchased our shares of common stock pursuant to subscription agreements entered into on January 26, 2022;
- additions and departures of key personnel;
- commencement of, or involvement in, litigation involving us;
- changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;
- the volume of shares of our common stock available for public sale; and
- general economic and political conditions, such as the effects of the COVID-19 pandemic, a potential government shutdown, recessions, interest rates, local and national elections, fuel prices, international currency fluctuations, corruption, political instability and acts of war, including the ongoing war in Ukraine and war between Israel and Hamas, or terrorism.

These market and industry factors may materially reduce the market price of our common stock regardless of our operating performance and you could lose all or part of your investment.

Low trading volume of our common stock on the Nasdaq Capital Market may increase price volatility.

Our common stock has been subject to price volatility, low trading volume and large spreads in bid and ask prices quoted by market makers. Due to the low volume of shares traded on any trading day, persons buying or selling in relatively small quantities may easily influence prices of our common stock. This low trading volume could also cause the price of our stock to fluctuate greatly, with large percentage changes in price occurring in any trading day session. Holders of our common stock may also not be able to readily liquidate their investment or may be forced to sell at depressed prices due to low trading volume. If large spreads between the bid and ask prices of our common stock exist at the time of a purchase, the stock would have to appreciate substantially on a relative percentage basis for an investor to recoup their investment. No assurance can be given that a higher volume active market in our common stock will develop or be sustained. If a higher volume active market does not develop, holders of our common stock may be unable to readily sell the shares they hold or may not be able to sell their shares at all.

We do not intend to pay dividends on our common stock.

We currently intend to retain our future earnings, if any, to finance the further development and expansion of our business and do not intend to pay cash dividends in the foreseeable future. Any future determination to pay dividends will be at the discretion of our Board and will depend on our financial condition, results of operations, capital requirements, restrictions contained in future agreements and financing instruments, business prospects and such other factors as our Board deems relevant.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that analysts publish about our business. We do not have any control over these analysts. If one or more of the analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research about our business, the price of our common stock would likely decline. If few analysts cover us, demand for our common stock could decrease and our common stock price and trading volume may decline. Similar results may occur if one or more of these analysts stop covering us in the future or fail to publish reports on us regularly. For example, we are aware of multiple analysts that have discontinued coverage of our business.

In recent months, there has been significant volatility in the market values of growth-oriented companies. Accordingly, securities of growth companies such as us may be more volatile than other securities and may involve special risks.

In recent months, there has been significant volatility in the market values of growth-oriented companies like us, likely due to, among other factors, inflationary pressures, increases in interest rates and other adverse economic and market events. As a result, shares of our common stock are subject to potential downward pressures.

Adverse developments affecting the financial services industry, such as the failure of banks and financial institutions, could have an adverse effect on our current and projected business operations and our financial condition and results of operations.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10 and March 12, 2023, the Federal Deposit Insurance Corporation took control and was appointed receiver of SVB, Signature Bank, and Silvergate Capital Corp. (“Silvergate Capital”), respectively, after each bank was unable to continue their operations. Since then, additional financial institutions have experienced similar failures and have been placed into receivership. It is possible that other banks will face similar difficulty in the future. These events exposed vulnerabilities in the banking sector, including legal uncertainties, significant volatility and contagion risk, and caused market volatility.

As of the date of this Quarterly Report, we have not been materially affected by the closing of SVB, Signature Bank, Silvergate Capital, or any other bank in financial difficulty. However, we are unable to predict the extent or nature of the impacts of any future instability in the banking sector at this time. If, for example, other banks and financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our existing cash, cash equivalents and investments may be threatened. While it is not possible at this time to predict the extent of the impact that high market volatility and instability of the banking sector could have on economic activity and our business in particular, the failure of other banks and financial institutions and the measures taken by governments, businesses and other organizations in response to these events could adversely impact our business, financial condition and results of operations.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

SVB Debt Repayment

On May 8, 2024, the Company, Silicon Valley Bank (“SVB”) and SVB Innovation Credit Fund VIII, L.P. entered into a payoff letter (the “Payoff Letter”) for a voluntary prepayment with respect to the Amended and Restated Loan and Security Agreement, dated May 25, 2021 (the “SVB Loan Agreement”). Pursuant to the Payoff Letter, the Company paid a total of approximately $8.3 million to SVB, representing the outstanding principal, accrued and unpaid interest, final payment and fees due to SVB under the SVB Loan Agreement, all facilities thereunder and related loan documents, in repayment of the Company’s outstanding obligations under the SVB Loan Agreement, all facilities thereunder and related loan documents, and thereby terminated the SVB Loan Agreement, all facilities thereunder and related loan documents.

Pursuant to the Payoff Letter, SVB's commitments to extend further credit to the Company terminated; SVB agreed to release and terminate all liens or security interests granted to secure the obligations under the SVB Loan Agreement and the Company was unconditionally released from its respective guaranties and obligations under the SVB Loan Agreement, all facilities thereunder and related loan documents without further action (other than with respect to customary provisions and agreements that are expressly specified to survive the termination).

Rule 10b5-1 Trading Plans

None of our directors or officers (as defined in Rule 16a-1(f) of the Securities Exchange Act of 1934) adopted, modified, or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement during our fiscal quarter ended March 31, 2024.

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 Number	Description
3.1	Certificate of Incorporation of Akili, Inc. (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on August 23, 2022).
3.2	By-Laws of Akili, Inc. (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K filed on August 23, 2022).
4.1	Specimen Common Stock Certificate of Akili, Inc. (incorporated by reference to Exhibit 4.2 to Akili, Inc.'s Amendment No. 3 to the Registration Statement on Form S-4 filed on June 10, 2022).
31.1*	Certification of Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

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

SIGNATURES

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

Akili, Inc.

Date: May 14, 2024

By: /s/ Matthew Franklin
Name: Matthew Franklin
Title: President, Chief Executive Officer and Director (Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)

EXHIBIT 31.1

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

I, Matthew Franklin, Principal Executive Officer and Principal Financial Officer, certify that:

1. I have reviewed this Form 10-Q for the Quarterly Period Ended March 31, 2024 of Akili, 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. I am 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 my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me 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 my 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 my 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. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):

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

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

Date: May 14, 2024

/s/ Matthew Franklin

Matthew Franklin
President and Chief Executive Officer
(Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)

EXHIBIT 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Akili, Inc. (the "Company") on Form 10-Q for the quarterly period ended March 31, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Matthew Franklin, Principal Executive Officer and Principal Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

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

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

Dated: May 14, 2024

/s/ Matthew Franklin
Matthew Franklin
President and Chief Executive Officer
(Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)