UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2023

OR

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

Commission File Number 001-40558

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, MA	**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**

Securities registered pursuant to Section 12(g) of the Act: **None**

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on the Nasdaq Capital Market on June 30, 2023 (the last business day of the Registrant's most recently completed second fiscal quarter), was $66,983,433.

The number of shares of the Registrant's Common Stock outstanding as of February 21, 2024 was 78,509,823.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive Proxy Statement relating to its 2024 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2023 are incorporated herein by reference in Part III of this Annual Report on Form 10-K.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this "Annual 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 Annual 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 Annual Report and in any document incorporated by reference in this Annual 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 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 strategic plan to transition from a prescription to a non-prescription model;
- our ability to successfully manage and execute on our strategy to obtain regulatory authorization and commercialize 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 commercialize 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;
- our inability to realize the anticipated benefits of the Business Combination;
- the outcome of any legal or governmental proceedings that may be instituted against us; and
- other factors detailed under the section titled "*Risk Factors*" in Part I, Item 1A of this Annual Report.

These forward-looking statements are based on information available as of the date of this Annual 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 have a history of significant losses, anticipate that expenses may increase in the future, 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 that are important to our business.
- 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

Item 1. Business.

Unless the context otherwise requires, all references in this section to the "company", "we", "us", or "our" refer to the business of Akili, Inc. and its subsidiaries and, prior to the consummation of the Business Combination, the business of Akili Interactive Labs, Inc. and its subsidiaries.

Overview

Akili is a leading digital medicine company, pioneering the development of cognitive treatments through game-changing technologies. Our approach of developing and commercializing 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. We began as a prescription digital medicine company; however, 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.

Impairments in cognition are associated with many different chronic diseases and acute illnesses, impacting approximately 85 million people in the U.S. These impairments include, but are not limited to attention-deficit/ hyperactivity disorder ("ADHD"), autism spectrum disorder ("ASD"), multiple sclerosis ("MS"), major depressive disorder ("MDD"), post-traumatic stress disorder ("PTSD"), cognitive impairments in COVID-19 survivors ("COVID fog"), traumatic brain injury ("TBI"), cancer-related cognitive impairment ("CRCI") and alzheimer's disease ("Alzheimer's"), among others. Global recognition of cognitive function by physicians and patients has increased in recent years, yet many current treatment approaches are inadequate, as they are either unable to effectively target the brain to address underlying impairments or lack clinical validation. Existing clinically-validated treatments for these indications are largely comprised of drugs, many of which have side effects that are intolerable or worrisome to patients and families. For example, the safety profile of ADHD drugs and lack of options to specifically address inattention creates a very high unmet need. Current ADHD treatment approaches are limited to traditional medications, lack precision, largely only treat symptoms, and are often accompanied by side effects that may include growth suppression, appetite suppression, weight issues, sleep issues and abdominal pain.

Our vision is to change this treatment paradigm with our development of the first digital prescription treatment to improve cognition across diseases, developed through a unique collaboration of cognitive neuroscientists and entertainment and technology designers.

Until recently, digital therapeutics have consisted of tools and technology used to deliver existing medical processes, such as cognitive behavioral therapy, through accessible and easy-to-use mobile applications. Our platform represents a fundamental paradigm shift where technology is the medicine itself, designed to target neural networks critical to cognitive function. We aim to evolve the field of digital health applications into clinically-validated treatments for cognitive functions that are designed to be entertaining.

With this approach, we introduced EndeavorRx®, the first prescription video game treatment (and first digital treatment for a cognitive impairment) reviewed and granted marketing authorization by the U.S. Food and Drug Administration (the "FDA") in June 2020, as a Class II medical device through the FDA's de novo process that reviews both safety and efficacy. EndeavorRx is now 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. The indication was expanded from children ages 8-12 to include older children ages 13-17 following our receipt of FDA marketing authorization in December 2023 for the expanded EndeavorRx label. In June 2020, EndeavorRx also received Conformité Européenne ("CE") Mark certification as a prescription-only digital therapeutic software intended for the treatment of attention and inhibitory control deficits in pediatric patients with ADHD, enabling EndeavorRx to be marketed in European Economic Area ("EEA") member countries. EndeavorRx should be considered for use as part of a therapeutic program that may include clinician-directed therapy, medication and/or educational programs, which further address symptoms of the disorder. It is not intended to be used as a stand-alone therapeutic and is not a substitution for a child's medication.

In May 2023, we announced topline results of the STARS-ADHD-Adult clinical trial in adults with ADHD evaluating the efficacy and safety of EndeavorRx (AKL-T01), the first product built on the Akili platform. STARS-ADHD-Adult was designed as a pivotal clinical trial to enable registration with the FDA. The trial demonstrated statistically significant improvement in attention functioning after six weeks of treatment, achieving its predefined primary efficacy outcome. Significant improvements were also seen across a range of secondary and exploratory outcomes, including clinical assessments of ADHD-related symptoms and a validated measure of quality of life. The treatment was well-tolerated, with minimal side effects and no serious device-related adverse events reported.

In June 2023, we released EndeavorOTC®, which is built on the same platform as EndeavorRx, nationwide as 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, 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 commercialize, distribute, and market EndeavorOTC under the COVID-19 Guidance. We will continue to work interactively with FDA on this submission and expect to provide information regarding the status of the application by the end of the second quarter of 2024.

More recently, in February 2024, our Japanese partner Shionogi & Co. Ltd. ("Shionogi") announced that it has submitted a marketing approval application for SDT-001, the Japanese localized version of Akili's AKL-T01 digital therapeutic, 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 of SDT-001 conducted by Shionogi in Japan in pediatric ADHD patients.

We built EndeavorRx and EndeavorOTC using our most advanced therapeutic engine, our selective stimulus management engine ("SSME") mechanism of action. SSME™ technology has been evaluated in clinical trials in pediatric and adult ADHD populations.

Within ADHD, there is a large and growing opportunity for innovative non-drug treatments. Current ADHD treatment options represent a $10 billion market with over 70 million prescriptions written every year for drugs in the U.S. According to the U.S. Centers for Disease Control and Prevention, nearly half the pediatric ADHD population uses behavioral therapy as well. However, the current standard of care for ADHD has been unchanged for several decades, despite continued negative outcomes across a range of functional domains (e.g., home, school, work, health) and poor long-term prognosis for patients with ADHD. For example, patients with ADHD continue to be at increased risk for lower educational achievement, poorer vocational advancement, and a range of adverse health outcomes including early mortality compared to non-diagnosed individuals. We believe the total ADHD population in the U.S. is approximately 17 million and that the total ADHD population with inattention issues is approximately 14.7 million. Estimates of the U.S. prevalence of ADHD in adults range from 1.12% to 4.4%, with the latter estimate derived from a study focused on a representative U.S. population and conducted with epidemiological assessment methods. Based on estimates from the 2020 census of approximately 250 million individuals aged 18 and above, we believe the total addressable market for adults with ADHD in the United States is approximately 11 million. EndeavorRx is now FDA authorized in the U.S. to treat children aged 8-17, and we believe the ADHD population with inattention issues in that age range totals approximately 3.7 million. 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 our EndeavorOTC and EndeavorRx products, are based on estimates, which are inherently uncertain and are subject to a wide variety of assumptions, risks and uncertainties that can cause actual results to differ materially.

Within this market we 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. In the digital health space, we compete with companies that have created non-regulated products to treat cognitive impairment.

In 2023, we conducted two restructurings. First, in January 2023, we restructured our business to preserve capital and focus primarily on commercializing EndeavorRx in ADHD and seeking a label expansion for EndeavorRx in ADHD patients, for which we received FDA marketing authorization in December 2023. This January 2023 restructuring resulted in the reprioritization of our pipeline of preclinical and clinical development programs and a reduction of our workforce by approximately 30% across different areas and functions. Then, in September 2023, we announced a strategic plan to transition from a prescription to a non-prescription business model, which is ongoing. As part of this strategic plan, our focus and the bulk of our investments are on our consumer-led subscription model for EndeavorOTC, our adult ADHD product. The September 2023 announcement also included

a related restructuring of our operations and reduction of our workforce by approximately 40%, primarily related to the elimination of our field sales force and market access teams. As part of this strategic plan, we are pursuing regulatory authorization for over-the-counter labeling of our products and investing in activities to drive consumer awareness and capital-efficient expansion of the business.

Our development and commercialization efforts are primarily focused on ADHD, with particular focus on managing and executing on our strategic plan announced in September 2023 to transition from a prescription to a non-prescription model, including obtaining regulatory authorization and commercializing EndeavorOTC in adults with ADHD, pursuing regulatory authorization for over-the-counter labeling of both our EndeavorRx and EndeavorOTC products and continuing to support the distribution and fulfillment of EndeavorRx during the transition. Further development of our pipeline outside of ADHD will be contingent upon a number of factors, including capital raising and supportive business development activities.

Our Proprietary Approach

Our platform is powered by proprietary therapeutic engines, which are software and associated algorithms that form the core of our products and product candidates, designed to target cognitive impairment at its source in the brain, informed by decades of research (including research conducted prior to the founding of Akili) and validated through rigorous clinical programs. Our most advanced therapeutic engine, SSME, presents specific sensory stimuli and simultaneous motor challenges designed to target the fronto-parietal cortex which plays a key role in attention function, while our earlier stage therapeutic engines also focus on cognitive functions, including spatial navigation, memory, and planning and organization. Each product and product candidate embodies a specific proprietary therapeutic engine with a variation of the video game-like user interface in an effort to optimize user engagement applicable to a particular disease or medical condition indication. Product candidates are clinically tested in development programs for particular disease or medical condition indications.

These products and product candidates are characterized by these key attributes:

- *Targeted treatments that are personalized to users' needs*. Delivered through closed-loop adaptive algorithms, the technology continuously learns and adapts based on a users' use of and progress in the treatment, which enables the delivery of tailored and personalized experiences that automatically adjust to each individual's therapeutic needs. Our technologies provide direct access to a de-identified, aggregate level view of each user's activity, informing our product development. The therapeutics' mechanics, algorithms and designs are protected by patents, trade secrets and copyrights, combining protections typically seen in both the medicine and technology industries to create a robust intellectual property portfolio.

- *Clinically validated like drugs and medical devices*. Our therapeutics have been studied in more than 20 clinical trials involving more than 2,600 patients across nine disease populations, including large prospective, randomized controlled trials. Using SSME, for instance, we have conducted five different clinical studies in children with ADHD, which collectively demonstrated the technology's ability to improve objective measures and caregiver observations of attention function. In addition, using SSME we have also conducted one clinical study in adults with ADHD, which demonstrated the technology's ability to improve attention, ADHD symptoms and quality of life, with these observed benefits for adults meaningfully exceeding the benefits observed in the data from our clinical studies in children and adolescents with ADHD. These results were further validated by visible changes in the brain's activity seen in clinical studies using electroencephalogram ("EEG") imaging. Results of our clinical studies have been published in 16 leading peer-reviewed scientific journals, including *The American Journal of Psychiatry, The Lancet Digital Health* and *Nature: Digital Medicine.*

- *Therapeutics that are experienced as entertainment*. We are blending medicine with entertainment and creating patient experiences like never before. Our treatments look and feel like high-quality video games. They change over time, incorporate rewards and increase challenges in ways that feel natural to users. Enabled by the adaptive ability of digital therapeutics and the dynamic nature of video games, and informed by extensive data infrastructure, we believe we can rapidly iterate our products to enhance user enjoyment and engagement, encouraging compliance with the treatment plan. Our ability to rapidly create unique user experiences also allows us to adapt the experience to appeal to different patient populations by developing and testing product candidates in clinical trials. We believe we have the potential to offer the first treatments that integrate the experience of consumer entertainment products and can be utilized as part of a treatment plan. One of the newest, and we believe most significant, product features that we introduced in the second half of 2023 is the Focus Score™ measure, initially released in our EndeavorOTC product for adults with ADHD and more recently released in our EndeavorRx Insight® companion app for caregivers of children using EndeavorRx. This is a personalized metric that allows a user or caregiver to track their attention improvement within the EndeavorOTC or EndeavorRx treatment. At the beginning of a user's treatment journey, the user receives a personalized baseline Focus Score, which represents how quickly and accurately the user can complete a task despite distractions present during gameplay. The user also receives a personalized, target Focus Score which

serves as the user's goal for their initial course of treatment. The Focus Score measure, ranging from 0 to 100, is calculated exclusively from user treatment using gameplay mission data and is based on cognitive neuroscience and skills that are foundational to improving a user's ability to maintain attention.

- *User focused and adaptive*. We are relentlessly focused on our users and caregivers and have developed a platform and infrastructure that allows us to continuously refine and optimize based on their feedback. Our products are widely accessible, are personalized and adaptable, and generate rich data users and caregivers can use to foster meaningful conversations with users and their health care providers, such as the Focus Score measure in our EndeavorOTC product and EndeavorRx Insight app, and the EndeavorRx gameplay data provided to caregivers via our EndeavorRx Insight app. With data from our platform and feedback from caregivers and users, we have released multiple enhancements to our product gameplay and changed our fulfillment system to better meet their needs.

This same technology platform also has potential applications beyond the treatment of cognitive impairments, with the potential to measure and monitor cognitive functioning. As we work towards improving cognitive impairments in users at scale, the ability to measure cognitive function is critical. Today, cognition is typically only assessed in response to a specific user complaint, and there is no consistent approach for this measurement. Clinical studies have shown our platform's potential to act as a sensitive cognitive measure that correlates with well-known in-person or paper-based cognitive measurements.

EndeavorRx®: The first prescription video game treatment

In June 2020, EndeavorRx, the first product built on the Akili platform, was granted marketing authorization and classified as a Class II medical device by the FDA through FDA's de novo process, which reviews both safety and efficacy of new treatments. EndeavorRx is indicated for children ages 8-17 with primarily inattentive or combined-type ADHD, who have a demonstrated attention issue. EndeavorRx was initially indicated for use to improve attention function for children ages 8-12 with primarily inattentive or combined-type ADHD, who have a demonstrated attention issue, and following our receipt of FDA marketing authorization in December 2023 for the expanded EndeavorRx label, now includes older children ages 13-17. EndeavorRx represents a fundamental paradigm shift in the treatment of cognitive disorders, where technology is not just delivering a therapy but is itself the medicine: EndeavorRx was the first game-based therapeutic granted marketing authorization by the FDA.

EndeavorRx is the only FDA-authorized prescription video game-based treatment designed to directly target cognitive functioning. For the first time, licensed health care providers have a treatment option that is purpose-built to target cognitive function and that is not taken as a pill, but delivered through a video game. EndeavorRx also obtained Conformité Européenne (CE) Mark certification in pediatric patients with ADHD, enabling EndeavorRx to be marketed in European Economic Area (EEA) member countries.

As announced in September 2023, as part of our strategic plan, we are pursuing regulatory authorization for over-the-counter labeling of both our EndeavorRx and EndeavorOTC products and continuing to support the distribution and fulfillment of EndeavorRx during the transition.

EndeavorRx Commercialization

Our commercial model for EndeavorRx has important levers that go beyond the traditional therapeutic model. Because we are building the model from the ground up, we have the ability to use the extensive data collected through our platform, not just to rapidly iterate our products, but to tailor the entire delivery system for our products. We are leveraging a fully digital process, from prescription to fulfillment to treatment, creating unparalleled optimization of the end-to-end patient experience and potentially enabling higher conversion, better compliance and optimal treatment.

Additionally, as we continue to focus on preserving capital, in the second half of 2023 we transitioned from a single third party digital pharmacy for the fulfillment of prescriptions for EndeavorRx to an internally developed in-house direct distribution system for EndeavorRx.

EndeavorOTC Commercialization

EndeavorOTC's commercial strategy leverages direct-to-consumer marketing efforts to deliver innovative concepts to core target audience segments. Akili's expertise in medical and cognitive science combined with an understanding of customer needs and motivations serves as the basis for our customer acquisition strategy on search, social and other digital and integrated properties. We believe our focus on delivering content designed to educate and inform customers has helped to improve customer adoption and advocacy, such as amplification of user success stories in media and word-of-mouth marketing.

Our Clinical Pipeline

Our therapeutic engines are designed to target cognitive functions with the potential to address multiple medical conditions presenting the same functional cognitive impairments.

There have been several updates to our pipeline as part of our 2023 restructurings, operating plan approvals and clinical pipeline reprioritization.

Based on unmet need and potential market opportunities our clinical pipeline is currently focused on pediatric, adolescent, and adult ADHD. We have completed data analysis from the following two Akili-sponsored studies:

- STARS-ADHD-Adolescents, a pivotal study of AKL-T01 (marketed and branded as EndeavorRx in the U.S.) in adolescents ages 13-17 with ADHD. This study completed enrollment in the fourth quarter of 2022 with 162 patients and top-line results were reported in January 2023. Results were presented at two scientific meetings in 2023, and the findings are currently under review for publication in a peer-reviewed journal.
- STARS-ADHD-Adults, a pivotal study of AKL-T01 in adults with ADHD. Enrollment for this study was discontinued early with 223 patients. This decision was made on the basis of the positive STARS-ADHD-Adolescents data previously announced and our desire to preserve capital. Results were presented at a scientific meeting in October 2023, and the findings are currently under review for publication in a peer-reviewed journal.

In February 2024, our Japanese partner 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 of SDT-001 conducted by Shionogi in Japan in pediatric ADHD patients.

In addition to our priority focus on advancing our products across the lifespan in ADHD, clinical studies are ongoing or completed in a number of other indications in which cognitive dysfunction plays an important role.

Two collaborative research studies were completed in 2023 to evaluate the effects of our product in patients with cognitive dysfunction following recent COVID-19 infection at Vanderbilt University Medical Center and Cornell Weill School of Medicine/New York Presbyterian Hospital. Results are being prepared for presentation at scientific meetings and submission to peer-reviewed journals in 2024.

In addition, we have several investigator-initiated studies that are currently being conducted across different indications.

We have also published clinical studies involving other populations with demonstrated cognitive challenges, including MDD, ASD, MS, lupus, and TBI.

Further development of our pipeline outside of ADHD will be contingent upon a number of factors, including capital raising and supportive business development activities.

We expect our model to be scalable and repeatable.

With our platform and business model, we believe we have created a set of capabilities and infrastructure that can be applied, again and again, with increased efficiency over time, creating a competitive advantage for Akili.

From technology sourcing through regulatory authorization and commercial growth, Akili is the first to take these types of innovative technologies that target brain function and bring them through every step of the product development, regulatory authorization and commercialization process for EndeavorRx. While EndeavorOTC has not been authorized by FDA for any indications, if we are successful in obtaining regulatory authorization from FDA with over-the-counter labeling for EndeavorOTC, we believe that model has the potential to be scalable and repeatable as well.

We have built the first platform uniquely designed to leverage these physiologically-targeting digital therapeutics, which we believe could be used to support future products as the field of physiologically-targeting digital therapeutics grows.

We meet users on their own terms.

We believe that we are the first to create a prescribed treatment product that is delivered in a way that feels like high-quality entertainment and designed in a way that fits seamlessly into people's lives.

With the aims of developing relationships with users and caregivers that rival that of successful consumer companies, we have created a user-adaptive model. Our products meet users on their own terms and engage them in their treatment. Our products are widely accessible, are personalized and automatically adaptable and generate rich data that users and caregivers can use to foster meaningful conversations with their health care providers. Users and caregivers are also our collaborators in product design. We

collect ongoing data and feedback through gameplay data, playtesting, workshops, research and Apple App Store and Google Play reviews from users and refine, adapt and aim to optimize both our products and our communications based on our learnings. Their valuable feedback has led us to add more choices during gameplay, including new quests, new creatures and costumes, the ability for children to build their own universes and the introduction of a Focus Score measure in our EndeavorOTC product and EndeavorRx Insight app.

Our hope is that, in the moment, users forget that they are being treated with a therapeutic. In our work to fully realize the promise of digital therapeutics, we believe we are just beginning to scratch the surface of what is possible as we develop experiences that capture the imagination and are akin to the best entertainment products.

About Akili

We were founded in 2011 with a vision of creating safe and effective cognitive medicine that is enjoyable for users, and we have since been pioneering the development of game-changing technologies with the potential to change the world's perception of medicine.

We provide robust compensation and benefits programs to help meet the needs of our employees, and to recruit, retain, and reward our existing and new employees. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel, whether existing employees or new hires, through the granting of stock-based and cash-based compensation, salary and bonus awards. We believe that this increases value to our stockholders and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives. Our benefits programs also include a 401(k) plan, healthcare and insurance benefits, health savings and flexible spending accounts, paid time off, family leave, donation matching and flexible work schedules and work locations, among others.

Because we believe the success of our business is fundamentally connected to the well-being of our employees, we are committed to their health, safety and wellness. We provide our employees and their families with access to a variety of innovative, flexible and convenient health and wellness programs, including benefits that: provide peace of mind concerning events that may require time away from work or that impact their financial well-being; support their physical and mental health by providing tools and resources to help them improve or maintain their health status and encourage engagement in healthy behaviors; and offer choice where possible so they can customize their benefits to meet their and their families' needs.

Our facilities

We lease approximately 43,600 square feet of office space in Larkspur, California pursuant to a lease that expires in November 2026. In May 2023, the Company entered into a sublease agreement, pursuant to which we agreed to sublease approximately 5,716 rentable square feet of the Larkspur, California office space to a third party for a term commencing on June 1, 2023 and ending coterminous with the Larkspur, California lease in November 2026. Our lease in Boston, Massachusetts expired in December 2023. In November 2023, we entered into a membership agreement which provides access to office space in Boston, Massachusetts, with such access commencing on January 1, 2024 and expiring on December 31, 2024. We believe that our facilities are sufficient to meet our current needs and that suitable additional space will be available as and when needed.

Our Strategy

Direct targeting of the brain's physiology to improve neural functions is nascent but an area that we believe is poised for growth in medicine as tens of millions of people worldwide live with cognitive and other brain health issues and many are actively searching for solutions. The growing global recognition of this unmet need comes at a time when patients are increasingly taking control of their own health and looking for medical products to fit into their lives and look and feel like consumer products. We believe we are uniquely positioned to capitalize on this opportunity, with our technologies designed to directly target the brain and delivered through high-end video game interfaces.

Establishing a commercial foothold in pediatric ADHD

Pediatric ADHD is our initial target market, which has a high-unmet need population, as well as families who are unsatisfied with current treatment and are looking for new options. Traditional ADHD drugs have shown side effects including growth suppression, appetite suppression, weight issues, sleep issues and abdominal pain. Many children with ADHD are not currently on or well-controlled by medication, and more than half of them have tried, are trying or plan to try non-pharmacological treatments. EndeavorRx's safety profile provides a significant advantage over traditional therapeutics as no serious side effects have been associated with its use. However, EndeavorRx should be used as part of an overall treatment regimen and is not intended to substitute for a child's medication. Our initial targeted market of pediatric ADHD with our flagship product will also allow us to

introduce this new type of treatment to a large patient population, building awareness and relationships on which we can build for future products.

Additionally within ADHD, there is a large and growing opportunity for innovative non-drug treatments. This is a $10 billion market with over 70 million prescriptions written every year for drugs. And, according to the U.S. Centers for Disease Control and Prevention, nearly half the ADHD population uses behavioral therapy as well. The total ADHD population in the U.S. is approximately 17 million and our initial target population includes those with inattentive or combined type ADHD, or 14.7 million of the total U.S. ADHD population. EndeavorRx was initially authorized in the U.S. to treat patients in the 8-12 age group, which represent approximately 14% of our target ADHD population.

Leveraging our initial success to expand into other ADHD populations

In January 2023, we announced topline results of the STARS-ADHD-Adolescents label expansion trial evaluating the efficacy and safety of AKL-T01 (marketed and branded as EndeavorRx in the U.S.) in adolescents ages 13-17 with ADHD, with the trial meeting its primary endpoint and showing statistically-significant improvement in a number of other symptom outcomes. In addition, we used the study data in our regulatory submission to the FDA to seek an expanded label for EndeavorRx and successfully obtained FDA authorization in December 2023 for this expansion to cover individuals aged 8 to 17.

In January 2023, we also announced that based on the clinical data from the pivotal trial in adolescents and our desire to maximize capital efficiency, we discontinued recruitment of the STARS-ADHD-Adults study in order to analyze the trial data. Based on our analysis of these data, in June 2023 we released EndeavorOTC, which is built on the same platform as EndeavorRx, nationwide as 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, 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 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.

In addition, in February 2024 our partner, Shionogi, announced the results of its Phase 3 clinical study of SDT-001 in Japan in pediatric ADHD patients ages 6-17 and also announced its submission of a marketing approval application for SDT-001 in Japan.

Applying our clinically-validated technology to other mental health and neurology conditions

Building on the clinical validation of the technology underlying EndeavorRx, we have studied the SSME therapeutic engine for its potential to improve the same cognitive impairment, attention function, in patients with impairments associated with MDD, ASD, MS, lupus, TBI, post-operative cognitive dysfunction, chemotherapy-related cognitive impairment, and cognitive dysfunction related to COVID-19. Further development of our pipeline outside of ADHD will be contingent upon a number of factors, including capital raising and supportive business development activities.

Further evolving the treatment paradigm by creating new methods of cognitive assessment

There is currently no consistent clinical protocol for how to use cognitive assessment tools, and most cognitive assessments have not changed in decades, with many still performed on pen and paper. Our technology has the potential to go beyond treatments and deliver a new way to measure and monitor cognitive function at scale. Early clinical data suggest that our technology may serve as a cognitive measure that correlates with well-known in-person or paper-based cognitive measurements and detect unique neurological events before symptoms even appear.

Our Platform

Our approach is designed to strengthen cognitive function while simultaneously delivering experiences that capture the imagination. We have built a proprietary platform engineered to induce clinically meaningful cognitive changes at the functional level. Informed by decades of research (including research conducted prior to the founding of Akili) and validated through rigorous clinical testing, our platform is powered by therapeutic engines that deploy sensory stimuli and simultaneous motor challenges designed to target and activate the neural networks that are key to certain cognitive functioning.

Our therapeutic engines employ adaptive closed-loop algorithms to personalize the treatment experience for each individual user. This enables live adaptation to patient progress within gameplay, causing the treatment to continuously adapt and challenge the user at an optimized level to drive engagement and improve the targeted cognitive function.

We designed our products and product candidates to deploy our technology to users in a way that feels exciting, unlike educational software or brain stimulation. We learned over time how to build these engines into products that look and feel like today's entertainment and high-quality games. And so, our products operate in users' hands like any other video game. Our technology changes over time, adds rewards and increases challenges in a way that feels natural to users.

Components of our digital therapeutics

Each of our products and product candidates has three basic components: (1) core mechanics (our therapeutic engines), (2) a self-adaptive closed-loop system and (3) a population specific UX/UI (the video game component interface).

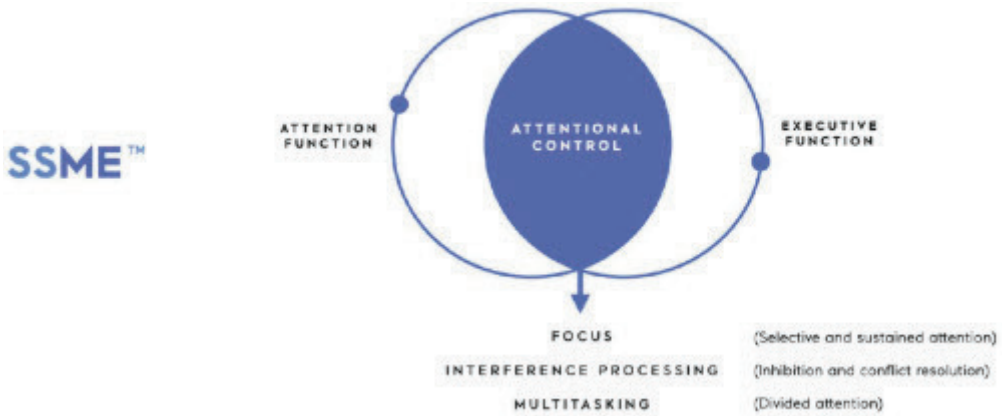
Core Mechanics (Our Therapeutic Engines)

We currently have three therapeutic engines, each with proprietary mechanics designed to activate specific systems in the brain responsible for different cognitive functions: *Selective Stimulus Management Engine* ("SSME"), *Body Brain Trainer* ("BBT") and *Spatial Navigation Engine* ("SNAV"). To date, we have only progressed the SSME therapeutic engine through clinical development and to market with EndeavorRx for children aged 8-17 with ADHD and EndeavorOTC for adults aged 18 and older with ADHD.

Selective Stimulus Management Engine ("SSME")

SSME technology is our most advanced therapeutic engine. SSME is specifically engineered to target and activate the systems in the brain that play a key role in attention function, a critical function that is often impaired in disorders including ADHD, ASD, MDD, MS, brain fog and others.

SSME is designed to activate the fronto-parietal cortex area in the brain.



Attentional Control is a set of cognitive processes that allow us to interact with our complex environment in a goal-directed manner. Specifically, it is the capacity to apply the necessary attention at an appropriate time and place, while monitoring the environment for new sources of information, in order to enable the optimal processing of task-relevant information to achieve a particular goal. SSME is designed to target attentional control and to activate the fronto-parietal cortex area in the brain.

To date, each of our development programs has been oriented toward a single indication and specific patient population. We refer to variations of our treatment software as our products or product candidates, each of which incorporates the core algorithms of one of our proprietary therapeutic engines (for example, our SSME therapeutic engine, which is incorporated into our EndeavorRx and EndeavorOTC products and into the majority of our existing product candidates). Within a single development

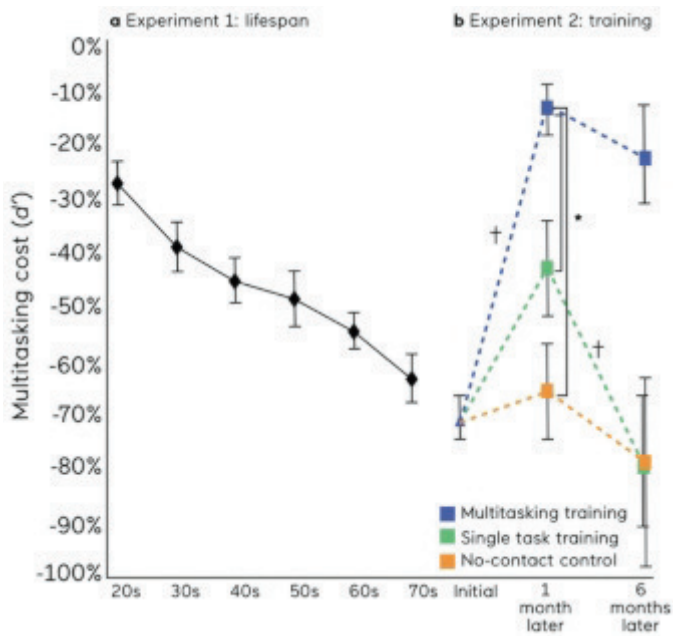
program, we may explore multiple product candidates in early research and studies to optimize user engagement applicable to a particular patient population and indication and to determine which product candidate(s) will be evaluated in later clinical studies within that development program. Based on results of our studies and regulatory feedback from our clinical studies, we may also introduce other product candidates into our ongoing development programs. Furthermore, a specific product candidate may be used for one specific development program or across different development programs. Multiple product candidates may embody a single proprietary therapeutic engine but are differentiated based on one or more characteristics, including the videogame-like user interface and gameplay difficulty and progression, and each product candidate includes unique characteristics optimized for a particular indication and population.

AKL-T01 (marketed and branded as EndeavorRx in the U.S. and FDA-authorized for children ages 8-17 old with primarily inattentive or combined-type ADHD, who have a demonstrated attention issue; and marketed and branded as EndeavorOTC in the U.S. for adults 18 years of age and older though not authorized by FDA for any indications), as well as our AKL-T02 and AKL-T03 product candidates, are each variations of Akili's treatment software targeting attention aspects of cognition, and each incorporates Akili's SSME therapeutic engine technology. For example, AKL-T02, while retaining the same user interface and SSME therapeutic engine as AKL-T01, has adapted gameplay difficulty intended to increase user engagement in an ASD population. Our SDT-001 product candidate is substantially the same SSME-based software as AKL-T01, but localized for Japanese language and culture for distribution in Japan in connection with our Shionogi partnership. As commercial products, EndeavorRx and EndeavorOTC maintain the same core gameplay functionality and therapeutic engine as the AKL-T01 product candidate used in the clinical studies that were the basis for FDA authorization of EndeavorRx, while being updated with incremental user interface changes and commercial compatibility modifications, such as compatibility modifications to enable access within applicable app stores. To the extent AKL-T01 is utilized, and authorized for marketing, under another development program (for example, a patient population and/or indication different from that authorized by FDA for EndeavorRx), the resulting commercial product may be marketed and branded under a different label and reflect different incremental user interface and/or gameplay changes than AKL-T01, EndeavorRx or EndeavorOTC.

SSME prototype study

An early prototype utilizing UCSF's patented technology was studied by UCSF for its potential to improve certain cognitive functioning in older adults. This study served as proof of concept for the patented technology exclusively licensed to us and embedded in the SSME therapeutic engine.

The prototype presented the user with two tasks: a motor function task focused on navigating along a racecourse and a set of go/no-go tasks. Presenting users with both tasks simultaneously was used to determine the individual user's ability to perform under the challenge of a specific interference. An interference (multitasking) cost was calculated based on the reduction in single-task performance when performing multiple tasks simultaneously.

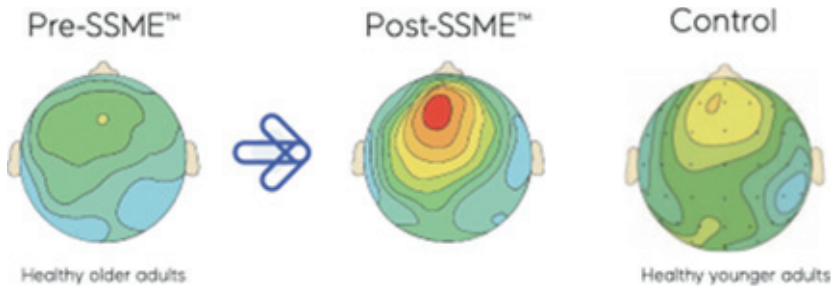


The prototype was used to quantify changes in the ability to process information as people age in a study of 174 subjects between the ages of 20 and 79 distributed with 26 to 30 subjects per age decade (experiment 1 above). With each decade of age, the ability to process interference was decreased (reducing multitasking cost in graph a, below). The impact of the prototype on cognitive

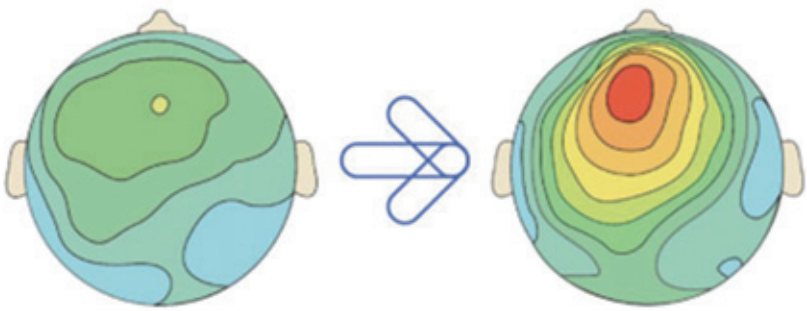
function was assessed in experiment 2 which involved randomly assigning 46 naive older adults 60-85 years old to one of three groups: Multitasking Training (n=16), Single-task Training (n=15), or No-Contact Control (n=15). Training involved playing the prototype on a laptop at home for one hour a day, three times a week for four weeks (12 total hours of training), with all groups returning for a one-month post-training and a six-month follow-up assessment. The multitasking group's performance significantly improved after four weeks, thus supporting the role of interference during game play as a key mechanistic feature of the prototype. These improvements remained stable six months after training without booster sessions. This group also showed cognitive 'near transfer' effects in improvements in measures of sustained attention and working memory after 4 weeks.

The neural basis of training effects were assessed by assessing midline frontal theta (MFT), a well-described EEG measure of attentional control, localized to the medial prefrontal cortex. The multitasking group demonstrated a significant increase in MFT between pre-and post-training after 4 weeks ($p<0.05$). Notably, these changes in neural processing reached a level comparable to neural activity patterns observed in younger adults (reference the figure below).

This groundbreaking research demonstrated that neural networks can be specifically and predictably activated and was published on the cover of the peer-reviewed scientific journal *Nature*.



Brain activity increase after proprietary multi-tasking intervention in older adults[1]



"Video game training enhances cognitive control in older adults" Nature Magazine, September 4, 2013

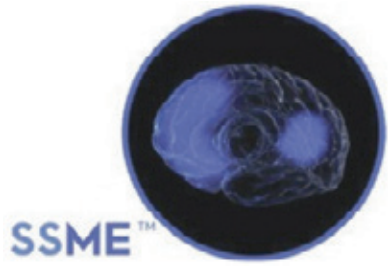
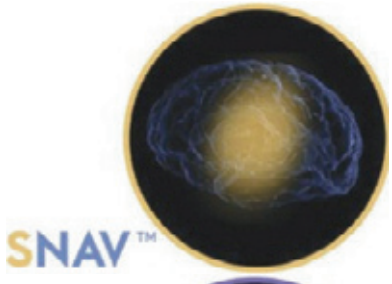
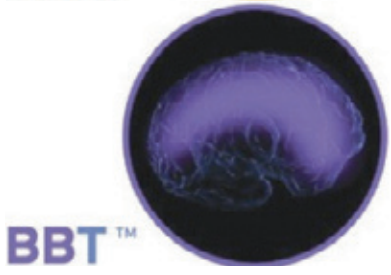
Building on this initial research, we built our SSME therapeutic engine from which we developed EndeavorRx and EndeavorOTC. SSME has been clinically validated across more than 20 research, proof-of-concept and pivotal clinical studies.

Body Brain Trainer ("BBT")

BBT is designed to target neural systems involved in attention, impulsivity, working memory and goal management (fronto-parieto-cerebellar areas of the brain). BBT integrates cognitive and physical training within a single interactive environment through a motion capture video game and utilizes adaptive closed-loop algorithms that drive individuals to work at their ideal target heart rate and cognitive challenge.

Spatial Navigation Engine ("SNAV")

SNAV is designed to leverage temporal, object and scene integration to target neural systems involved in spatial navigation, memory and planning and organization (extended hippocampal system in the brain).

Core Mechanic	Description	Targeted Physiology
SSME or Selective Stimulus Management Engine	Targets attentional control	
SNAV or Spatial Navigation Engine	Targets spatial navigation and episodic memory	
BBT or Body Brain Trainer	Targets attentional control, goal management and working memory	

A Self-Adaptive Closed-Loop System

Each user's experience is algorithmically customized and adapts in real-time based on a closed-loop feedback system. This allows the therapy to optimize and provide the most engaging and effective benefit to each individual. With this ability to adapt real-time based on a user's individual performance, the therapeutic is assessed and updated automatically, without the need for ongoing "titration" from health care providers.

A Population Specific UX/UI (Video Game Component Interface)

Our video game mechanics are the means of delivering our digital therapeutics, and we optimize these games to keep users fully engaged for the duration of the therapy as well as appropriately challenged. Virtually every aspect of gameplay, from audio feedback to on-screen rewards, is designed to maximize the user's engagement.

We customize gameplay for each specific patient population that it is intended to address. For example, when adapting a game originally designed for children for adult applications, we built four prototype games using the same clinically-validated

technology but reimagined with new themes, art and music, solely for the purpose of testing each treatment product with our target population. Each of our game concepts are focus tested with the target population.

Game mechanics overview of EndeavorRx, our first FDA-authorized digital therapeutic, and EndeavorOTC

The gameplay experience of EndeavorRx and EndeavorOTC is designed to look and feel like a familiar 3D mobile action video game. Players attempt to successfully navigate their character through courses while collecting targets and avoiding obstacles. Players chase mystic creatures and race through different worlds. Successfully navigating each level requires focus and flexibility to manage multiple tasks at the same time, while filtering out distractions.

The game adapts in real-time as well as between treatment sessions, continuously challenging and encouraging the user to improve their performance—individualizing each user's experience. As is the case with all of our product candidates, EndeavorRx and EndeavorOTC are engineered with adaptive algorithms and designed to automatically adjust the cognitive challenge for each person's individual treatment needs. For our EndeavorRx product, second by second tracking of individual progress allows caregivers to continuously monitor and assess treatment and share progress with their child's health care provider. In our EndeavorOTC product and EndeavorRx Insight app, we have also introduced a Focus Score measure, which is a personalized metric that allows a user or caregiver to track their or their child's attention improvement within the treatment.

EndeavorRx and EndeavorOTC involve three key skills: Navigation, Targeting and Multitasking:

- Navigation: Steering over gates and/or avoiding obstacles
- Targeting: Tap for targets and ignore non-targets
- Multitasking: Simultaneous navigation and targeting

The multitasking complexity increases through the different worlds of the game, as illustrated below:

Through the development of EndeavorRx, EndeavorOTC and our SSME technology, we developed specialized technologies and practices that allow us to create additional therapeutics with increased efficiency, highlighted in the section below. With the development of EndeavorRx, our FDA-authorized prescription digital therapeutic for pediatric ADHD, and EndeavorOTC, our non-prescription digital therapeutic for adult ADHD (which is currently under review by FDA), we have built a platform that we believe will enable us to continue developing innovative technologies designed to target brain function and efficiently advance them to commercialization.

Our unique development capabilities

Through our collaboration with world-renowned cognitive neuroscientists and acclaimed entertainment and technology designers, we have development capabilities that allow us to build unique video game interfaces tailored for each target audience. For instance, we have advanced a number of different gameplay experiences through clinical trials, each delivering our SSME technology through completely unique experiences designed for specific audiences. This enables us to efficiently create audience-

specific products that, once authorized by the applicable regulatory body, can be prescribed or purchased over-the-counter, as applicable, and used at scale.

Market Opportunity

While we believe we have the opportunity to develop a new pillar of medicine across potentially dozens of medical conditions, our focus is currently on ADHD.

The U.S. market opportunity in ADHD, our primary area of focus, is as follows:

Disease Area	Total U.S. Population with ADHD Diagnosis*	Initial Target ADHD Population Subset with Inattentive or Combined-Type ADHD*
Attention-deficit/hyperactivity disorder ("ADHD"), all ages	~17 million (ADHD + inattention)	~14.7 million

* Figures in table above are based on our management's good faith estimates based on various publications, public health data and national health statistics including from the NIH, CDC, and 2020 U.S. Census.

In our initial focus area, ADHD, there is a large and growing opportunity for innovative non-drug treatments. ADHD currently represents a $10 billion annual market with over 70 million prescriptions written every year for traditional drugs. According to the U.S. Centers for Disease Control and Prevention, nearly half the ADHD population uses behavioral therapy in addition to prescription medicines. Our estimated market for inattentive or combined type ADHD in the U.S. is approximately 14.7 million patients for all age groups, including approximately 11 million adults and approximately 3.7 million children in the 8-17 year old age group, which is the pediatric population EndeavorRx is currently authorized to treat.

Inadequacies of the Current Treatment Paradigm

Widely recognized in aging, cognitive impairments are also associated with dozens of chronic diseases and acute illnesses, including MDD, ASD, ADHD, MS, dementia, anxiety, schizophrenia, PTSD, "chemo-fog" and more. This manifests in ways like the inability to concentrate, memory issues, difficulty learning new things or issues making decisions that affect everyday life.

The safety profile of ADHD drugs and lack of options to specifically address inattention creates a very high unmet need. Current treatment approaches are limited to traditional medication, which lack precision, largely only treat symptoms, and are often accompanied by side effects. Traditional ADHD drugs have shown side effects that may include growth suppression, appetite suppression, weight issues, sleep issues and abdominal pain. Many children with ADHD are not currently on or well-controlled by medication, and more than half of them have tried, are trying or plan to try non-pharmacological treatments. In adults, rates of ADHD have continued to rise in the U.S., and a large proportion of adults with ADHD are dissatisfied with their current treatment regimen, or receive no treatment at all. People with ADHD are looking for new options to improve upon the inadequate existing treatment paradigm. Additionally, behavioral therapies teach coping mechanisms rather than addressing the underlying impairment. Furthermore, people with ADHD are turning to supplements and brain trainers, which lack clinical evidence of effectiveness.

The stress of the global pandemic, the impact of technology in our lives, and the shortage of traditional ADHD drugs is aggravating these challenges, and recognition of the impact on society is increasing. The World Health Organization estimates that 139 million people will be living with dementia by 2050. In 2021, a coalition of the U.S.'s leading experts in pediatric health declared a national emergency in child and adolescent mental health, and the U.S. Surgeon General issued an advisory to highlight the urgent need to address the mental health crisis among U.S. youth. On August 1, 2023, the FDA and the Drug Enforcement Administration jointly issued a letter regarding actions being taken to try and resolve the shortages of prescription stimulant medications. This FDA and Drug Enforcement Administration letter specifically referenced the June 2020 FDA marketing authorization of our EndeavorRx product for children with ADHD and stated that the product offers a non-drug option for improving symptoms associated with ADHD in children.

We believe that now is the right time to apply technology to treating human diseases, in particular, cognitive conditions for which existing approaches have fallen short in providing clinically meaningful therapeutic options and for which there remains a significant unmet need.

Our Advantages

Disease agnostic

Our therapeutic engines are designed to target specific neural networks independent of the cause of the disease, and therefore a single therapeutic engine can potentially power dozens of products that target the same cognitive impairments, serving many different disease populations and creating a highly efficient technology-centric medicine model.

Personalized and adaptable

Our technology continuously learns and adapts based on a user's use of and progress in the treatment, resulting in tailored and personalized experiences that automatically adjust to each individual's therapeutic needs.

Rich data infrastructure

Our platform gives us real-time direct access to a de-identified aggregate level view of each user's activity in real-world conditions, enabling continuous innovation and rapid product iteration and allowing us to be truly user adaptive.

Repeatable and efficient model

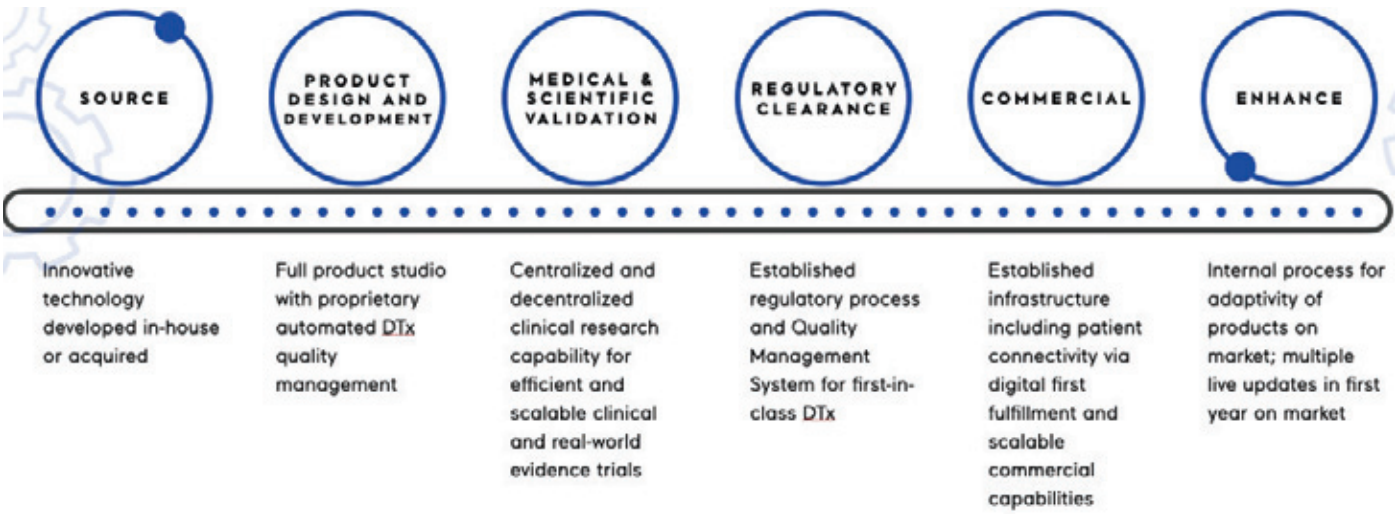
Building on clinically-validated technologies, with the regulated therapeutic engine intact, we can rapidly build different front-end experiences for different patient populations, creating completely unique games tailored for each audience.

Strong intellectual property protection

We seek to protect our platform, including unique algorithm mechanics, through the use of patents, copyrights, trademarks and trade secrets, providing Akili with a rich intellectual property estate to develop, strengthen and maintain our proprietary position in the digital therapeutics field.

Ability to leverage our platform and infrastructure to achieve scale

We have developed specialized technologies and practices to support our first FDA-authorized pediatric ADHD product, EndeavorRx, and our adult ADHD product, EndeavorOTC, that are designed to enable us to repeat that success with increased efficiency over time. Highlighted in the figure below, from technology sourcing all the way up through regulatory authorization, commercialization and growth on the market, our platform takes innovative technologies that target brain function and brings them through every step of the process. We are the first company to have built a platform to leverage these types of physiologically-targeting digital therapeutics, and we intend to further develop our SSME therapeutic engine as this field of digital therapeutics grows.



We believe that our work to obtain marketing authorization for EndeavorRx, including with regulators to define the product category, clinical endpoints and labeling approach, paves the way not only for our future products on our current platform such as

EndeavorOTC, our adult ADHD product that is currently under review by FDA, but for other novel clinically validated and FDA-authorized digital therapeutics from other technology sources to increasingly come to market.

We have established commercial capabilities that we believe have the potential to support an expanded clinical pipeline.

EndeavorRx represents our first commercial offering, demonstrating to the world what is possible using game-changing technology as medicine. But we believe this is just the beginning. Leveraging the clinical success of our products, we have built commercial and operational capabilities that we believe can support other product candidates in our clinical pipeline. These capabilities include a flexible fulfillment infrastructure and in-house distribution system, marketing resources, customer relationship management systems and service and support systems, and we have worked to leverage many of these capabilities for the commercialization of EndeavorOTC, our adult ADHD product. We believe that these capabilities along with our technology platform could enable us to potentially improve cognitive impairments across dozens of other diseases and disorders.

Product Portfolio Commercialization Strategy

EndeavorOTC

EndeavorOTC's commercial strategy leverages direct-to-consumer marketing efforts to deliver innovative concepts to core target audience segments. Akili's expertise in medical and cognitive science combined with an understanding of customer needs and motivations serves as the basis for our customer acquisition strategy on search, social and other digital and integrated properties. We believe our focus on delivering content designed to educate and inform customers has helped to improve customer adoption and advocacy, such as amplification of user success stories in media and word-of-mouth marketing.

EndeavorRx

Our commercial model for EndeavorRx has important levers that go beyond the traditional therapeutic model. Because we are building the model from the ground up, we have the ability to use the extensive data collected through our platform, not just to rapidly iterate our products, but to tailor the entire delivery system for our products. We are leveraging a fully digital process, from prescription to fulfillment to treatment, creating optimization of the end-to-end patient experience and potentially enabling higher conversion, better compliance and optimal treatment.

Additionally, as we continue to focus on preserving capital, in the second half of 2023 we transitioned from a single third party digital pharmacy for the fulfillment of prescriptions for EndeavorRx to an internally developed in-house direct distribution system for EndeavorRx.

Product Portfolio

In the U.S., we continue to offer the EndeavorOTC and EndeavorRx products commercially so that users can continue to access our products for the treatment of ADHD. Outside of the U.S., we will consider regional partnerships in relevant markets, leveraging existing and established brands and will franchise on an indication per indication basis. For example, Akili has formed a strategic partnership with Shionogi in Japan and Taiwan, leveraging each party's distinct expertise to build a novel commercial model and launch a new class of treatment to patients.

Current Programs and Clinical Validation

We have completed over 20 clinical studies of our SSME technology to evaluate its potential to diagnose, treat and monitor certain cognitive functions in patients. Our studies, including large prospective randomized controlled trials, have been conducted in over 2,600 patients across nine disease areas. Our research has been published in leading peer-reviewed scientific journals, including *The American Journal of Psychiatry, The Lancet Digital Health* and *Nature: Digital Medicine*.

SSME is the therapeutic engine underlying our first two commercial products in ADHD, EndeavorRx for pediatric ADHD and EndeavorOTC for adult ADHD, and we have achieved pilot and/or proof of concept with SSME in MDD, MS and ASD, though clinical programs in MDD, MS, and ASD have been deprioritized as we focus our efforts primarily on ADHD. Further development of our pipeline outside of ADHD will be contingent upon a number of factors, including capital raising and supportive business development activities.

Attention-deficit hyperactivity disorder ("ADHD")

ADHD is a neurobehavioral disorder characterized by a persistent pattern of symptoms such as inattention, hyperactivity and impulsive behavior that interferes with functioning and development. ADHD can have a profound impact on an individual's life, causing disruption at school, work, home and in relationships. It is one of the most common developmental disorders in children and often persists into adulthood.

ADHD market size

Current ADHD treatment options represent a $10 billion market with over 70 million prescriptions written every year for drugs in the U.S. According to the U.S. Centers for Disease Control and Prevention, nearly half the pediatric ADHD population uses behavioral therapy. We believe the total ADHD population in the U.S. is approximately 17 million and that the total ADHD population with inattention issues is approximately 14.7 million. Estimates of the U.S. prevalence of ADHD in adults range from 1.12% to 4.4%, with the latter estimate derived from a study focused on a representative U.S. population and conducted with epidemiological assessment methods. Based on estimates from the 2020 census of approximately 250 million individuals aged 18 and above, we believe the total addressable market for adults with ADHD in the United States is approximately 11 million.

Current ADHD treatment guidelines recommend a multi-faceted approach that uses medications in conjunction with behavioral interventions. For children with ADHD younger than 6 years of age, the American Academy of Pediatrics recommends parent training in behavior management as the first line of treatment, before medication is tried. For children 6 years of age and older, the recommendations include medication and behavior therapy used in combination. About 77% of children aged 2 to 17 with ADHD in the U.S. receive treatment, with about 47% receiving behavioral treatment and about 15% receiving only behavioral treatment without any medication. First- line medications used to treat ADHD are stimulants such as methylphenidate, marketed as Ritalin and Methylin, dexmethylphenidate, marketed as Focalin, dextroamphetamine, marketed as Dexedrine and Zenzedi, amphetamine-dextroamphetamine, marketed as Adderall, and lisdexamfetamine, marketed as Vyvanse. Other approved medications include atomoxetine, extended-release guanfacine, and extended-release clonidine. As of 2018, stimulants command 88% of the U.S. ADHD market at a value of $8 billion, with approximately 50% of the total market being amphetamines.

It is estimated that 44% of patients are not currently on or well controlled by ADHD medication, and 64% experience adverse effects from medication. Data show that 55% of patients have tried, are trying or plan to try non-pharmacological treatments. However, current validated non-pharmacological treatments and approaches—e.g. behavioral therapy—can lead to mixed results and can have accessibility and cost issues.

Our targeted population for EndeavorRx is U.S. children ages 8-17 with ADHD who have a demonstrated impairment in attention function. This market represents a large and growing opportunity with caregivers actively searching for new non-drug solutions and allows us to build relationships with consumers that can be extended to support future market opportunities.

For our target population of U.S. adults 18 years of age and older, we released EndeavorOTC nationwide in June 2023 for adults with primarily inattentive or combined-type ADHD, under the FDA's COVID-19 Guidance.

Our first commercial product—EndeavorRx for pediatric ADHD patients

Supported by data across five clinical trials, in June 2020, EndeavorRx was granted marketing authorization and was classified as a Class II medical device by the FDA through FDA's de novo process. EndeavorRx is currently indicated to improve attention function as measured by computer-based testing in children ages 8-17 years old with primarily inattentive or combined-type ADHD, who have a demonstrated attention issue. Patients who engage with EndeavorRx demonstrate improvements in a digitally assessed measure Test of Variables of Attention ("TOVA®") of sustained and selective attention and may not display benefits in typical behavioral symptoms, such as hyperactivity. EndeavorRx should be considered for use as part of a therapeutic program that may include clinician-directed therapy, medication and/or educational programs, which further address symptoms of the disorder. EndeavorRx is available by prescription only. It is not intended to be used as a stand-alone therapeutic and is not a substitution for a child's medication.

According to the FDA, EndeavorRx represents the first game-based digital therapeutic to improve attention function associated with ADHD and the first game-based therapeutic to be granted FDA marketing authorization for any type of condition.

The impact of EndeavorRx as a digital therapeutic treating children with ADHD is two-fold—it is transforming how the world experiences medicine and bringing a new clinically-validated non-drug solution to patients living with ADHD. It is the first and only FDA-authorized treatment of its kind and is currently being prescribed by health care providers and helping patients with ADHD and their families.

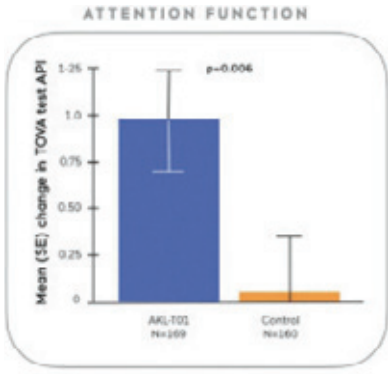
Created by a team of neuroscientists and game designers, EndeavorRx is built on our SSME therapeutic engine and uses sensory stimuli and simultaneous motor challenges designed to target areas of the brain that play a key role in attention function. Patients who engaged with AKL-T01 in clinical studies demonstrated improvements in specific ADHD impairments and symptoms in daily life, as detailed in our clinical study data below.

Clinical evidence supporting EndeavorRx

The EndeavorRx research program includes three studies in ADHD (STARS-ADHD, STARS-Adjunct and ADHD-POC) and pilot studies in ADHD with Sensory Processing Disorder and in ADHD with ASD (see below section for a description of the ASD study).

STARS-ADHD pivotal study

The pivotal STARS-ADHD study was a 4-week multi-center, randomized, blinded, controlled trial conducted between July 2016 and November 2017 in 348 children aged 8-12 years and diagnosed with ADHD. Children enrolled into the study were instructed to use AKL-T01 or an educational-style video game control for approximately 25 minutes a day for 28 days.



Significant improvement in objective attention compared to matched control[1]

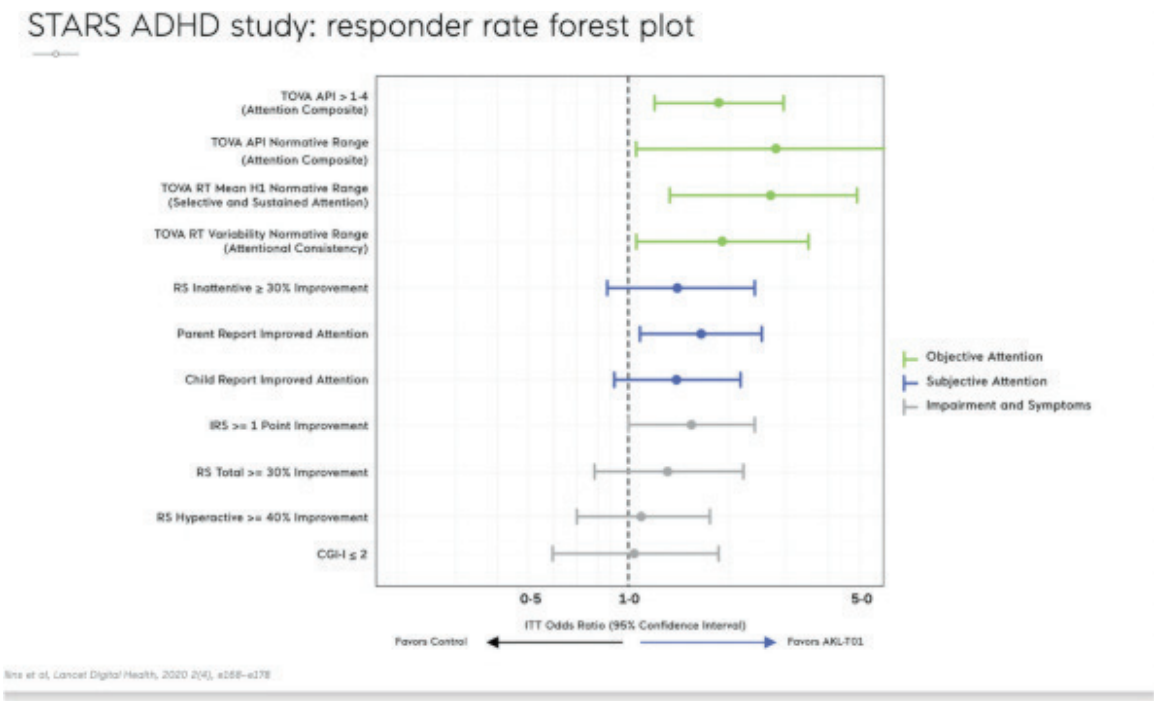
The predefined primary endpoint of the study was the change from baseline in the TOVA Attention Performance Index (TOVA API), a measure of objective attention for which the study was statistically powered. TOVA is a computerized test cleared by the FDA to assess attention deficits and evaluate the effects of interventions in ADHD; the API is a composite measure of attention functioning. This objective attention endpoint was the primary endpoint for which the study was statistically powered. The control condition used in this study was specifically designed to enable the assessment of changes in the primary endpoint of objective attention. The control was in the form of an educational style word search digital game matched to AKL-T01 for expectation of benefit and time on task. AKL-T01 showed a statistically significant improvement on the TOVA API compared to the control (p=0.006).

The mean ("SD") change from baseline on the TOVA API was 0.93 in the AKL-T01 group and 0.03 in the control group. Forty-seven percent of children met the prespecified clinical responder analysis for TOVA API improvement, which was greater than control (47% vs 32%, p=0.0058). In addition to the improvement in the TOVA API, treatment with AKL-T01 resulted in significantly greater improvements across other objective TOVA attention-related measures (sustained attention, attentional consistency, and long attentional lapses). Overall, after treatment with AKL-T01, 36% of children moved into the normative range of objective attention as measured by TOVA and no longer showed an objective attention deficit in at least one aspect of attention functioning, which was statistically greater than control (36% vs 21%, p=0.0027).

In addition to these objective measures of attention, the study also looked at secondary outcome measures comparing AKL-T01 to control on parent- and clinician-reported ADHD impairment and symptom ratings scales, specifically the Impairment Rating Scale ("IRS"), ADHD Rating Scale (ADHD-RS-IV—Total, Inattentive, Hyperactive subscales), Clinical Global Impressions of Improvement ("CGI-I") and the Behavior Rating Inventory of Executive Function ("BRIEF"). Children using AKL-T01 showed statistically significant change from baseline improvement across all measures. Though there was not a statistically significant separation on the mean magnitude of improvement between AKL-T01 and control on these secondary outcome measures, there was a trend towards differential improvement in IRS and ADHD-RS-Inattentive for children using AKL-T01.

Predefined responder analyses of these parent- and clinician-reported measures also showed differential improvement, with a significantly greater proportion of children benefiting from AKL-T01 versus control in the clinician-administered IRS, a parent-reported scale of ADHD-specific impairments (48% vs 37%, p=0·049). Further, 24% of children in the AKL-T01 group were considered responders on the ADHD-RS (≥30% reduction in ADHD-RS) compared to 19% in the control group (p=0.23; post-hoc analysis). Additionally, 56% of parents said the intervention helped their child's attention in real life, and 73% of children reported feeling an improvement in their attention when asked via an exit survey. Overall, the effects of AKL-T01 were strongest

for measures of attention function, and weakest for measures of hyperactivity in ADHD. We further investigated these and similar secondary endpoints in other studies described herein.

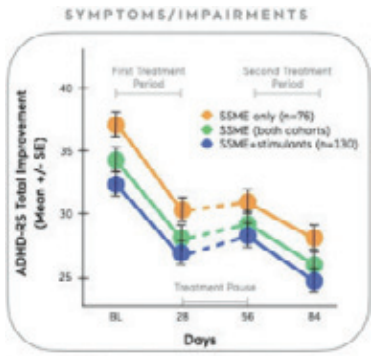


AKL-T01 was shown to be safe in this study, with no serious adverse events observed. All adverse events reported were mild in 7% of patients, and included frustration (3%), headache (2%), emotional reaction (1%), dizziness (1%), nausea (1%) and aggression (1%).

STARS-ADHD Adjunctive clinical study

The STARS-ADHD Adjunctive clinical study was a three-month open-label study conducted between December 2018 and September 2019 which enrolled 206 children, aged 8-14 years with a diagnosis of ADHD. The children were separated into two groups: one with children on stimulant medications and one with children not taking ADHD medication. Both groups received a first period of AKL-T01 treatment in the first month of the study, followed by a pause in AKL-T01 treatment in the second month, and then a second period of AKL-T01 treatment in the third month. The primary efficacy outcome of the study was change in IRS after one month of treatment.

The study demonstrated statistically significant improvement in the IRS from baseline after one month as well as to the end of the three- month trial in both the children on-stimulants and off-stimulants (both cohorts: $p<0.001$). The second period of AKL-T01 treatment resulted in further increases in efficacy on this primary outcome measure, beyond the effects already seen after the first period of treatment. The magnitude of improvement in IRS throughout the study was similar for children independent of their ADHD medication use. Responder rates for IRS (improvement of greater than 1 point or more on the IRS scale) were 41% and 56% at the end of the first period of treatment with AKL-T01 in the off-stimulant and on-stimulant groups respectively (50% across both groups). This increased to 69% and 68% respectively by the end of the second period of treatment. Further, across both groups, responder rates for ADHD-RS Total (% children with ≥30% improvement) after the first period of treatment was 27% and increased to 45% after the second period of treatment. Additionally, after the second period of treatment, 60% of parents said the intervention helped their child's attention in real life, and 75% of children reported feeling an improvement in their attention when asked via an exit survey.



ADHD symptom and impairment improvement sustained after 1st treatment, increased after 2nd treatment, and similar with or without medications[6]

The treatment was well-tolerated. There were no serious adverse events and the total reported adverse events were in 18% of patients. The most common treatment-related adverse events reported were frustration (13.1%), headache (1.9%), irritability (1.5%), dizziness (1%), agitation (0.5%), anxiety (0.5%), asthenopia (0.5%), nausea (0.5%), feeling abnormal (0.5%) and pruritus (0.5%).

ADHD proof of concept study in pediatric ADHD

Our proof of concept ("POC") study in ADHD was a 4-week study with recruitment conducted between January 2014 and August 2014 in children between the ages of 8-12 with a primary aim to assess treatment safety and acceptability and explore outcomes for AKL-T01 as a novel digital treatment targeting cognitive processes implicated in pediatric ADHD. Participants included 40 children with ADHD and 40 children without an ADHD diagnosis. Following psychiatric screening, ADHD ratings, and baseline neuropsychological measures (TOVA, CANTAB and BRIEF), participants completed the 28-days of at-home treatment and then returned to the clinic for follow-up safety, acceptability and neuropsychological measures. A neuropsychological assessment was repeated at the end of the study, and treatment satisfaction measures were assessed.

Eighty-four percent of treatment sessions were completed and AKL-T01 was feasibly deployed in the home setting over the treatment period of four weeks with positive ratings of acceptability by both parents and children. AKL-T01 was well-tolerated by children with ADHD, with no treatment-related adverse events reported. The results of the neurocognitive measures were as follows:

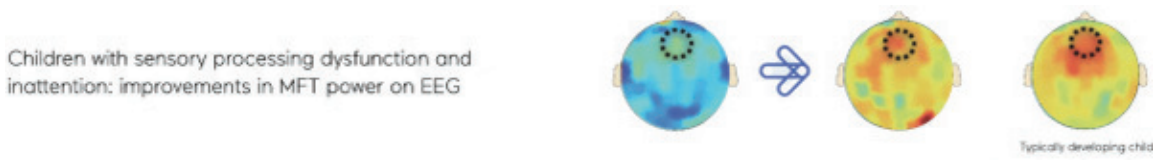
Significant improvements compared to baseline were observed in the ADHD group on the TOVA Attention Performance Index (TOVA API) ($p = 0.033$, Effect Size (d) = 0.35). There was no significant change in TOVA API scores for the non-ADHD group ($p = 0.30$, Effect Size (d) = 0.17).

The ADHD group showed significant improvement compared to baseline ($p < 0.05$) on 8 of 12 variables within the CANTAB Spatial Working Memory (SWM) test, 3 of 10 variables within the CANTAB Rapid Visual Processing (RVP) test, and 0 of 16 within the CANTAB Delayed Match to Sample (DMS) test. The non-ADHD group showed significant improvement ($p < 0.05$) on 5 of 12 variables within the SWM, 6 of 10 variables within the RVP, and 9 of 16 within the DMS.

The BRIEF summary scores (i.e., Metacognition, Behavioral Regulation, Global Executive Composite) did not change significantly for any of the groups. Findings from the study provided preliminary support that this digital therapy intervention may be effective for improving attention in pediatric ADHD, especially among children with greater symptom severity and impaired attention.

Studies in ADHD with sensory processing disorder

AKL-T01 was evaluated in a pilot study in children between 8-12 years old with Sensory Processing Dysfunction ("SPD") who also met research criteria for ADHD. Recruitment for this study began in February 2014 and ended in January 2015. These children experience attention deficits that often impact their academic and social development. A sample of 38 SPD and 25 typically developing children were tested on behavioral, neural and parental measures of attention before and after a four-week iPad-based at-home cognitive remediation program. The primary endpoints were a Test of Variables of Attention (TOVA) reaction time (mean RT first half) and RT variability (RT-var first half) and ADHD-inattention symptoms (as measured with Vanderbilt inattention subscale, parent report). The secondary endpoints were Neurophysiology EEG Midline Frontal Theta (MFT) during TOVA and perceptual discrimination task. This was a feasibility study and a power analysis was not conducted. At baseline, 54% of children with SPD met or exceeded criteria on a parent report measure for inattention/hyperactivity. Notable deficits involving sustained attention, selective attention and goal management were observed only in the subset of SPD children with parent-reported inattention. This subset of children also showed reduced midline frontal theta activity, a well-established measure of attentional control derived from the electrical activity of the brain. Following the cognitive intervention, only the SPD children with inattention/ hyperactivity showed both improvements in midline frontal theta activity and on a parental report of inattention. Notably, 33% of these individuals no longer met the clinical cut-off for inattention, with the parent-reported improvements persisting for nine months. These findings support the benefit of a targeted attention intervention for a subset of children with SPD, while simultaneously highlighting the importance of having a multifaceted assessment for individuals with neurodevelopmental conditions to optimally personalize treatment.

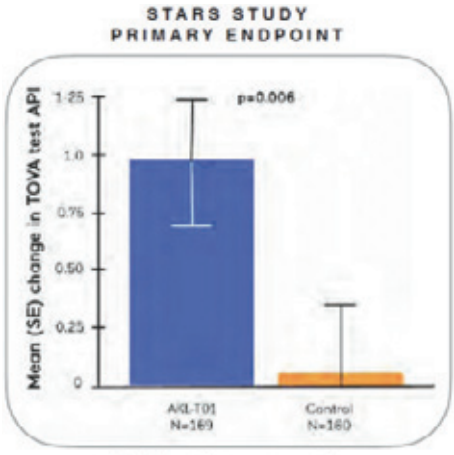


A 9 months follow up study (no intervention with AKL-T01 and continued treatment as usual) revealed that participants showed a significant decrease in parent-observed inattentive behaviors ($p = 0.66$, Cohen's D = 0.14), which remained stable in a nine-month follow-up assessment. A Generalized Estimating Equations analysis was used to assess changes in symptoms over time, specifically to determine whether the initial improvements were retained. The SPD plus inattention cohort continued to show sustained benefits on their parent-reported scores of inattention, with 54% of SPD plus inattention individuals no longer meeting criteria for ADHD three years following intervention.

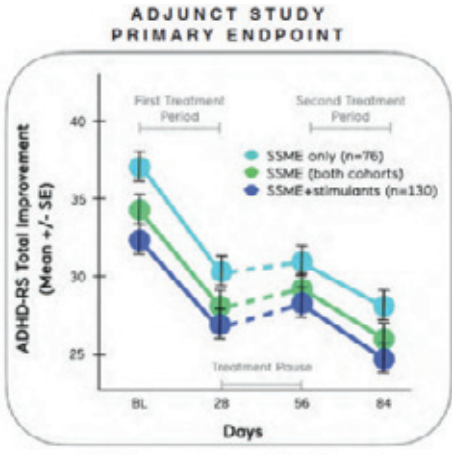
Consistent and Clinically Meaningful Improvements in Objective Attention across Studies in ADHD

We observed consistent improvements in TOVA API and related key measures of objective attention (reaction time (RT Mean H1) and reaction time variability (RT Var)) across all studies of AKL-T01 in children with attention impairment.

We believe the overall efficacy profiles of the ADHD studies described herein reflect the targeted nature of the treatment and underlying technology, i.e., to target attention networks. We believe these efficacy profiles meet an important need for children in ADHD, which is reinforced by the indication of EndeavorRx. Specifically, the FDA-authorized indications for use specify that EndeavorRx is intended to improve attention function, and that EndeavorRx is for children ages 8-17 years old with primarily inattentive or combined-type ADHD, who have a demonstrated attention issue, and to be used alongside their current treatment program, and that EndeavorRx should be considered for use as part of a therapeutic program that may include clinician-directed therapy, medication, and/or educational programs, which further address symptoms of the disorder.



Significant improvement in objective attention compared to matched control



ADHD symptom and impairment improvement sustained after 1st treatment, increased after 2nd treatment, and similar with or without medications

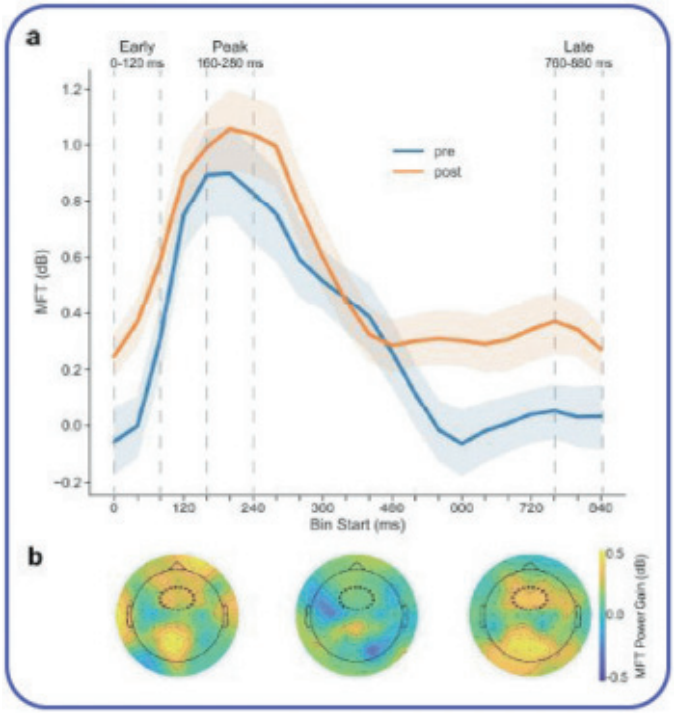
Electroencephalography ("EEG") study of AKL-T01 in ADHD

This single-arm, unblinded 4-week study was conducted at UCSF and assessed a sample of 25 children with ADHD (8–12 years old) on neural, behavioral, and clinical metrics of attention before and after a four-week at-home intervention with AKL-T01. The primary endpoints were neural assessment of attentional control, change in midline frontal theta (MFT) power as measured by Perceptual Discrimination Task (PDT)-Locked Electroencephalogram (EEG) from day 0 to day 28. The exploratory endpoints were objective behavioral measures of attention, such as a perceptual discrimination task, reaction time and reaction time variability metrics, and sustained attention task (a continuous performance task similar to TOVA). The parent reported ADHD symptoms were measured on the Vanderbilt inattention subscale. This was a feasibility study and a power analysis was not conducted.

The study found that children showed enhancements on MFT, as well as on objective behavioral measures of attention and parent reports of clinical ADHD symptoms. There were also observed relationships between the neural and behavioral cognitive improvements, demonstrating that those children who showed the largest intervention-related neural gains were also those that improved the most on the behavioral tasks indexing attention.

Graph (a) shows the time course of MFT EEG changes during treatment with AKL-T01 and shows there was a general increase in MFT magnitude following four weeks of treatment with AKL-T01 (change from pre- to post- intervention).

Graph (b) illustrates improvements in MFT following four weeks of treatment with AKL-T01 at the corresponding early, peak and late time windows during treatment, through topographic heat maps with the MFT area of interest highlighted with a dotted bounding box.



Clinical development program in ADHD

U.S. study of AKL-T01 in adolescents (STARS-ADHD-Adolescents)

Akili has conducted a multi-center pivotal trial to evaluate objective attention functioning and ADHD symptoms and impairments in adolescents, ages 13 to 17, with a diagnosis of ADHD (combined or Inattentive subtypes), who are stable on or off ADHD medication, after four-weeks of SSME treatment.

In January 2023, we announced top-line results of this STARS-ADHD-Adolescents label expansion trial evaluating the efficacy and safety of AKL-T01 (marketed and branded as EndeavorRx in the U.S.) in 162 adolescents ages 13-17 with ADHD, with the trial meeting its primary endpoint and showing statistically significant improvement in a number of other symptom outcomes.

These data were the basis of our 510(k) submission to FDA in May 2023; and in December 2023, we obtained marketing authorization from FDA for the label expansion of EndeavorRx to include adolescents ages 13-17 with ADHD. Results from this study were presented at two scientific meetings in 2023 and are currently under review for publication in a peer-reviewed journal.

Shionogi study of SDT-001 in Japan

Through our strategic partnership with Shionogi announced in March 2019, Akili conducted a study of SDT-001, which is substantially the same SSME-based software as the AKL-T01 product candidate, but localized for Japanese language and culture for distribution in Japan, in children with ADHD in Japan. The study was designed to evaluate the feasibility, safety and efficacy of the investigational digital therapeutic in children with ADHD and to inform the design of a future pivotal study. To enable this clinical trial, Akili localized AKL-T01 for use in the Japanese market, which included adapting for language and culture and establishing infrastructure in Japan to support the investigational device.

The randomized, controlled study of SDT-001 enrolled children ages 6-17 years diagnosed with ADHD whose ADHD RS-IV Inattention score was 15 or over. A total of 261 patients were enrolled across three study groups: (1) participants who received the Akili SDT-001 digital treatment, (2) participants who continued treatment as usual ("TAU"), consisting of psychoeducation and environmental support, and (3) participants who received a version of the treatment with reduced cognitive tasks and adaptability ("Sham"). The SDT-001 treatment group showed larger improvements across the clinical endpoints compared to both the TAU and the Sham groups. In the total population, the improvements seen over Sham did not meet statistical significance, but post hoc

analysis applying the propensity score suggested that SDT-001 improvements over TAU were statistically significant ($p < 0.05$). SDT-001 was generally well-tolerated and there were no serious adverse events. Adverse events reported were consistent with previous clinical studies of AKL-T01. There were 4 adverse device reactions reported in patients treated with SDT-001, which were mild in severity including irritability, headache, tinnitus and nausea.

In August 2022, we announced that following a successful Phase 2 trial, Shionogi had commenced a pivotal Phase 3 portion of this study.

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. The trial aimed to evaluate the efficacy and safety of SDT-001 in 164 pediatric ADHD patients aged 6 to 17 who received conventional treatments such as environmental adjustments and psychosocial therapies. The SDT-001 group, undergoing approximately 25 minutes of treatment once daily for 6 weeks (1 cycle), demonstrated statistically significant improvements in the change from baseline in the Attention-Deficit/Hyperactivity Disorder Rating Scale IV (ADHD-RS-IV) Inattention score compared to the control group (continuing conventional treatments) at the 6-week mark ($p < 0.05$), achieving the primary endpoint of the trial. Moreover, statistically significant improvements were observed in the change from baseline in the total ADHD-RS-IV score and the hyperactivity/impulsivity score at the 6-week mark in the SDT-001 group compared to the control group ($p < 0.05$). No safety concerns or serious adverse events related to SDT-001 were observed. Furthermore, symptom improvements were sustained even after two cycles of SDT-001 use, with no safety concerns noted.

Clinical evidence supporting EndeavorOTC

U.S. study of AKL-T01 in adults (STARS-ADHD-Adults)

In January 2023, we announced that based on the slower-than anticipated trial recruitment and the positive clinical data from the above STARS-ADHD-Adolescents pivotal trial and our desire to maximize capital efficiency, we discontinued recruitment of STARS-ADHD-Adults, the multi-center pivotal trial to assess the efficacy of AKL-T01 in adults 18 years and older diagnosed with ADHD in order to analyze the trial data. The study enrolled 223 patients and evaluated objective attention functioning and ADHD symptoms/impairments in adults with a diagnosis of ADHD (combined or inattentive subtype), stably on or off ADHD medication, after six-weeks of AKL-T01 treatment.

In May 2023, we announced topline results of the STARS-ADHD-Adult clinical trial in adults with ADHD evaluating the efficacy and safety of EndeavorRx (AKL-T01), the first product built on the Akili platform. STARS-ADHD-Adult was designed as a pivotal clinical trial to enable registration with the FDA. The trial demonstrated statistically significant improvement in attention functioning after six weeks of treatment, achieving its predefined primary efficacy outcome. Significant improvements were also seen across a range of secondary and exploratory outcomes, including clinical assessments of ADHD-related symptoms and a validated measure of quality of life. The treatment was well-tolerated, with minimal side effects and no serious device-related adverse events reported.

In June 2023, we released EndeavorOTC®, which is built on the same platform as EndeavorRx, nationwide as 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, 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 still 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. We will continue to work interactively with FDA on this submission and expect to provide information regarding the status of the application by the end of the second quarter of 2024.

Autism spectrum disorder ("ASD")

ASD is a neurodevelopmental disorder characterized by impairments in social communication and social interaction and restricted repetitive patterns of behavior, interests and activities. Children with ASD are at high risk for impairments in attention function and are often initially diagnosed because of delays in language development or deviant language skills, or because of lack of the intent to communicate. The presence of ADHD symptoms in children with ASD is associated with worse cognitive (attention) control.

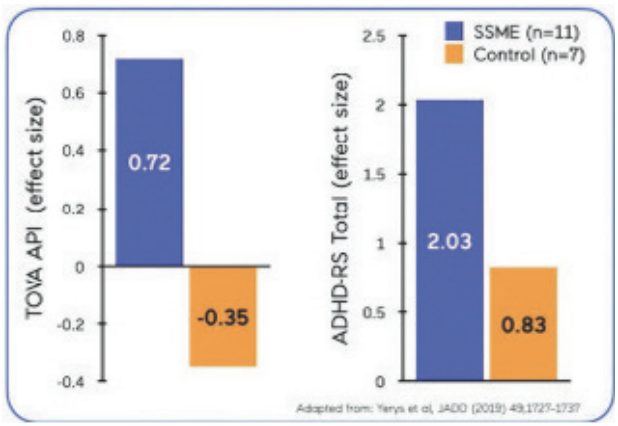
Individuals with ASD have varying degrees of impairment that require customized management based on the child's age and needs. Treatment for ASD is focused on behavioral and educational interventions as well as pharmacological interventions to treat targeted symptoms such as hyperactivity, inattention, impulsivity, aggression, anxiety and obsessive-compulsive behaviors. Risperidone and aripiprazole are the only approved treatments for the behavioral disturbances associated with ASD. Common adverse effects from these drugs include weight gain, sedation and Parkinson's-like symptoms such as muscle spasms and stiffness.

Clinical evidence in ASD

We have conducted a pilot study of an investigational new treatment product built on our SSME technology engine in patients with ADHD with ASD, utilizing the AKL-T02 variation of our treatment software. While leveraging the same SSME core mechanics and video game interface found in our EndeavorRx product, to address the distinct needs of ASD patients, the rate of change in challenge levels of our investigational treatment product in ASD is decreased. Our pilot study demonstrated high acceptability and engagement of the treatment and an improvement in attention measures compared to a control condition. The study demonstrated an improvement in TOVA scores following use of the Akili investigational treatment compared to a control educational style video game. The primary endpoint was TOVA API. The secondary endpoints were the ADHD Rating Scale IV, parent report and the Behavior Regulation Inventory of Executive Function-2 (BRIEF-2), social skills improvement system and the spatial working memory task from the Cambridge Neuropsychological Test Automated Battery (CANTAB). This study was a feasibility study and no power analysis was performed.

The study was conducted at the Children's Hospital of Philadelphia Center for Autism Research, which enrolled 19 children with autism, aged 9-13 years old and with an average age of 10 years old. Patients received either our investigational treatment (AKL-T02) or a control educational style video game based on a word challenge game. Patients were asked to play the game for 30 minutes a day, five days a week, for four weeks.

This pilot study found that not only did the child participants like and engage with our investigational treatment, their attention on the TOVA test of attention improved similar to what was seen in our studies of children with only an ADHD diagnosis. The control video game did not demonstrate improvement in the mean TOVA score. There was one adverse event (decreased frustration tolerance) in the AKL-T02 group; no serious adverse events were reported.



Clinical development program and upcoming milestones in ASD

As noted previously with our updated strategic plan, this clinical program has been de-prioritized while we focus resources on the ADHD population. Further development of our pipeline outside of ADHD will be contingent upon a number of factors, including capital raising and supportive business development activities.

Major depressive disorder ("MDD")

Major depressive disorder is the most prominent subtype of depression, and people suffering from MDD typically have a depressed spirit or mood, known as dysphoria, reduced energy and decreased activity level. They also have a reduced capacity for enjoyment, a lowered self-esteem and reduced self-confidence.

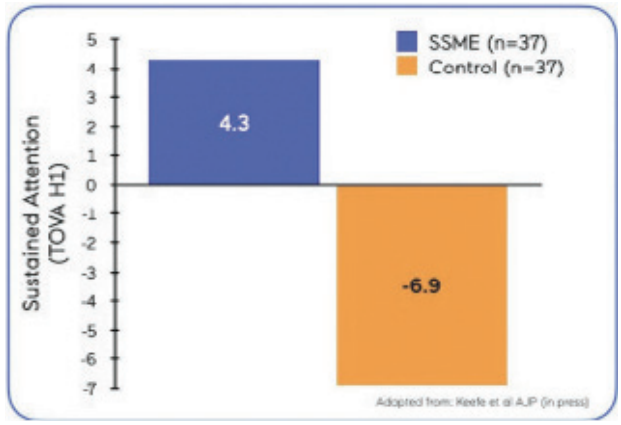
Cognitive impairment is a fundamental diagnostic criterion of depression. Data show that cognitive symptoms are present during up to 94% of depressive episodes and, for many patients, persist even after successful antidepressant treatment (seen in up to 44% of periods of remission). Such cognitive impairments have been shown to be a predictor of daily function.

The most common treatments for a person diagnosed with depression are medication and psychotherapy. There are approximately three dozen medications approved by FDA for managing depression. Commonly prescribed antidepressant medications include fluoxetine, sertraline, paroxetine, escitalopram, venlafaxine, desvenlafaxine and duloxetine. While these drugs are effective for many patients, approximately two-thirds of subjects do not achieve remission with a single medication, and approximately one-third of subjects did not achieve remission despite trying four medications. As such, there are large numbers of MDD patients for whom medication therapy is insufficient to alleviate their symptoms. Non-pharmacological approaches for depression include psychotherapy, physical activity and neurostimulation (interventions that deliver mild electrical or magnetic pulses to the brain) for severe, treatment-resistant depression.

Clinical evidence in MDD

Our development program in MDD utilizes the same SSME core mechanics and video game interface found in our EndeavorRx product, but is customized to appeal to an adult patient population.

Our proof of concept study in MDD was a multi-center, randomized, controlled trial of our SSME technology engine, utilizing the AKL-T03 variation of our treatment software, in 74 adult patients diagnosed with mild-to-moderate MDD symptoms and with mild-to-moderate cognitive impairment. All participants were on stable antidepressant medication. Participants were randomized 1:1 to AKL-T03 or a control game. Both groups used the treatment/control at home, five days per week for 25 minutes per day, on a tablet device for six weeks. Following the treatment period, an in-clinic assessment was conducted to assess key outcomes. The primary outcome of the study assessed sustained attention as measured by TOVA, an FDA-cleared objective measure of attention.



In the study, AKL-T03 showed a statistically significant improvement in sustained attention compared to control (p=0.002) on the predefined primary endpoint, as measured by the TOVA engagement with AKL-T03 also showed a strong correlation with improved processing speed. There were no serious adverse events observed for AKL-T03. Two (5.5%) of 37 patients using AKL-T03 reported an intervention-related adverse event (headache) Results of the study were published in *The American Journal of Psychiatry* in 2022.

Clinical development program and upcoming milestones in MDD

As noted previously with our updated strategic plan, this clinical program has been de-prioritized while we focus resources on the ADHD population. Further development of our pipeline outside of ADHD will be contingent upon a number of factors, including capital raising and supportive business development activities.

Multiple sclerosis ("MS")

Multiple sclerosis is an inflammatory neurologic disease in which the destruction of myelin inhibits communications between the nerves in the brain. MS frequently causes extreme fatigue, numbness, weakness, difficulty with eyesight, spasticity, speech problems, problems with coordination and problems with memory and concentration.

Cognitive symptoms in patients with MS are predictive of loss of employment, loss of quality of life, and affects all aspects of daily life.

Treatment of MS focuses on symptom management, treatment of attack, and reduction of disease progression. A number of immunosuppressive disease-modifying therapies have been approved that reduce the rate of disease progression, but they do not stop it. Therefore, MS treatment management includes symptomatic treatments as well as rehabilitative and psychological approaches such as physical therapy, speech therapy, occupational therapy and cognitive rehabilitation. There are no current treatments for MS that are specifically designed to address cognitive impairments.

Clinical evidence in MS

Our development program in MS leverages the SSME therapeutic engine and is focused on treating adult patients. We initially conducted a pilot study in 21 patients with UCSF. Participants completed an in-clinic baseline neurological evaluation and then used our investigational digital therapeutic in-home for 25 minutes daily, five days weekly, for four weeks. This was followed by

a repeat in-clinic evaluation. The study showed significant improvement in processing speed in patients who used our investigational digital therapeutic.

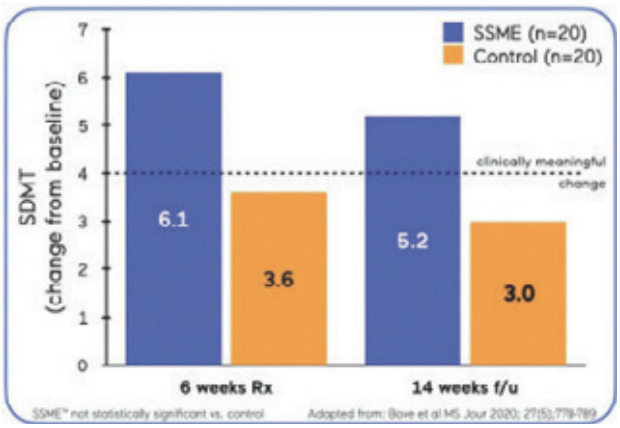
We then conducted a proof of concept study designed to assess our investigational digital therapeutic's ability to improve processing speed in adults with MS as compared to control. Recruitment for this study was between March and September 2018 for adults between the ages of 18-70 years old. The double-blind randomized controlled clinical trial enrolled 40 adults with MS and baseline Symbol Digit Modalities Test ("SDMT") *z*- scores between -2 and 0. After completing a baseline in-clinic evaluation (Visit 1), subjects were randomized to complete our in-home investigational digital therapeutic utilizing the AKL-T03 variation of our treatment software or a control word game for up to 25 minutes/day, five days/week, for six weeks. A repeat in-clinic evaluation occurred at six weeks (Visit 2), and again eight weeks later to determine persistence of effects (Visit 3). The primary endpoint was SDMT and the secondary endpoint was Paced auditory Serial Addition Test ("PASAT"). No power analysis was reported by the study investigators.

The pre-specified primary outcome was change in SDMT score between Visits 1 and 2. The study demonstrated clinically significant improvement in SDMT (>4) following six weeks of AKL-T03 use (vs. baseline). This clinically meaningful 4+ point increase in SDMT was maintained after a further eight weeks observation period. No adverse events were reported. The statistical analysis from the study showed:

- SDMT: No difference between group, p=0.21. Both the AKL-T03 and control groups showed statistically significant improvements, p<0.001 and p=0.024, respectively.
- At 8 weeks follow up, responders analysis (clinically meaningful +4 point increase in SDMT relative to baseline SDMT score) was statistically significant favoring AKL-T03, p=0.038.
- PASAT: No difference between group, p=0.93. Both the AKL-T03 and control groups showed statistically significant improvements, p=0.002 and p=0.07 (marginally significant), respectively.

Clinical development program and upcoming milestones in MS

As noted previously with our updated strategic plan, this clinical program has been de-prioritized while we focus resources on the ADHD population. Further development of our pipeline outside of ADHD will be contingent upon a number of factors, including capital raising and supportive business development activities.



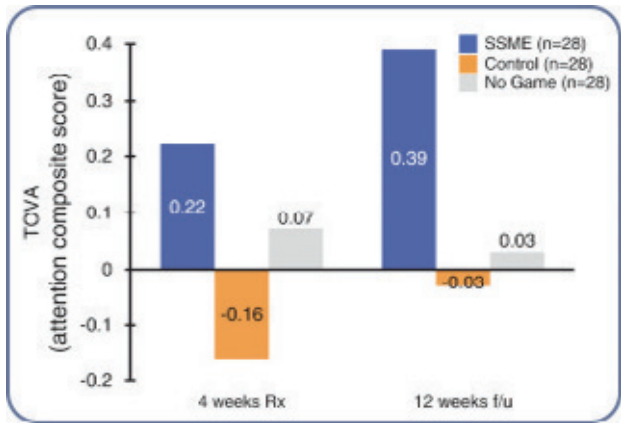
Acute cognitive dysfunction

Cognitive impairments can occur after acute insults to the brain due to trauma, infection, hypoxia, inflammation, medication, toxins, critical illness, cancer and more. Patients with acute cognitive dysfunction may experience issues related to attention, processing speed, multi-tasking, immediate recall and short- and long-term memory among other impairments.

These impairments can have a significant impact on individuals' daily functioning and quality of life. Cancer- related cognitive dysfunction ("CRCI") has a negative impact on survivors' ability to work, carry out routine activities, and engage in social and family relationships. And, in a recent study of COVID-19 survivors, for instance, "COVID fog" symptoms including cognitive impairment impacted their ability to work for six months or more.

Clinical evidence in acute cognitive function

Evaluating the ability of our SSME technology to improve impairments related to acute cognitive dysfunction, we conducted a pilot study between September 2015 and April 2019 of 84 patients with TBI, including 60 85-year-old veterans with a history of multiple mild TBIs, or at least one incident of moderate TBI, and related subjective cognitive complaints. The primary endpoint was attention as measured by TOVA API, RT, and RT variability. The secondary endpoints were working memory as measured by WAISS Letter number sequencing, and the symbol span, processing speed as measured by the WAISS symbol search, Trail Making Test A and the color naming, color reading response time, executive functioning as measured by Trail Making Test B, the color word inhibition test, and tower test, and memory as measured by HVLT-R learning, delayed recall and recognition.



The data from the study showed significant improvement in measures of attention (reaction time) and working memory, compared to controls.

This was a feasibility study and no specific power analysis was conducted. There was a statistically significant difference for attention, p=0.045. Only AKL-T01 showed significant improvement, p=0.006. Neither the control group (p=0.43) nor the no contact group (p=0.79) changed their attention performance. This improvement was maintained for 3 months post-intervention. There were no other changes on the other cognitive domains, all $p<0.05$. No adverse events were reported.

Pilot studies in COVID fog

There are currently no FDA-approved treatments for cognitive dysfunction following COVID-19 infection ("COVID fog") and research suggests that it can affect between 20-80% of COVID-19 survivors who had been hospitalized. We worked with research teams at Weill Cornell Medicine, NewYork-Presbyterian Hospital and Vanderbilt University Medical Center to conduct randomized, controlled clinical studies evaluating the ability of our investigational digital therapeutic to target and improve cognitive functioning in COVID-19 survivors who have exhibited a deficit in cognition.

The Akili, Weill Cornell Medicine and NewYork-Presbyterian Hospital randomized, controlled study was evaluating AKL-T01 in approximately 100 COVID-19 survivors ages 18-89 who have exhibited a deficit in cognition. The study took place over 10 weeks, with six weeks of treatment and four weeks of follow-up. Half of the study participants received the investigational digital treatment and half served as a control group. The primary endpoint of the study was mean change in cognitive function, as assessed by a measure of attention and processing speed. Secondary endpoints include additional measures of cognitive functioning. The study was conducted remotely in patients' homes, and patients in the control arm had the option to receive the AKL-T01 intervention after the conclusion of their participation in the control group.

The Akili and Vanderbilt randomized, controlled study evaluated AKL-T01 in approximately 100 COVID-19 survivors ages 18 and older who have exhibited a deficit in cognition. The study recruited subjects who had completed the SARS-CoV-2 Household Transmission Study. Half of the study participants received the investigational digital treatment for four weeks and half served as a control group. The primary endpoint of the study was mean change in cognitive function, as measured by CNS Vital Signs (composite score of cognitive function, especially attention and processing speed). Secondary endpoints included additional measures of cognitive functioning. The study was conducted remotely in patients' homes.

In August 2023, we reported that topline analysis had been completed on the Cornell and Vanderbilt trials evaluating EndeavorRx in adults with COVID fog. These independent proof-of-principle studies randomized eligible patients to receive either EndeavorRx or treatment as usual. We did not see statistical separation between the groups on the primary outcome measures, but we did observe compelling improvements in a number of secondary measures that assessed functional outcomes, such as fatigue, depression, anxiety and quality of life, as well as secondary measures of cognitive functioning specifically associated with attentional control. Across these functional and cognitive outcomes, we observed statistically significant changes from baseline to end of treatment in the group receiving EndeavorRx, and these changes were statistically significant or trending toward significance when compared to the control group. We are working with the study investigators to present the data at an upcoming scientific meeting and submit findings for publication.

Pilot study in post-operative patients

Working with Vanderbilt's Critical Illness, Brain Dysfunction and Survivorship (CIBS) Center, we are conducting a pilot study of AKL-T01 in older surgical patients. The ongoing COPE-iOS study will assess the efficacy of AKL-T01 in improving cognitive

outcomes in post-op patient populations by combining cognitive and physical training as part of interventions that occur before surgery and up to three months after hospital discharge.

The COPE-iOS controlled study will randomize approximately 250 patients 60 years and older undergoing elective major non-cardiac surgery to evaluate the efficacy of a comprehensive cognitive training program (digital cognitive intervention and supervised progressive multimodal physical exercise) in improving long-term cognitive outcomes as compared to an active control (control computer game, health information, stretching exercises) for two to four weeks prior to surgery and for three months after discharge. The primary endpoint of the five year study is the difference in global cognition between intervention and active control three and 12 months after discharge. Neuropsychological professionals blinded to treatment assignment and hospital course will assess global cognition at baseline and after discharge using the CNS Vital Signs neurocognitive battery. In addition, Vanderbilt will obtain blood to evaluate biomarkers of neuronal injury and will be performing brain MRI imaging at baseline and three months after discharge, providing a robust mechanistic aim of the study in addition to evaluation of cognition and physical function outcomes. This is a long term study and no results are expected before mid-to late 2024.

Pilot study in CRCI

We worked with UCSF to conduct a pilot study in patients with cancer-related cognitive dysfunction. The study plan included randomizing approximately 60 patients to evaluate the feasibility, safety and initial signals of efficacy of AKL-T01 as compared to control game. Half of the study participants received the investigational digital treatment for four weeks and half served as a control group. They used the treatment or control game for 25 minutes per day, five days a week for four weeks. Cognitive measures include TOVA and Adaptive Cognitive Evaluation ("ACE"), a mobile cognitive control assessment battery. This pilot study in CRCI is now closed and any additional updates will be based on investigator discretion.

Clinical development program and upcoming milestones in acute cognitive dysfunction

As noted previously with our updated strategic plan, this clinical program has been de-prioritized while we focus resources on the ADHD population. Further development of our pipeline outside of ADHD will be contingent upon a number of factors, including capital raising and supportive business development activities.

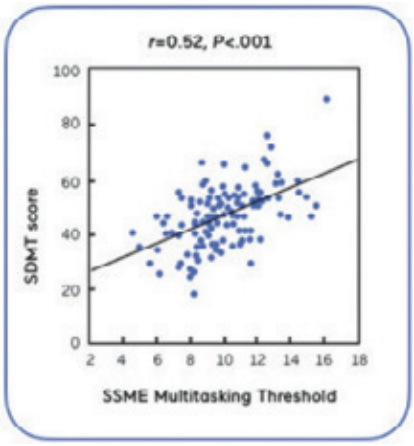
Cognitive Assessment

Cognition is often only assessed when there is a specific, subjective complaint from patients, family members or caregivers. There is no consistent clinical protocol for how to use cognitive assessment tools. Most cognitive assessments have not changed in decades, and many are still performed on pen and paper.

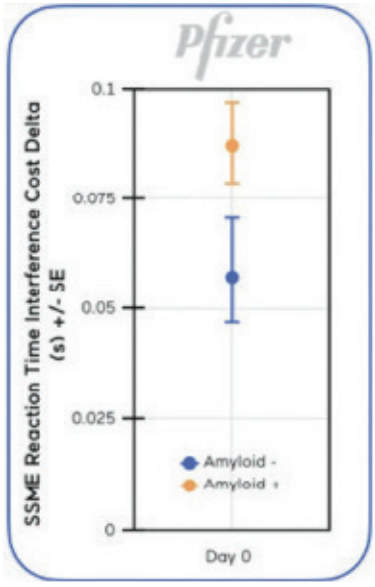
Clinical evidence in cognitive assessment

Our development program in this space leverages our SSME therapeutic engine, but with a focus on assessment as opposed to treatment.

A pilot study was conducted in 100 patients with MS, which showed positive correlation between our SSME technology and a recognized cognitive function measure, known as SDMT, in assessing cognition in MS (graph on left below).



We also conducted a pilot study in 54 healthy older adults in collaboration with Pfizer. The study showed the potential for SSME assessment to detect cognitive differences between amyloid positive and amyloid negative status, where amyloid is a protein biomarker associated with a higher risk of progression to dementia, in otherwise healthy individuals (graph on right).



Clinical development program and upcoming milestones in acute cognitive assessment

As noted previously with our updated strategic plan, this clinical program has been de-prioritized while we focus resources on the ADHD population. Further development of our pipeline outside of ADHD will be contingent upon a number of factors, including capital raising and supportive business development activities.

Additional technology engines

We have previously developed or licensed two additional technologies beyond SSME – SNAV and BBT. SNAV targets spatial navigation and episodic memory, and BBT targets attention, goal management and working memory. These technologies have potential to improve certain cognitive impairments associated with a number of medical conditions, including Alzheimer's and Mild Cognitive Impairment ("MCI").

Intellectual Property

We actively seek to obtain patent protection in the U.S. and other countries for inventions covering our products and technologies. We also license patents and technologies from third parties. Further, we rely on copyrights (including copyright registrations for software designs), trademarks and trade secrets relating to our proprietary algorithms or processes, in order to develop, strengthen and maintain our proprietary position in the digital therapeutics field.

We solely own or exclusively license twenty-one (21) utility patent families directed to software or methods related to cognition and/or digital therapeutics, including, as of February 23, 2024, fifty-five (55) patents allowed or granted worldwide (eighteen in the U.S., fifteen in Japan, three in Canada, two in Australia, eight in China/Hong Kong/Macau, six in South Korea, one in the European Union and two in Taiwan). Patent expiration dates noted below refer to earliest potential statutory expiration dates and do not take into account any potential patent term adjustments or extensions that may be available.

Exclusively licensed utility patent families include the following:

- An exclusive license from UCSF to a patent family directed to software and methods for enhancing cognition via a task performed in the presence of interferences (distractions and/or interrupters) (see "Agreements/Third Parties—UCSF NeuroRacer Agreement" below for a description of this exclusive license agreement). Three U.S. patents, six Japanese patents and one Canadian patent have been allowed in this family, the patents expiring as early as 2031 (Japan and Canada) and 2032 (U.S.). Additional applications are pending in this family in the U.S., Australia, Canada, Japan and Europe.

- An exclusive license from UCSF to a patent family directed to software and methods for enhancing cognition via a task with both a physical and cognitive component. Two Japanese patents have been allowed in this family, expiring as early as 2035. Additional applications are pending in this family in the U.S., Australia, Canada, Europe, Hong Kong and Japan.

Solely owned utility patent families include the following:

- A patent family directed to a personalized cognitive training regimen through difficulty progression. One U.S. patent, one Japanese patent, one Canadian patent, and one South Korean patent have been allowed in this family and will expire as early as 2035. Additional applications are pending in this family in Europe and Hong Kong.
- A patent family directed to processor-implemented systems and methods for measuring cognitive abilities. Two U.S. patents and one South Korean patent have been allowed in this family and will expire as early as 2036. Additional applications are pending in this family in the U.S. and Canada.
- A patent family directed to signal detection metrics in adaptive response-deadline procedures. One U.S. patent, one Japanese patent, one Chinese patent, one Macau patent and one South Korean patent have been allowed in this family and will expire as early as 2037. An additional application is pending in this family in Canada.
- A patent family directed to audio-only interference training for cognitive disorder screening and treatment. Two U.S. patents have been allowed in this family and will expire as early as 2039. Additional applications are pending in this family in China, Hong Kong, South Korea, Canada, Australia and Japan.
- A patent family directed to facial expression detection for screening and treatment of affective disorders. One U.S. patent has been allowed in this family and will expire as early as 2039.
- A patent family directed to a platform configured to render computerized emotional/affective elements for use as stimuli in computerized tasks. One South Korean patent, one Chinese patent, one Hong Kong patent and one Macau patent have been allowed in this family and will expire as early as 2037. An additional application is pending in this family in Japan.
- A patent family directed to a cognitive platform coupled with a physiological component. Two U.S. patents, one Japanese patent, one Australian patent, one Chinese patent and one South Korean patent have been allowed in this family and will expire as early as 2037. Additional applications are pending in this family in the U.S., Canada, Europe, Macau and Hong Kong.
- A patent family directed to a distributed network for the secured collection, analysis, and sharing of data across platforms. One Japanese patent and one Chinese patent have been allowed in this family and will expire as early as 2038. An additional application is pending in the U.S.
- A patent family directed to systems and methods for scientific evaluation of program code outputs. One U.S. patent has been allowed in this family and will expire as early as 2040. An additional application is pending in the U.S.
- A patent family directed to a cognitive platform including computerized elements. Two U.S. patents, one Canadian patent, one European patent, one Japanese patent, and one Chinese patent have been allowed in this family and will expire as early as 2038. Additional applications are pending in the U.S., Europe and Hong Kong.
- A patent family directed to a cognitive platform for identification of biomarkers and other types of markers. One U.S. patent, one Australian patent and one Japanese patent have been allowed in this family and will expire as early as 2037. Additional applications are pending in the U.S., Europe and Canada.
- A patent family directed to a platform for identification of biomarkers using navigation tasks and treatments using navigation tasks. One Japanese patent and one South Korean patent have been allowed in this family and will expire as early as 2037. Additional applications are pending in the U.S., Canada and Japan.
- A pending patent family directed to a cognitive platform for deriving effort metric for optimizing cognitive treatment, with applications pending in the U.S., Canada, Australia, South Korea, China and Hong Kong. If any patents are allowed in this family, they could expire as early as 2039.
- A pending patent family directed to systems and methods for software design control and quality assurance. One U.S. patent and one Taiwanese patent have been allowed in this family and will expire as early as 2040. Additional applications are pending in Australia, Canada, Europe, China, Hong Kong, Japan and South Korea.
- A pending patent family directed to a system and method for adaptive configuration of computerized cognitive training programs, with applications pending in the U.S. and Taiwan. If any patents are allowed in this family, they could expire as early as 2041.

- A patent family directed to a method for algorithmic rendering of graphical user interface elements. One U.S. patent and one Taiwanese patent have been allowed in this family and will expire as early as 2041. Additional applications are pending in the U.S. and pursuant to the International Patent Cooperation Treaty.
- A pending patent family directed to a method and system for determining equitable benefit in digital products and services, with an application pending in the U.S. If any patents are allowed in this family, they could expire as early as 2042.
- A pending patent family directed to cognitive screens, monitor and cognitive treatments targeting immune-mediated and neuro-degenerative disorders, with applications pending in the U.S., Canada, China, Hong Kong and South Korea. If any patents are allowed in this family, they could expire as early as 2039.
- A pending patent family directed to scaled analysis of performance data in digital health interventions, with a provisional application pending in the U.S. If any patents are allowed in this family, they could expire as early as 2044.

In addition to our utility patents, we own three families of design patents worldwide, relating to various former and/or current Company logos or designs for our software applications, including over 40 granted or allowed design patents as of February 23, 2024. One family of design patents is directed to a graphical user interface with an animated logo for a display screen, with one allowed patent in the U.S., which patents would expire as early as 2034. A second family of design patents is directed to an animated graphical user interface for a display screen, with allowed patents in the U.S., Australia, Canada, Europe, Japan, China and South Korea, which patents would expire as early as 2030. A third family of design patents is directed to a graphical user interface for a display screen, with allowed patents in the U.S., Australia, Canada, China, Europe, Japan and South Korea, which patents would expire as early as 2027. The foregoing design patent expiration dates assume all applicable renewals are paid when due.

Copyrights

In addition to our portfolio of utility and design patents, we hold copyright in our PDTs and companion software apps and pursue federal copyright registration where appropriate. We have registered copyrights with the U.S. Copyright Office in certain core designs and images in our PDTs and companion apps, and can additionally utilize international copyright protection such as the Berne Convention as applicable.

Trademarks

We also protect our trademarks and associated brand recognition by registering trademarks with the United States Patent and Trademark Office and foreign trademark offices.

While we consider these proprietary technology rights to be important to us, a range of factors help to mitigate the future effects of patent and license expiration on our results of operations and financial position. These factors include: publications, including peer-reviewed third-party studies, that demonstrate the efficacy of our products; our brand strength and reputation in the marketplace; our existing distribution platform and our customer support; the applicable regulatory authorization status for certain products; our continued investments in innovative product improvements that often result in new technologies and/or additional patents; our investment in innovations that results in new product offerings that often are patentable; and our significant know-how, scale and investments related to the clinical development and commercialization of associated product offerings.

Our commercial success may depend in part on our ability to: obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business; defend and enforce our patents, copyrights, trademarks and other proprietary rights; preserve the confidentiality of our trade secrets; and operate without infringing the valid, enforceable patents and other proprietary rights of third parties. Our ability to limit third parties from making, using, selling, offering to sell or importing our products may depend on the extent to which we have rights under valid and enforceable licenses, patents, copyrights or trade secrets that cover these activities. In some cases, enforcement of these rights may depend on third-party licensors or co-owners. With respect to both company-owned and licensed intellectual property, we cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our commercial products.

Agreements/Third Parties

Shionogi Collaboration Agreement

In March 2019, Shionogi & Co. Ltd. exercised its option to enter into an exclusive collaboration and license agreement (the "Shionogi Agreement") with us, pursuant to which we and Shionogi agreed to collaborate in the development and

commercialization of certain digital therapeutic products, including EndeavorRx and AKL-T02, variations of Akili's SSME technology, in the licensed field in Japan and Taiwan. Under the agreement, Shionogi is primarily responsible for the development and commercialization of such licensed products at its own cost and expense. Shionogi has agreed to use commercially reasonable efforts to obtain regulatory approval for certain licensed products, including EndeavorRx and AKL-T02, in each indication in the licensed field throughout Japan and Taiwan. The development and commercialization of the licensed products are overseen by a joint steering committee comprised of an equal number of representatives from each of us and Shionogi. We maintain control over the development and commercialization of the licensed products worldwide for all indications, and in Japan and Taiwan for all indications outside of Shionogi's licensed field. Additionally, we provide certain technical support services to Shionogi, and we have agreed to certain responsibilities with respect to licensed product development activities under the agreement.

Pursuant to the Shionogi Agreement, for a given licensed product, we have granted to Shionogi an exclusive license, with the right to grant sublicenses, under certain patent rights and know-how controlled by us (1) to clinically develop such licensed product anywhere in the world for the purposes of obtaining regulatory approval and commercializing such licensed product in the licensed field in Japan and Taiwan and (2) commercialize such licensed product in the licensed field in Japan and Taiwan.

To date, we have received an aggregate amount of approximately $25.4 million from Shionogi under the Shionogi Agreement, which includes an initial upfront fee payment of $10.0 million, an additional $10.0 million option exercise payment, proceeds from a $5.0 million corporate bond and $0.4 million to produce a control version of our software for the trials in Japan. In addition to what we have received from Shionogi to date, we are also entitled to receive up to a total of $110.0 million in total development and commercial milestones across all licensed products in the licensed territories. Additionally, we are entitled to royalties, in a range between 20-30%, on annual net sales of licensed products in the territory so long as Shionogi continues to sell the licensed products in such territory, subject to certain specified reductions. Shionogi will also help fund development costs in Japan and Taiwan.

In connection with Shionogi exercising its option to enter into the agreement, we issued a $5.0 million corporate bond to Shionogi for cash. The corporate bond is unsecured and is subordinated to our obligations under indebtedness for borrowed money owed by us to any bank or other financial institution.

Unless earlier terminated, the Shionogi Agreement will continue in effect until the expiration of all of Shionogi's payment obligations thereunder. Either party may terminate the agreement upon an uncured material breach of the agreement by the other party or upon the occurrence of certain events of insolvency of the other party. Additionally, Shionogi may terminate the agreement for any or no reason, in its entirety or on a licensed product-by-licensed product basis, upon specified written notice to us. Shionogi may also terminate the agreement on a licensed product-by-licensed product basis for safety reasons, certain clinical failures, or in the event that any third-party in-license entered into by us is terminated and cannot be reestablished within a specified period to allow Shionogi to continue exercising its rights under the agreement.

In the event that Shionogi has the right to terminate the Shionogi Agreement, in whole or with respect to a particular target, upon our uncured material breach, then in lieu of so terminating, Shionogi has the right to elect to the have the agreement continue in full force and effect; provided that Shionogi shall pay a reduced royalty. In the event that Shionogi terminates the agreement at will, or if we terminate for a breach or insolvency, we are entitled to certain reversionary rights with respect to the terminated licensed products.

In the event that we want to develop or commercialize certain digital therapeutic products (other than the licensed products) in Japan or Taiwan, we agreed to allow Shionogi a one-time first right of negotiation to expand the scope of the agreement to include such products.

UCSF NeuroRacer Agreement

On October 18, 2013, we entered into an exclusive license agreement with The Regents of the University of California (the "UCSF NeuroRacer Agreement"), which was amended on May 17, 2018, and February 25, 2019. Certain granted patent claims licensed under the agreement cover aspects and/or functionality of EndeavorRx and EndeavorOTC. Under the agreement, UCSF grants us an exclusive, worldwide, sublicensable license under UCSF's rights in certain patents and copyrights controlled by UCSF, to, in the case of the licensed patents, make, use, sell, offer for sale and import, and to reproduce, prepare derivative works, distribute, perform, and, in the case of the licensed copyrights, display, certain licensed products, services, software, and methods covered by such patents and copyrights. Under the agreement, UCSF retains the right to use the licensed technology for educational and research purposes, including sponsored research performed for or on behalf of commercial entities. Under this agreement, we have rights to three allowed U.S. patents, six allowed Japanese patents and one Canadian patent. These patents expire as early as 2031 (for the Japanese and Canadian patents) and 2032 (for the U.S. patents).

As consideration for entering into the UCSF NeuroRacer Agreement, we paid UCSF a license issue fee of $10,000. We also paid UCSF an aggregate license maintenance fee of $25,000 ($5,000 annually for five years up to the first sale of a licensed product).

Additionally, we are obligated to pay to UCSF up to a total of $1.1 million in total milestone payments for products covered by the license (including EndeavorRx and EndeavorOTC), including for certain patent-related, regulatory and commercial milestones. To date, we have paid UCSF a total of $185,000 in such milestone payments.

In addition, we are obligated to pay to UCSF certain mid-single digit percentage royalties on annual net sales of licensed products, methods, or services depending on if such products, methods, or services are clinically tested or not, subject to certain specified reductions. Royalties are payable to UCSF from the date of first commercial sale of a licensed product or licensed service on a country-by-country basis until the later of expiration or abandonment of the licensed patents or on the tenth anniversary of the first commercial sale of each such licensed product or licensed service in such country. To date , we have paid to UCSF a total of $491,877 in such royalty payments. In total, we have paid UCSF $711,877 under the UCSF NeuroRacer Agreement for the above-referenced license issue fee, aggregate license maintenance fee, milestone payments to date, and royalty payments to date.

We are also obligated to pay UCSF certain tiered payments upon a change of control transaction (as defined in the agreement), up to a maximum of $2.5 million in such payments, depending on the total amount of payments to shareholders resulting from such transaction.

We must also pay to UCSF a tiered, low- to mid-double-digit percentage of any sublicensee revenue (as defined in the agreement), depending on the regulatory status of the licensed product applicable to such sublicense agreement. To date, we have not made any payments to UCSF in sublicensee revenue.

The UCSF NeuroRacer Agreement will remain in effect until the later of (i) expiration or abandonment of the last of the licensed patents or (ii) expiration of the licensed copyrights in all countries. UCSF may terminate the agreement upon an uncured breach of the agreement by us and the agreement will automatically terminate upon our insolvency. Additionally, we may terminate the agreement for any or no reason, in its entirety, or terminate our rights under the licensed patents on a country-by-country basis, upon specified written notice to UCSF.

TALi Agreement

In August 2021, we entered into a license agreement with TALi Digital Limited (the "TALi Agreement") pursuant to which we licensed TALi's technology designed to address early childhood attention impairments. On October 16, 2023, we mutually agreed with TALi to terminate such license agreement, with such termination effective as of October 16, 2023. As a result, we do not have plans at present to pursue additional clinical or regulatory efforts in children under 8 years old with ADHD. To date, we paid $0.1 million to TALi pursuant to the TALi Agreement.

Government Regulation

Coverage and Reimbursement

Sales of any product depend, in part, on the extent to which such product will be covered by third-party payers, such as federal, state and foreign government healthcare programs, commercial insurance and managed healthcare organizations and the level of reimbursement for such product by third-party payers. Decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. These third-party payers are increasingly reducing reimbursements for medical products, drugs and services.

In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on coverage and reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit sales of any product.

While coverage and reimbursement are no longer a focus area for our business strategy, decreases in third-party reimbursement for any product or a decision by a third-party payer not to cover a product could reduce health care provider usage and user demand for the product and also have a material adverse effect on sales.

Health Care Laws and Regulations

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payers, patient organizations and customers, may be subject to broadly applicable healthcare laws and regulations, including fraud and abuse laws. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if authorized. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or

indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- federal civil and criminal false claims laws, including the False Claims Act ("FCA"), which can be enforced through civil "qui tam" or "whistleblower" actions and civil monetary penalty laws, impose criminal and civil penalties against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other federal health care programs that are false or fraudulent; knowingly making or causing a false statement material to a false or fraudulent claim or an obligation to pay money to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing such an obligation. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payers if they are deemed to "cause" the submission of false or fraudulent claims. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in the proceeds of any monetary recovery;

- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payer (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating these statutes without actual knowledge of the statutes or specific intent to violate them in order to have committed a violation;

- the federal Physician Payment Sunshine Act, created under the ACA and its implementing regulations, which require manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the US Department of Health and Human Services ("HHS") information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other licensed health care practitioners and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and

- analogous state and foreign laws and regulations, such as state and foreign anti-kickback, false claims, consumer protection and unfair competition laws which may apply to pharmaceutical business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving healthcare items or services reimbursed by any third-party payer, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to healthcare providers and other potential referral sources; state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to healthcare professionals and entities; and state and local laws requiring the registration of pharmaceutical sales representatives.

In the U.S., to help patients afford our authorized product, we may utilize programs to assist them, including patient assistance programs and co-pay coupon programs for eligible patients. Government enforcement agencies have shown increased interest in pharmaceutical companies' product and patient assistance programs, including reimbursement support services, and a number of investigations into these programs have resulted in significant civil and criminal settlements. In addition, at least one insurer has directed its network pharmacies to no longer accept co-pay coupons for certain specialty drugs the insurer identified. Our co-pay coupon programs could become the target of similar insurer actions. In November 2013, the CMS issued guidance to the issuers of qualified health plans sold through the ACA's marketplaces encouraging such plans to reject patient cost-sharing support from third parties and indicating that the CMS intends to monitor the provision of such support and may take regulatory action to limit it in the future. The CMS subsequently issued a rule requiring individual market qualified health plans to accept third-party premium and cost-sharing payments from certain government-related entities. In September 2014, the OIG of the HHS issued a Special Advisory Bulletin warning manufacturers that they may be subject to sanctions under the federal anti-kickback statute

and/or civil monetary penalty laws if they do not take appropriate steps to exclude Part D beneficiaries from using co-pay coupons. Accordingly, companies exclude these Part D beneficiaries from using co-pay coupons. It is possible that changes in insurer policies regarding co-pay coupons and/or the introduction and enactment of new legislation or regulatory action could restrict or otherwise negatively affect these patient support programs, which could result in fewer patients using affected products, and therefore could have a material adverse effect on our sales, business, and financial condition.

Third party patient assistance programs that receive financial support from companies have become the subject of enhanced government and regulatory scrutiny. The OIG has established guidelines that suggest that it is lawful for pharmaceutical manufacturers to make donations to charitable organizations who provide co-pay assistance to Medicare patients, provided that such organizations, among other things, are bona fide charities, are entirely independent of and not controlled by the manufacturer, provide aid to applicants on a first-come basis according to consistent financial criteria and do not link aid to use of a donor's product. However, donations to patient assistance programs have received some negative publicity and have been the subject of multiple government enforcement actions, related to allegations regarding their use to promote branded pharmaceutical products over other less costly alternatives. Specifically, in recent years, there have been multiple settlements resulting out of government claims challenging the legality of their patient assistance programs under a variety of federal and state laws.

Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the current U.S. presidential administration may reverse or otherwise change these measures, both the current U.S. presidential administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

Healthcare Reform

In 2010, the ACA was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly affected the pharmaceutical industry. The ACA contained a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement adjustments and changes to fraud and abuse laws. For example, the ACA:

- increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1% of the average manufacturer price;
- required collection of rebates for drugs paid by Medicaid managed care organizations; and
- imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell “branded prescription drugs” to specified federal government programs.

Other legislative changes have been proposed and adopted in the U.S. since the ACA was enacted. The Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, which remain in effect through 2031.

There has been increasing legislative and enforcement interest in the U.S. with respect to specialty drug 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.

President Biden has issued multiple executive orders that have sought to reduce prescription drug costs. In February 2023, HHS also issued a proposal in response to an October 2022 executive order from President Biden that includes a proposed prescription drug pricing model that will test whether targeted Medicare payment adjustments will sufficiently incentivize manufacturers to complete confirmatory trials for drugs approved through FDA’s accelerated approval pathway. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

In addition, other legislative and regulatory changes have been proposed and adopted in the U.S. since the ACA was enacted:

- The U.S. American Taxpayer Relief Act of 2012 further reduced Medicare payments to several types of providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.
- On April 13, 2017, CMS published a final rule that gives states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.

- On May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.
- On May 23, 2019, CMS published a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020.

These laws and regulations may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory authorization or frequency with which any such product candidate is prescribed or used.

The Inflation Reduction Act of 2022 ("IRA") includes several provisions that may impact our business to varying degrees, including provisions that reduce the out-of-pocket cap for Medicare Part D beneficiaries to $2,000 starting in 2025; impose new manufacturer financial liability on certain drugs under Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition, require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation, and delay the rebate rule that would limit the fees that pharmacy benefit managers can charge. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one orphan designation and for which the only approved indication is for that disease or condition. If a product receives multiple orphan designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. The effects of the IRA on our business and the healthcare industry in general is not yet known.

Individual states have also been increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once authorized, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, particularly in light of the new presidential administration, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Data Privacy and Security Laws

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 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, restrict 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 U.S. Federal Trade Commission 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 or other personal 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.

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 that 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 California Consumer Privacy Act (the "CCPA"), as amended by the California Privacy Rights Act (the "CPRA"), which went into effect on January 1, 2023. The amendments to the CCPA introduced by the CPRA created additional obligations with respect to processing and storing personal information and established a new state agency that is vested with authority to implement and enforce the CCPA. Additionally, some observers have noted that the CCPA and CPRA could mark the beginning of a trend toward more stringent privacy legislation in the U.S., which could increase our potential liability and adversely affect our business. Already, in the U.S., we have witnessed significant developments at the state level. In addition to the CCPA, new privacy and data security laws have been enacted in numerous other states and have been proposed in even more states as well as in the U.S.

Congress, reflecting a trend toward more stringent privacy legislation in the U.S., which may accelerate. If enacted, such proposed legislation 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. 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.

Furthermore, other states have proposed or enacted legislation that is focused on more narrow aspects of privacy. For example, a number of states have passed laws that protect biometric information and a smaller number of states have passed or are considering laws that are specifically focused upon health privacy, such as Washington's My Health My Data Act. The effects of state and federal privacy laws are potentially significant and may require us to modify our data processing practices and policies and to incur substantial costs and potential liability in an effort to comply with such legislation.

Our international operations are subject to international laws and regulations, regulatory guidance, and industry standards relating to data protection, privacy, and information security. For our EU and UK future operations, this includes the EU General Data Protection Regulation (the "GDPR") as well as other national data protection legislation in force in relevant EU member states (including the GDPR in such form as incorporated into the law of England and Wales, Scotland and Northern Ireland by virtue of the European Union (Withdrawal) Act 2018 and any regulations thereunder and the UK Data Protection Act 2018 (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 significant changes from the 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, the European Commission ("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 the EU 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 the US, certain laws such as Washington's My Health My Data Law and Illinois' Biometric Information Privacy Act also have a private right of action.

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 them 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.

U.S. Medical Device Regulations

General Requirements

Our products and product candidates are medical devices subject to extensive and ongoing regulation by the FDA under the Federal Food, Drug, and Cosmetic Act (the "FDCA") and its implementing regulations, as well as other federal and state regulatory bodies in the U.S. and comparable authorities in other countries under other statutes and regulations. These laws and regulations govern, among other things, product design and development, preclinical and clinical testing, manufacturing, packaging, labeling, storage, recordkeeping and reporting, clearance or approval, marketing, distribution, promotion, import and export and post-marketing surveillance. Failure to comply with applicable requirements may subject a device and/or its manufacturer to a variety of administrative sanctions, such as issuance of warning letters, import detentions, civil monetary penalties and/or judicial sanctions, such as product seizures, injunctions and criminal prosecution.

In the U.S., medical devices considered to be moderate to high risk by FDA generally require premarket review and marketing authorization from the FDA prior to commercial distribution. The primary types of FDA marketing authorization applicable to a medical device are clearance of a premarket notification (also called 510(k) clearance), approval of a premarket approval application ("PMA"), or grant of a de novo request for classification, or de novo grant. Each 510(k), PMA, or de novo request must be accompanied by a user fee, although the fee may be waived under certain circumstances.

Each product candidate we seek to commercially distribute in the U.S. will require either a prior de novo classification grant, 510(k) clearance, unless it is exempt, or a PMA from the FDA under its medical device authorities.

510(k) Clearance Process

Under the FDCA, medical devices are classified into one of three classes – Class I, Class II or Class III – depending on the degree of risk associated with the device and the level of control necessary to provide reasonable assurance of safety and effectiveness.

Class I devices are those for which safety and effectiveness can be reasonably assured by adherence to a set of regulations referred to as General Controls, which require compliance with the applicable portions of FDA's Quality System Regulation ("QSR"), facility registration and device listing, reporting of adverse events and malfunctions, which is referred to as medical device reporting, and appropriate, truthful and non-misleading labeling and promotional materials. Most Class I devices are exempt from the premarket notification requirements.

Class II devices are those that are subject to General Controls, as well as Special Controls, which can include performance standards, specialized labeling and post-market surveillance. Most Class II devices are subject to the premarket notification requirements.

To obtain 510(k) clearance, a manufacturer must submit a premarket notification, or 510(k), to the FDA and demonstrate to the FDA's satisfaction that the proposed device is "substantially equivalent" to a previously 510(k)-cleared device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of a PMA. The previously cleared device is known as a predicate device. A proposed device is substantially equivalent if, with respect to the predicate device, it has the same intended use and has either (i) the same technological characteristics or (ii) different technological characteristics and does not raise different questions of safety and effectiveness, and the information submitted to the FDA that the device is substantially equivalent to the predicate device contains information that demonstrates that the proposed device is as safe and effective as a legally marketed device.

Before the FDA will accept a 510(k) for substantive review, the FDA will first assess whether the submission satisfies a minimum threshold of acceptability to ensure that the 510(k) is administratively complete. The acceptance review, which occurs prior to the substantive review, is generally conducted and completed within 15 calendar days of the FDA receiving the 510(k). If the FDA

determines that the 510(k) is incomplete, the FDA will issue a "Refuse to Accept" letter which generally outlines the information the FDA believes is necessary to permit a substantive review and to reach a determination regarding substantial equivalence. The 510(k) submitter must submit the requested information within 180 days before the FDA will proceed with additional review of the submission. As specified in FDA's Medical Device User Fee Amendments of 2022 ("MDUFA V") commitment letter, which defines performance goals for the FDA for fiscal years 2023 through 2027, the FDA aims to review and issue a determination on most 510(k)s within 90 FDA Days, although clearance often takes longer in practice. "FDA Days" are those calendar days when a submission is considered to be under review at the FDA for submissions that have been accepted or filed, as applicable. The FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence.

If the FDA determines that the device is "not substantially equivalent" to a previously cleared device, for example, due to a finding of a lack of a predicate device, or that the proposed device has a new intended use or different technological characteristic that raise different questions of safety or effectiveness when the proposed device is compared to the cited predicate device, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements, or can request a risk-based classification determination for the device in accordance with the de novo process.

Alternatively, if the FDA determines that the information provided in a 510(k) is insufficient to demonstrate substantial equivalence to the predicate device, the FDA generally identifies the specific information that is needed so that the FDA may complete its evaluation of substantial equivalence, and such information may be provided by the 510(k) sponsor within the time allotted by the FDA or in a new 510(k) should the original 510(k) be withdrawn.

If the FDA agrees that the proposed device is substantially equivalent to a predicate device currently on the market, it will grant 510(k) clearance to commercially market the device. After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, will require a new 510(k) clearance, or depending on the modification, PMA approval. The determination as to whether or not a modification could significantly affect the device's safety or effectiveness is initially left to the manufacturer. Many minor modifications are accomplished by a "letter to file" in which the manufacturer documents the rationale for the change and why a new 510(k) is not required. However, the FDA may review such letters to file to evaluate the regulatory status of the modified device at any time and may require the manufacturer to cease marketing and recall the modified device until 510(k) clearance or PMA approval is obtained. The manufacturer may also be subject to significant regulatory fines or penalties for marketing a modified device without the requisite 510(k) clearance or PMA approval.

De Novo Classification Process

For novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device, a manufacturer may request a risk-based classification determination, called a "Request for Evaluation of Automatic Class III Designation," for the device in accordance with de novo classification process. This procedure allows a de novo requester whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA. A requestor may submit a de novo request for classification after receiving a "not substantially equivalent" determination in response to a 510(k) submission. Alternatively, a requestor may submit a de novo request absent the submission of a 510(k) when the sponsor determines that there is no legally marketed device upon which to base a determination of substantial equivalence. Under the FDCA, FDA must make a classification determination for the device that is the subject of a de novo request within 120 days of receipt of the request. However, as specified in FDA's MDUFA V commitment letter, the FDA's goal is to make a decision on most de novo requests within 150 FDA Days, although in practice the FDA's review may take significantly longer. During the pendency of FDA's review, the FDA may issue an additional information letter, which places the de novo request on hold and stops the review clock pending receipt of the additional information requested. In the event the de novo requestor does not provide the requested information within 180 calendar days, the FDA will consider the de novo request to be withdrawn.

The FDA may reject the de novo request if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low to moderate risk or that General Controls would be inadequate to control the risks and Special Controls cannot be developed. In the event the FDA determines that the data and information submitted demonstrate that General Controls or General and Special Controls are adequate to provide reasonable assurance of safety and effectiveness, the FDA will grant the de novo request and a classification regulation will be established for the device type. When the FDA grants a de novo request for classification, the device is granted marketing authorization and can further serve as a predicate device for a future 510(k) by any person for future devices of that type.

PMA Process

Class III devices include devices deemed by FDA to pose the greatest risk, such as life-supporting or life- sustaining devices, or implantable devices, in addition to those deemed not substantially equivalent following the 510(k) process. The safety and effectiveness of Class III devices cannot be reasonably assured solely by the General Controls and Special Controls described

above. With few exceptions for certain types of devices classified into Class III that were in commercial distribution in the U.S. before May 28, 1976, Class III devices are subject to the PMA process, which is generally more costly and time consuming than the 510(k) process. The PMA process requires proof of safety and effectiveness of the device to the FDA's satisfaction.

After a PMA is submitted, the FDA has 45 days to determine whether the application is sufficiently complete to permit a substantive review and thus whether the FDA will file the application for review. Under the FDCA, the FDA has 180 days to review a filed PMA, although the review of an application generally occurs over a significantly longer period of time and can take up to several years. During this review period, the FDA may request additional information or clarification of the information already provided. Also, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. Although the FDA is not bound by the advisory panel decision, the panel's recommendations are important to the FDA's overall decision making process. In addition, the FDA may conduct a preapproval inspection of the manufacturing facility to ensure compliance with QSR requirements. The agency also may inspect one or more clinical sites to assure compliance with FDA's regulations.

Upon completion of the PMA review, the FDA may: (i) approve the PMA which authorizes commercial marketing with specific prescribing information for one or more indications, which can be more limited than those originally sought; (ii) issue an approvable letter which indicates the FDA's belief that the PMA is approvable and states what additional information the FDA requires, or the post-approval commitments that must be agreed to prior to approval; (iii) issue a not approvable letter which outlines steps required for approval, but which are typically more onerous than those in an approvable letter, and may require additional clinical trials that are often expensive and time consuming and can delay approval for months or even years; or (iv) deny the application. If the FDA issues an approvable or not approvable letter, the applicant has 180 days to respond, after which the FDA's review clock is reset.

Approval by the FDA of original PMAs or PMA supplements may be required for modifications to the manufacturing process, labeling, device specifications, materials or design of a device that is approved through the PMA process. PMA supplements often require submission of the same type of information as an original PMA, except that the supplement is limited to information needed to support any changes from the device covered by the approved PMA and may or may not require as extensive clinical data or the convening of an advisory panel.

Exempt Devices

If a manufacturer's device falls into a generic category of Class I or Class II devices that FDA has exempted by regulation, a premarket notification is not required before marketing the device in the U.S. Manufacturers of such devices are required to comply with FDA's General Controls, including FDA's establishment registration and device listing requirements. Some 510(k)-exempt devices are also exempt from QSR requirements, except for the QSR's complaint handling and recordkeeping requirements.

Clinical Trials

Clinical trials are almost always required to support a PMA or de novo request and are sometimes required for a 510(k). For significant risk devices, the FDA regulations require submission of an application for an investigational device exemption ("IDE") to the FDA prior to commencement of a human clinical investigation. A nonsignificant risk device does not require the submission of an IDE application; however, the clinical trial must still be conducted in compliance with certain requirements of FDA's IDE regulations. An IDE application is considered approved 30 calendar days after it has been received by the FDA, unless the FDA informs the sponsor prior to the 30 days that the IDE is approved, approved with conditions, or disapproved.

An IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE application must also include a description of product manufacturing and controls, and a proposed clinical trial protocol. The FDA typically grants IDE approval for a specified number of patients to be treated at specific study centers. The FDA's approval of an IDE allows clinical testing to go forward but does not bind the FDA to accept the results of the trial as sufficient to prove the device's safety and efficacy, even if the trial meets its intended success criteria.

During the study, the sponsor must comply with the FDA's IDE requirements for investigator selection, trial monitoring, reporting and recordkeeping. The investigators must rigorously follow the investigational plan and study protocol, control the disposition of investigational devices, and comply with all reporting and recordkeeping requirements. These IDE requirements apply to all investigational devices, whether considered a significant or nonsignificant risk.

Clinical trials must further comply with the FDA's regulations for approval by an institutional review board (IRB) and for informed consent and other human subject protections. The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial subjects. An IRB may also require the clinical trial at

the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Information about certain clinical trials must be submitted within specific timeframes for public dissemination on the ClinicalTrials.gov website. Required records and reports are subject to inspection by the FDA. The results of clinical testing may be unfavorable or, even if the intended safety and efficacy success criteria are achieved, may not be considered sufficient for the FDA to grant clearance or approval of a device.

Post-Market Regulation

After a device is placed on the market, numerous regulatory requirements apply. These include:

- establishment registration and device listing;
- compliance with FDA's QSR requirements;
- labeling regulations;
- medical device reporting regulations, which, for example, require that manufacturers report to the FDA if a device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur;
- voluntary and mandatory device recalls to address problems when a device is defective and/or could be a risk to health; and
- corrections and removal reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health.

Also, the FDA may require manufacturers of certain devices to conduct post-market surveillance studies or order such manufacturers to establish and maintain a system for tracking their devices through the chain of distribution to the patient level. The FDA enforces regulatory requirements, such as those set forth in the QSR, by conducting periodic, unannounced inspections and market surveillance.

Failure to comply with applicable regulatory requirements, including those applicable to the conduct of clinical trials, can result in enforcement action by the FDA, which may lead to any of the following sanctions:

- warning letters or untitled letters that require corrective action;
- fines, injunctions and civil penalties;
- recall or seizure of products;
- operating restrictions, partial suspension or total shutdown of production;
- withdrawing PMA approvals already granted; and
- criminal prosecution.

Labeling and promotional activities are subject to scrutiny by FDA and, in certain circumstances, by the Federal Trade Commission. Medical devices approved or cleared by FDA may not be promoted for unapproved or uncleared uses, otherwise known as "off-label" promotion. FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including substantial monetary penalties and criminal prosecution.

FCPA and Other Anti-Bribery and Anti-Corruption Laws

The U.S. Foreign Corrupt Practices Act (the "FCPA") prohibits U.S. corporations and their representatives from offering, promising, authorizing or making payments of anything of value to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business abroad or to otherwise influence a person working in an official capacity. The scope of the FCPA would include interactions with certain health care professionals in many countries. We maintain a compliance program designed to comply with the FCPA and anti-bribery laws and regulations applicable to our business. Our present and future business has been and will continue to be subject to various other U.S. and foreign laws, rules and/or regulations.

International Regulation

International sales of medical devices are subject to foreign government regulations, which may vary substantially from country to country. The time required to obtain approval in a foreign country may be longer or shorter than that required for FDA approval or clearance, and the requirements may differ. There is a trend towards harmonization of quality system standards among the European Union, U.S., Canada and various other industrialized countries.

The primary regulatory body in Europe is that of the European Union, which includes most of the major countries in Europe. Other countries, such as Switzerland, have voluntarily adopted laws and regulations that mirror those of the European Union with respect to medical devices. The European Union has adopted numerous directives and standards regulating the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices. Devices that comply with the requirements of a relevant directive will be entitled to bear the CE conformity marking, indicating that the device conforms to the essential requirements of the applicable directives and, accordingly, can be commercially distributed throughout Europe. The method of assessing conformity varies depending on the class of the product, but normally involves a combination of self-assessment by the manufacturer and a third-party assessment by a "Notified Body." This third-party assessment may consist of an audit of the manufacturer's quality system and specific testing of the manufacturer's product. An assessment by a Notified Body of one country within the European Union is required in order for a manufacturer to commercially distribute the product throughout the European Union. Outside of the European Union, regulatory approval needs to be sought on a country-by-country basis in order for us to market our products. The European Union regulatory bodies finalized a new Medical Device Regulation ("MDR") in 2017, which replaced the existing Directives on May 26, 2021 and provided three years for transition and compliance. However, in response to concerns raised about Notified Body capacity and the ability for devices to be re-certified within such time period, the EC has adopted a proposal to extend the transition period by some years, depending on the risk class of the device. Such proposal is currently being considered for adoption by the European Parliament and Council. The MDR has changed several aspects of the regulatory framework for medical devices.

Outside the U.S. a range of anti-bribery and anti-corruption laws, as well as some industry-specific laws and codes of conduct, apply to the medical device industry and interactions with government officials and entities and health care professionals. Further, the EU member countries have emphasized a greater focus on healthcare fraud and abuse and have indicated greater attention to the industry by the European Anti-Fraud Office. MedTech Europe, the medical device industry association, also introduced the Code of Ethical Business Practices, which came into effect on January 1, 2017. Countries in Asia have also become more active in their enforcement of anti-bribery laws and with respect to procurement and supply chain fraud.

Employees and Human Capital

At Akili, we are passionate about bringing together elements of science, technology and entertainment, along with a great user experience, to change how medicine is designed and delivered. We represent a combination of backgrounds and skills that are not typically found together in a single company, bringing talent together from various industries including biotech, medical device, entertainment and engineering. Aligning such a diverse group around this lofty goal requires a unique culture—one that is inclusive, bold and creative.

In response in part to the economic environment and our strategic plan to transition from a prescription to a non-prescription business model, we took decisive action to become a more capital-efficient company and made the difficult decisions to announce workforce reductions of approximately 30% of our employees in January 2023 and 40% of our employees in September 2023. The cost reduction efforts related to these announcements included efficiency focused efforts such as scaling back budgets and operating expenses, restructuring teams, reprioritizing our clinical pipeline and efforts to align our business with a new strategic plan to transition our business to a non-prescription model and to increase efficiency – and a necessary but difficult part of this was parting ways with colleagues and friends. We made it a priority to treat outgoing employees with respect and announced a severance package for these employees that included severance payments of at least two months' salary. The severance package also extended exercise deadlines for vested stock options and helped pay for any elected COBRA healthcare benefits during the length of severance.

As of February 1, 2024 we had 68 full-time employees, of which nine have M.D., D.Phil. or Ph.D. degrees. Of our full-time employees, 37 were engaged in research and development activities and 31 were engaged in commercial activities, business development, finance and general management and administration. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, motivating and integrating our existing and future employees. The principal purposes of our equity incentive plans are to attract, retain and reward high performing employees, consultants and directors through grants of stock-based compensation awards and payments of cash-based performance bonus awards, in order to increase stockholder value and the success of our company by motivating our employees to perform to the best of their abilities and achieve our objectives.

Available Information

We maintain an internet website at https://www.akiliinteractive.com/ and make available free of charge through our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, including exhibits and amendments to those reports filed or furnished pursuant to Sections 13(a) and 15(d) of the Exchange Act of 1934 (the "Exchange Act"). We make these reports available through our website as soon as reasonably practicable after we electronically file such reports with, or furnish such reports to, the SEC. You can review our electronically filed reports and other information that we file with the SEC on the SEC's web site at http://www.sec.gov. We also make available, free of charge on our website, the reports filed with the SEC by our executive officers, directors and 10% stockholders pursuant to Section 16 under the Exchange Act as soon as reasonably practicable after copies of those filings are provided to us by those persons. In addition, we regularly use our website to post information regarding our business, product development programs and governance, and we encourage investors to use our website, particularly the information in the section entitled "Investors," as a source of information about us.

The information on our website is not incorporated by reference into this Annual Report on Form 10-K and should not be considered to be a part of this Annual Report on Form 10-K. Our website address is included in this Annual Report on Form 10-K as an inactive technical reference only.

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 Annual 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 Annual 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 our Business and Industry

We are a technology company with a limited operating history that is focused on the delivery of digital therapeutics. We announced a strategic plan to transition from a prescription to a non-prescription business model and are pursuing regulatory authorization for over-the-counter labeling of our products. We have a history of significant losses, anticipate that expenses may increase in the future, 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. We have generated limited revenue from product sales, and we do not expect to generate significant revenue from product sales in the foreseeable future.

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. 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. 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 $59.5 million and $8.0 million for the years ended December 31, 2023 and 2022 respectively, and we had an accumulated deficit of $299.8 million as of December 31, 2023. Our net cash used in operating activities was $57.9 million and $83.5 million for the years

ended December 31, 2023 and 2022, 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 managing and executing our strategic plan to transition from a prescription to a non-prescription model, including obtaining regulatory authorization and commercializing EndeavorOTC in adults with ADHD, pursuing regulatory authorization for over-the-counter labeling of both our EndeavorRx and EndeavorOTC products and continuing to support the distribution and fulfillment of EndeavorRx during the transition. Further development of our programs outside of ADHD will be contingent upon a number of factors, including capital raising and supportive business development activities. We expect to continue to incur significant marketing-related expenses as we commercialize EndeavorOTC. We will also continue to incur costs associated with operating as a public company. 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. 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 execute on our commercial strategy, including direct-to-consumer marketing efforts to drive customer acquisition and promote customer advocacy and ambassadorship;
- 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 heavily on whether we can successfully commercialize our products.

Our overall success will rely heavily on the commercial success of EndeavorOTC and EndeavorRx. Failure to successfully commercialize our products would likely cause our business to fail. While we believe we have seen positive results thus far from the release of Endeavor OTC, 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 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. 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 engaged and intend to continue to engage through those platforms 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 strategy to grow our revenue is to focus our efforts primarily on managing and executing our strategic plan to transition from a prescription to a non-prescription model, including obtaining regulatory authorization and commercializing EndeavorOTC in adults with ADHD, pursuing regulatory authorization for over-the-counter labeling of both our EndeavorRx and EndeavorOTC products and continuing to support the distribution and fulfillment of EndeavorRx during the transition. If we are not successful in demonstrating the benefits of our products or do not achieve the support of customers and the medical community, our sales may decline, or we may fail to increase our revenue. 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;
- lack of success in any of our marketing strategies;
- 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.

As we transition from a prescription to a non-prescription model, we expect to focus our sales and marketing efforts primarily on trying to grow awareness and adoption of EndeavorOTC. However, 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. 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.

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. Our future financial performance will depend 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. In addition, in connection with our September 2023 announced change in business strategy and related ongoing testing of pricing, marketing and distribution strategies, we are unable to confirm our prior potential revenue estimates of the opportunity across ADHD as the assumptions underlying these estimates have changed.

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 primarily 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 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, MDD 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 capital raising and supportive business development activities. We are currently focused primarily on managing and executing our strategic plan to transition from a prescription to a non-prescription model, including obtaining regulatory authorization and commercializing EndeavorOTC in adults with ADHD, pursuing regulatory authorization for over-the-counter labeling of both our EndeavorRx and EndeavorOTC products and continuing to support the distribution and fulfillment of EndeavorRx during the transition. There can be no assurance that we have prioritized optimally, that our non-prescription model 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. 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. From time to time, there may be changes in our executive management team resulting from the hiring or departure of executives, 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 growth 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 and September 2023, we introduced cost reduction efforts, including a reduction 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, 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. And 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. We had 68 full-time employees as of December 31, 2023.

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, 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 and September 13, 2023, 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 our 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. 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 managing and executing our strategic plan to transition from a prescription to a non-prescription model, including obtaining regulatory authorization and commercializing EndeavorOTC in adults with ADHD, pursuing regulatory authorization for over-the-counter labeling of both our EndeavorRx and EndeavorOTC products and continuing to support the distribution and fulfillment of EndeavorRx during the transition, 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 capital raising and supportive business development activities. 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 substantial 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, which is currently undergoing technical review by 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. 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 and customers 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 this Annual Report on Form 10-K.

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 this Annual Report on Form 10-K.

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 Quality System Regulation ("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 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. 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 this Annual Report on Form 10-K.

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, direct market our products and make investments in our human capital in order to scale up our business. While further development of Akili's programs outside of the ADHD space will be contingent upon a number of factors, including capital raising and supportive business development activities, we expect to continue to spend substantial amounts to manage and execute on our strategic plan to transition from a prescription to a non-prescription model, including obtaining regulatory authorization and commercializing EndeavorOTC in adults with ADHD, pursuing regulatory authorization for over-the-counter labeling of both our EndeavorRx and EndeavorOTC products and continuing to support the distribution and fulfillment of EndeavorRx during the transition. This spending will also likely include substantial amounts as we seek to achieve and maintain market acceptance by customers, physicians, healthcare providers, and patients, expand our marketing channels and operations, enhance our products, and make the necessary investments in human capital to scale our business. Other unanticipated costs may arise in the course of these efforts. If we are able to gain marketing authorization for EndeavorOTC or for other

products or product candidates, we will require significant additional amounts of funding in order to continue to commercialize EndeavorOTC or any other such additional products or product candidates. 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;
- 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 believe that we will be able to fund our operating expenses and capital expenditure requirements into the second half of 2025. 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 October 24, 2023, we received a letter of notification of noncompliance from the Listing Qualifications Staff of Nasdaq (the "Nasdaq Staff") notifying us that they had determined that for the 30 consecutive business days from September 11, 2023, through October 23, 2023, the bid price of our common stock had closed below $1.00 per share. Accordingly, the Nasdaq Staff notified us that we were no longer in compliance with Nasdaq's continued listing requirements, specifically the minimum closing bid price requirement of $1.00 per share for inclusion on Nasdaq (the "Minimum Bid Price Rule").

We must regain compliance with and satisfy Nasdaq's continued listing requirements, including, among other things, the Minimum Bid Price Rule, or risk delisting, which would have a material adverse effect on our business. In accordance with Nasdaq Listing Rules, we have an initial period of 180 calendar days (the "Initial Cure Period") after receipt of such deficiency letter to regain compliance with the Minimum Bid Price Rule. If at any time before the end of the Initial Cure Period the bid price for our common stock closes at $1.00 or more per share for a minimum of 10 consecutive business days, the Nasdaq Staff will provide written notification to us that we are in compliance with the Minimum Bid Price Rule, unless the staff exercises its discretion to extend this 10-day period pursuant to the Nasdaq Listing Rules.

If we do not regain compliance with the Minimum Bid Price Rule by the end of the Initial Cure Period, we may be eligible for an additional 180 calendar day compliance period under certain conditions, but we can provide no assurance that we will receive an additional 180 calendar day compliance period.

If we do not regain compliance with the Minimum Bid Price Rule by the required date and we are not eligible for any additional compliance period at that time, the Nasdaq Staff will provide us written notification that our common stock may be delisted. Additionally, Nasdaq Rule 5810(c)(3)(A)(iii) provides that if during any such 180 calendar day compliance period for the Minimum Bid Price Rule, the closing bid price of our common stock is $0.10 per share or less for 10 consecutive trading days, the Nasdaq Staff shall issue a staff delisting determination. Following receipt of a delisting notification, we may appeal the Nasdaq Staff's delisting determination to a Nasdaq Listing Qualifications Panel. We expect that our common stock would remain listed pending the panel's decision. However, there can be no assurance that, even if we appeal the staff's delisting determination to the Nasdaq Listing Qualifications Panel, such appeal would be successful.

We intend to monitor the closing bid price of our common stock and may, if appropriate, consider available options to regain compliance with the Minimum Bid Price Rule, which could include seeking to effect a reverse stock split. However, there can be no assurance that we will be able to regain compliance with the Minimum Bid Price Rule.

There are many factors that may adversely affect our minimum bid price, including those described in the Risk Factors section of this Annual Report on Form 10-K. Many of these factors are outside of our control. As a result, we may not be able to sustain compliance with the Minimum Bid Price Rule in the long term.

In addition, on December 20, 2023, we received a letter from the Nasdaq Listing Qualifications Staff notifying us that with a former director's resignation from the Board and audit committee, effective as of December 19, 2023, our Board no longer had a majority of "independent directors" (as defined in Nasdaq Stock Market ("Nasdaq") Rule 5605(a)(2)) as required by Nasdaq Rule 5605(b)(1) and the audit committee no longer had three members as required by Nasdaq Rule 5605(c)(2). However, following the appointment of John Spinale to the Board and audit committee, effective February 16, 2024, on February 20, 2024, we received a

letter from the Nasdaq Listing Qualifications Staff notifying us that the Company was now in compliance with Nasdaq Rule 5605(b)(1) and Nasdaq Rule 5605(c)(2).

The foregoing has no immediate effect on our Nasdaq listing and our common stock will continue to be listed and traded on the Nasdaq Capital Market under the symbol "AKLI" subject to the listing rules. We are in the process of reviewing and evaluating potential options to regain compliance with the Minimum Bid Price Rule, and as part of these efforts, in February 2024 we disclosed plans to seek stockholder approval of a proposal (among other agenda items) at our upcoming annual meeting of stockholders that, if approved, would give our Board the discretionary authority to effect a reverse stock split.

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 may be 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 at least one analyst that recently discontinued its 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 Annual Report, we have not been materially affected by the closing of SVB, Signature Bank, Silvergate Capital, or any other bank in financial difficulty, as the Amended and Restated Loan and Security Agreement has been assumed by First Citizens BancShares, Inc. 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 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Risk Management and Strategy

We have implemented and maintain various information security processes designed to identify, assess, and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, communications systems, hardware and software, and our critical data, including intellectual property, confidential information and data that is proprietary, strategic or competitive in nature (together, "Information Systems and Data").

Our information security team (with oversight from our Chief Information Security Officer ("CISO") and support from our head of information technology) helps to identify, assess, and manage the Company's cybersecurity threats and risks. Our information security team works to identify and assess risks from cybersecurity threats by monitoring and evaluating the Company's threat environment and risk profile using various methods including, for example, vulnerability scanning and monitoring and periodic testing and audits.

Depending on the environment, we have implemented various technical, physical, and organizational measures, processes, standards, and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, from time to time, vulnerability management, information classification and data protection, asset management, software patching processes and procedures, access control, encryption, back-up procedures, disaster recovery plans, training, executive oversight, event logging, endpoint detection, multi-factor authentication, continuous monitoring, audits and engagement of third parties to conduct analysis of our Information Systems and Data.

Our assessment and management of material risks from cybersecurity threats are integrated into our overall risk management processes. For example, cybersecurity risk is addressed as a component of the Company's enterprise risk assessment and our information security team works with management to prioritize our risk management processes and mitigate cybersecurity threats that we believe are more likely to lead to a material impact to our business. In addition, our senior management evaluates material risks to the Company, including material risks from cybersecurity threats against the Company's overall business objectives and reports to the audit committee of our Board, which evaluates our overall enterprise risk and related management of such risk.

In addition, we use third party service providers to perform a variety of functions throughout our business. As a result of such use of third party service providers, we face additional cybersecurity-related risks. We have a vendor management program designed to help us manage cybersecurity risks associated with our use of third party service providers. We maintain a risk-based approach to evaluating and overseeing cybersecurity risks presented by our third party service providers. Third party service providers that meet certain criteria, such as owning and operating any information technology networks and systems on which the Company relies or where the Company's anticipated use of such third party service providers may result, for example, in the provider's access or processing of certain Company information or data, are evaluated to assess their performance across several domains, including data security, operations management, and privacy. We seek to maintain effective communication with our third party service providers to facilitate timely notification of cybersecurity incidents that might impact the Company.

We do not believe that any risks from cybersecurity threats, including as a result of any previous cybersecurity incidents, have materially affected our overall business strategy, results of operations, or financial condition. While we have mitigating and compensating controls in place to protect against what we believe are some of the most significant types of cybersecurity threats that our business faces, such as ransomware attacks, denial of service attacks, theft of resources and unauthorized use or disclosure of customer data or confidential information, if such an event were significant and successful, it would be reasonably likely to materially affect our business strategy, results of operations, or financial condition by, for example, causing substantial disruptions to our product offering, services or support or incurring significant costs to mitigate and remediate the damage caused by such an attack. For information regarding cybersecurity risks that may materially affect our Company, see Part I, Item 1A. "Risk Factors" of this Annual Report for more information regarding cybersecurity and other risks we face.

Governance

Our Board has overall responsibility for risk oversight and has delegated to the audit committee primary enterprise risk oversight responsibility for overseeing the Company's risk assessment and risk management related to cybersecurity. The audit committee of our Board receives periodic updates from our Security and Privacy Council and/or Information Security team concerning the Company's significant cybersecurity threats and risks and the processes the Company has implemented to address them.

We have established a Security and Privacy Council (the "Council"), which as of the date of this Annual Report includes our CISO, Chief Legal Officer and other employees from our legal, engineering, information security, and information technology

departments, which meets at least quarterly to review and evaluate information security and privacy risks and mitigations, information security resources and budget, audits, and monitoring programs. The Council includes certain members who have extensive experience assessing and managing risks from cybersecurity threats, including multiple decades of combined experience across information technology and information security positions; serving in leadership positions at other public companies; and having other significant experience in the areas of risk management, engineering, information technology, and information security.

Our management team is responsible for hiring appropriate personnel, helping to integrate cybersecurity risk considerations into our business processes and our overall risk management strategy, and communicating key priorities to relevant personnel. Our management team is also responsible for approving budgets, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports.

Our cybersecurity incident response policy and procedures are designed to escalate certain cybersecurity incidents to members of management depending on the circumstances. Members of management and other technical experts will work with the Company's incident response team to help the Company mitigate and remediate cybersecurity incidents of which they are notified.

Item 2. Properties.

We lease approximately 43,600 square feet of office space in Larkspur, California pursuant to a lease that expires in November 2026. In May 2023, the Company entered into a sublease agreement, pursuant to which we agreed to sublease approximately 5,716 rentable square feet of the Larkspur, California office space to a third party for a term commencing on June 1, 2023 and ending coterminous with the Larkspur, California lease in November 2026. Our lease in Boston, Massachusetts expired in December 2023. In November 2023, we entered into a membership agreement which provides access to office space in Boston, Massachusetts, with such access commencing on January 1, 2024 and expiring on December 31, 2024. We use these facilities for finance, legal, human resources, information technology, engineering, product, sales and marketing, and other administrative functions. The Company believes its existing facilities are adequate for its current requirements.

See Note 7 in the accompanying notes to the consolidated financial statements included in this Annual Report for additional information regarding our specific leaseholds.

Item 3. 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 December 31, 2023, 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 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock trades on The Nasdaq Capital Market under the symbol AKLI (formerly DNAA).

Holders

As of February 21, 2024, there were approximately 38 stockholders of record of our common stock.

The number of record holders is based upon the actual number of holders registered on our books at such date and does not include holders of shares in street name or persons, partnerships, associations, corporations, or other entities identified in security position listings maintained by depository trust companies.

Dividend Policy

We have never declared or paid any cash dividends on our common stock, and we do not anticipate paying cash dividends in the foreseeable future.

Securities Authorized for Issuance Under Equity Compensation Plans

The equity compensation plan information required by Item 201(d) of Regulation S-K will be set forth in the definitive Proxy Statement for the Company's annual meeting of stockholders, which we intend to file with the SEC within 120 days of the end of our 2023 fiscal year, and is incorporated by reference in this Annual Report. Additionally, refer to Note 12 to the Notes to Consolidated Financial Statements for additional information on our equity compensation plans.

Recent Sales of Unregistered Securities and Use of Proceeds

None.

Issuer Purchases of Equity Securities and Affiliated Purchases

None.

Item 6. [Reserved]

Not applicable.

Item 7. 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 consolidated financial statements for the years ended December 31, 2023 and 2022, together with the related notes thereto, included elsewhere in this 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" included elsewhere in this Annual Report. 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 following the Business Combination (as defined below).

Overview

Akili is a leading digital medicine company, pioneering the development of cognitive treatments through game-changing technologies. Our approach of developing and commercializing 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 commercialize, distribute, and market EndeavorOTC under the COVID-19 Guidance.

Our efforts are primarily focused on managing and executing on our strategic plan to transition from a prescription to a non-prescription model, including obtaining regulatory authorization and commercializing EndeavorOTC in adults with ADHD, pursuing regulatory authorization for over-the-counter labeling of both our EndeavorRx and EndeavorOTC products and continuing to support the distribution and fulfillment of EndeavorRx during the transition. Further development of our pipeline outside of ADHD will be contingent upon a number of factors, including capital raising and supportive business development activities. We are headquartered in Boston, Massachusetts.

Recent Developments

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. As we continue to commercialize EndeavorOTC in the adult ADHD market under the COVID-19 Guidance, we submitted a marketing submission to FDA for EndeavorOTC on October 30, 2023 and are pursuing regulatory authorization for over-the-counter labeling of both our EndeavorOTC and EndeavorRx products. We will continue to work interactively with FDA on our EndeavorOTC submission and expect to provide information regarding the status of the application by the end of the second quarter of 2024.

In December 2023, we received authorization from FDA to expand the label for EndeavorRx from children ages 8-12 with primarily inattentive or combined-type ADHD who have a demonstrated attention issue to include children ages 13-17.

In February 2024, our Japanese partner 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 of SDT-001 conducted by Shionogi in Japan in pediatric ADHD patients.

Potential Revenue Opportunity

In connection with our recently announced change in business strategy and related ongoing testing of pricing, marketing and distribution strategies, we are unable to confirm our prior potential revenue estimates of the opportunity across ADHD as the assumptions underlying these estimates have changed.

Key Commercial Metrics for EndeavorOTC

For EndeavorOTC, our non-prescription product for adults with ADHD, we monitor two key commercial metrics on a quarterly basis to evaluate our performance, identify trends, formulate financial projections, and make strategic decisions, and define the growth of our non-prescription business model: active subscribers and average revenue per paying user. Accordingly, we believe that these metrics provide useful information to investors and others in understanding and evaluating our results of operations. These metrics are presented for supplemental information purposes only, should not be considered a substitute for financial information presented in accordance with GAAP, and may be different from similarly-titled metrics or measures presented by other companies.

- **Active Subscribers.** We define "active subscribers" as the total number of users with a paid subscription for EndeavorOTC in a given period. We review active subscribers as an indication of the demand for EndeavorOTC.
- **ARPU.** We define "average revenue per paying user," or "ARPU," as EndeavorOTC revenues divided by Active Subscribers within the period. We believe that ARPU provides helpful information regarding the economic contribution of each EndeavorOTC subscriber in the period.

ENDEAVOROTC METRIC	Q4 '23	Q3 '23	Q4 '23 vs. Q3 '23
Active Subscribers	11,571	7,535	54%
ARPU	$88	$93	-5%

In addition, there were 139,499 first-time app downloads of EndeavorOTC in the fourth quarter of 2023 compared to 176,559 first-time app downloads of EndeavorOTC in the third quarter of 2023.

Non-GAAP Financial Measures

In addition to financial information prepared and presented in accordance with GAAP, the key commercial metrics for EndeavorOTC in this Annual Report include the following non-GAAP financial measure: billings on a historical basis. Billings is defined as EndeavorOTC GAAP revenues plus the change in EndeavorOTC deferred revenue in that period. Billings is used by management to manage the business, make planning decisions, and evaluate the company's performance. Akili's management believes that this non-GAAP financial measure is useful to investors to provide useful supplemental information to help investors better understand underlying trends in our business. Management does not intend the presentation of this non-GAAP financial measure to be considered in isolation or as a substitute for results prepared in accordance with GAAP, but as a complement to provide greater transparency. In addition, this non-GAAP financial measure may differ from similarly-named measures used by other companies. A reconciliation of the historical non-GAAP financial measure to the most comparable GAAP financial measure is included below.

	Three Months Ended December 31,		Year Ended December 31,		Three Months Ended September 30,	Q4' 23 vs. Q3 '23
	2023	2022	2023	2022	2023	
EndeavorOTC GAAP Revenues	$ 596	$ -	$ 1,155	$ -	$ 553	8%
Deferred revenue, end of period	-	-	-	-	-	-
Deferred revenue, beginning of period	-	-	-	-	(20)	*
EndeavorOTC Billings	$ 596	$ -	$ 1,155	$ -	$ 533	12%

Reduction in Workforce

On January 12, 2023, we announced a restructuring of our operations and a reduction in workforce due to the macroeconomic environment. As a result of the restructuring, we incurred a restructuring charge of $2.3 million associated primarily with severance and other termination-related benefits related to 48 employees, representing approximately 31% of the employee base

at the time of the restructuring. The costs associated with the restructuring were recorded in the quarter ended March 31, 2023. The restructuring reduced costs related to certain of our pipeline programs in order to prioritize certain of our commercial efforts and our ADHD label expansion programs.

On September 13, 2023, we announced a further restructuring of our operations and a reduction in our workforce. As a result of the restructuring, we incurred a restructuring charge of $2.4 million associated primarily with severance and other termination-related benefits related to 47 full-time employees, representing approximately 40% of our employee base at the time of the restructuring. All costs associated with the restructuring were recorded within operating expenses in the same functional category as the employees' operating expenses in the quarter ended September 30, 2023. The restructuring reduced costs primarily related to our field sales force and market access teams in order to implement our announced plan to transition from a prescription to a non-prescription business model.

Leadership Update

Effective October 5, 2023, Edward Martucci II, Ph.D. resigned from his role as Chief Executive Officer of the Company and transitioned into a new role as Chair of the Board following the October 4, 2023 resignation of Chamath Palihapitiya from the Board and from his role as Chair of the Board and Dr. Martucci further agreed to assist the Company in an advisory capacity. In addition, also effective October 5, 2023, Matthew Franklin, our President and Chief Operating Officer, was appointed to the role of President and Chief Executive Officer and as a member of our Board.

Effective January 12, 2024, Santosh Shanbhag resigned from his role as Chief Financial Officer of the Company. Matthew Franklin, our President, Chief Executive Officer and Chief Operating Officer assumed the duties of principal financial officer and principal accounting officer.

Effective February 16, 2024, John Spinale was appointed to the Board and to the audit committee of the Board.

Development Pipeline and Commercial Update

Our development and commercialization efforts are primarily focused on ADHD. 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.

Also, on October 16, 2023, we mutually agreed with TALi Digital Limited to terminate the License, Development and Commercialization Agreement dated as of August 16, 2021, with such termination effective as of October 16, 2023. As a result, we do not have plans at present to pursue additional clinical or regulatory efforts in children under 8 years old with ADHD.

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

Our efforts are primarily focused on managing and executing on our strategic plan announced in September 2023 to transition from a prescription to a non-prescription model, including obtaining regulatory authorization and commercializing EndeavorOTC in adults with ADHD, pursuing regulatory authorization for over-the-counter labeling of both our EndeavorRx and EndeavorOTC products and continuing to support the distribution and fulfillment of EndeavorRx during the transition. Further development of our pipeline outside of ADHD will be contingent upon a number of factors, including capital raising and supportive business development activities.

Business Combination

Closing of Business Combination

On January 26, 2022, Akili Interactive Labs, Inc. entered into an Agreement and Plan of Merger (the "Merger Agreement") with Social Capital Suvretta Holdings Corp. I ("SCS") and Karibu Merger Sub, Inc. ("Merger Sub"). Pursuant to completion of the Merger (the "Closing") on August 19, 2022 (the "Closing Date"), Merger Sub merged with and into Akili Interactive Labs, Inc., with Akili Interactive Labs, Inc. surviving the merger as a wholly-owned subsidiary of SCS (the "Merger"). In connection with the Merger, SCS was renamed Akili, Inc. and listed on Nasdaq under the symbol "AKLI". Each share of Akili Interactive Labs, Inc. common stock that was issued and outstanding immediately prior to the Closing Date, after giving effect to the conversion of all issued and outstanding shares of Akili Interactive Labs, Inc. preferred stock to Akili Interactive Labs, Inc. common stock, was canceled and converted into the right to receive a number of shares of Akili common stock equal to the Conversion Ratio multiplied by the number of shares of Akili Interactive Labs, Inc. common stock. As a condition to the consummation of the

Merger, SCS deregistered as an exempted company in the Cayman Islands and domesticated as a corporation incorporated under the laws of the State of Delaware (the "Domestication" and, together with the Merger, the "Business Combination").

Accounting Impact of the Business Combination

The Business Combination was accounted for as a reverse recapitalization, whereby for accounting and financial reporting purposes, Akili was the acquirer. A reverse recapitalization does not result in a new basis of accounting, and the financial statements of the combined entity represent the continuation of the consolidated financial statements of Akili in many respects. The SCS Class A ordinary shares ("Public Shares") and private placement shares held by the sponsor and its affiliates remaining after redemptions and the unrestricted net cash and cash equivalents on the date the Business Combination was consummated were accounted for as a capital infusion to Akili.

Cash proceeds of the Business Combination were funded through a combination of $2.3 million in cash held in trust by SCS (following satisfaction of redemptions by public stockholders), and $162.0 million in aggregate gross proceeds from the PIPE Investors in exchange for 16,200,000 shares of Akili, Inc. common stock that closed substantially contemporaneously with the Closing.

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 Annual 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.

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

Product Adoption

To continue to grow our business, we will need to execute on our recently announced strategic plan to 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. This will be driven by increased investment in direct-to-consumer acquisition and retention activities. If we are not successful in demonstrating the benefits of our products or do not achieve the support of customers, our sales may decline, or we may fail to increase our revenue.

Pricing

In the future, we aim to continue 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 ongoing transition to a new non-prescription model, we have limited conversations with commercial insurers and government payers regarding reimbursement coverage for our treatments. However, we 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 only through direct purchase or via the Apple App Store or Google Play.

Collaboration Revenue

We currently have a collaboration and licensing agreement (the "Collaboration Agreement") with Shionogi & Co., Ltd ("Shionogi") and we are eligible to receive development and commercial milestones as well as royalties on the sales of licensed products. If our development efforts for 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 increase as we further commercialize our EndeavorOTC product and increase the volume of EndeavorOTC sales.

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.

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. We are continuing to support existing customers using 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 a core part of our strategy is to continue making sustained investments in this area. 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 managing and executing on our strategic plan announced in September 2023 to transition from a prescription to a non-prescription model, including obtaining regulatory authorization and commercializing EndeavorOTC in adults with ADHD, pursuing regulatory authorization for over-the-counter labeling of both our EndeavorRx and EndeavorOTC products and continuing to support the distribution and fulfillment of EndeavorRx during the transition. Further development of our pipeline outside of the ADHD space will be contingent upon a number of factors, including capital raising and supportive business development activities. As a result, our R&D expenses decreased in the three months ended December 31, 2023, and we expect R&D expenses to remain consistent during 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 previously-launched investigator-initiated studies. Further development of our pipeline outside of ADHD will be contingent upon a number of factors, including capital raising and supportive business development activities.

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 decrease in 2024 primarily due to the elimination of the Company's field sales force and market access teams. As we pursue a regulatory and commercial strategy for our EndeavorOTC product, we intend to focus on improving unit economics as we scale back traditional advertising and focus on lower cost direct-to-consumer marketing.

Other income (expense)

Other income consists of interest earned on cash balances held in interest-bearing accounts and interest earned and accretion on short-term investments. 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.

Change in fair value of earn-out liabilities includes the change in fair value of the earn-out liabilities related to Earn-Out Shareholders from its initial recognition on August 19, 2022, the Closing Date, through December 31, 2022 and for the year ended December 31, 2023.

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 2023 and 2022 is immaterial because Akili has historically incurred net operating losses and maintains a full valuation allowance against its deferred tax assets.

Results of Operations

Years Ended December 31, 2023 and 2022

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

	Year Ended December 31,			
(dollars in thousands, except percentages)	2023	2022	$ Change	% Change
Revenues	$ 1,678	$ 323	$ 1,355	420%
Cost of revenues	819	441	378	86%
Gross profit (loss)	859	(118)	977	*
Operating expenses:				
Research and development	19,925	28,858	(8,933)	-31%
Selling, general and administrative	45,419	61,701	(16,282)	-26%
Total operating expenses	65,344	90,559	(25,215)	-28%
Operating loss	(64,485)	(90,677)	26,192	-29%
Other income (expense):				
Other income	4,040	1,482	2,558	173%
Interest expense	(2,358)	(1,484)	(874)	59%
Change in estimated fair value of earn-out liabilities	3,363	82,734	(79,371)	-96%
Total other income	5,045	82,732	(77,687)	-94%
Loss before income taxes	(59,440)	(7,945)	(51,495)	648%
Income tax expense	(53)	(19)	(34)	179%
Net loss	**$ (59,493)**	**$ (7,964)**	**$ (51,529)**	647%
Unrealized gain (loss) on short-term investments	$ 21	$ (21)	$ 42	-200%
Comprehensive loss	**$ (59,472)**	**$ (7,985)**	**$ (51,487)**	645%

* Percentage change not meaningful

Revenue—Revenue was $1.7 million and $0.3 million for the years ended December 31, 2023 and 2022, 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 on the Apple App Store and in September 2023 on Google Play.

Cost of revenue—Cost of revenue was $0.8 million and $0.4 million for the years ended December 31, 2023 and 2022, respectively. The increase of $0.4 million in product-related costs of revenue in the year ended December 31, 2023 was due to the increased sales volume.

Research and development—R&D expenses were $19.9 million and $28.9 million for the years ended December 31, 2023 and 2022, respectively. Most expenses in the current period were related to the development of and updates to the EndeavorOTC product and most expenses in the prior period were related to the development of our SSME platform, which was 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 $9.0 million was primarily due to the following:

- a decrease of $3.8 million of clinical studies and expenses due to the timing of our clinical trials, the restructuring of our business to preserve capital and focus primarily on commercializing EndeavorRx and EndeavorOTC in ADHD and seeking a label expansion for EndeavorRx in adolescent ADHD patients, which resulted in the reprioritization of our pipeline of preclinical and clinical development programs. As a result, clinical studies and expenses decreased from $5.2 million in the year ended December 31, 2022 to $1.4 million in the year ended December 31, 2023;
- a decrease of $3.7 million of personnel-related expenses primarily due to the lower headcount from the restructurings, partially offset by severance payments, which decreased the expense from $19.7 million in the year ended December 31, 2022 to $16.0 million in the year ended December 31, 2023. The estimated fair value of earn-out liabilities related to Earn-Out Service Providers accounted for $(0.2) million of the expense in the year ended December 31, 2023;
- a decrease of $1.1 million related to various other expenses such as a decrease in external consulting fees, rent and travel, which decreased the expense from $2.7 million for the year ended December 31, 2022 to $1.6 million for the year ended December 31, 2023; and

- a decrease of $0.4 million of computer equipment and software expenses due to a decrease in software subscriptions, which decreased the expense from $1.3 million for the year ended December 31, 2022 to $0.9 million for the year ended December 31, 2023.

Selling, general and administrative—SG&A expenses were $45.4 million and $61.7 million for the years ended December 31, 2023 and 2022, respectively. The decrease of $16.3 million was primarily due to the following:

- a decrease of $8.3 million in consulting, legal, accounting and other professional services costs;
- a decrease of $5.9 million in marketing and advertising costs;
- a decrease of $1.4 million related to various other expenses. As part of the Business Combination in 2022, there was a one-time allocation of transaction costs to Earn-out Shares of $3.0 million based on the relative fair value of these instruments as compared to the other newly issued instruments. This was the primary cause of the decrease as there was no related expense in 2023. This was partially offset by increased business insurance costs due to being a public company for the full year in 2023; and
- a decrease of $0.7 million in personnel-related costs, primarily due to a lower headcount and stock compensation, partially offset by severance pay. The change in estimated fair value of earn-out liabilities related to Earn-Out Service Providers accounted for $(0.3) million of the expense in the year ended December 31, 2023.

Other income—Other income was $4.0 million and $1.5 million in the years ended December 31, 2023 and 2022, respectively. The increase was due to an increase in short-term investments held on average throughout 2023 and higher interest rates.

Interest expense—Interest expense was $2.4 million and $1.5 million in the years ended December 31, 2023 and 2022, respectively. The $0.9 million increase was primarily related to an increase in the average outstanding principal of the note payable during 2023 and rising variable interest rates during the year ended December 31, 2023.

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 years ended December 31, 2023 or 2022. 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 years ended December 31, 2023 and 2022, we incurred net operating losses of $64.5 million and $90.7 million, respectively.

As of December 31, 2023, we had an accumulated deficit of $299.8 million. As of December 31, 2023, we had outstanding debt of $13.0 million, net of debt issuance costs and debt discount. As of December 31, 2023, we had cash and cash equivalents of $75.2 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. We expect to continue to generate operating losses and negative operating cash flows for the foreseeable future.

In May 2021, we entered into an Amended and Restated Loan and Security Agreement with SVB and SVB Innovation Credit Fund VIII, L.P., (such agreement, 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 December 31, 2023, there was $10.6 million outstanding under the SVB Term Loan facility and there is no

remaining available undrawn debt. Additionally, the corporate bond issued with Shionogi in March 2019 continues to have $5.0 million outstanding as of December 31, 2023.

Our primary uses of capital are, and we expect will continue to be for the near future, personnel costs, costs of product development, costs related to commercialization of our EndeavorRx and EndeavorOTC products, legal, patent and other regulatory expenses and general overhead costs. We may also pursue acquisitions, investments, joint ventures and other strategic transactions.

We will need substantial additional funding to pursue our business strategy 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 December 31, 2023 was $75.2 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, commercialization of EndeavorOTC products, and spending on other strategic business initiatives.

Short-term investments

We held short-term investments during 2023 which consisted of United States Treasuries with original maturity dates of more than three months but less than one year. We did not hold any short-term investments as of December 31, 2023.

Liquidity Risks

We expect to incur substantial additional expenditures in the near term to support our ongoing activities, including obtaining regulatory authorization and commercializing EndeavorOTC in adults with ADHD, pursuing regulatory authorization for over-the-counter labeling of both our EndeavorRx and EndeavorOTC products, continuing to support the distribution and fulfillment of EndeavorRx 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:

- 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 marketing efforts;
- 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;
- 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:

	Year Ended December 31,	
	2023	2022
	(in thousands)	
Net cash used in operating activities	$ (57,867)	$ (83,521)
Net cash provided by (used in) investing activities	83,413	(81,216)
Net cash provided by (used in) financing activities	(4,493)	141,935
Net increase (decrease) in cash	$ 21,053	$ (22,802)

Net Cash Used in Operating Activities

Years Ended December 31, 2023 and 2022

Net cash used in operating activities was $57.9 million for the year ended December 31, 2023. Net cash used in operating activities consists of net loss of $59.5 million, adjusted for non-cash items and the effect of changes in working capital. Non-cash adjustments primarily include decreases related to amortization of premium on short-term investments of $1.5 million and the change in estimated fair value of earn-out liabilities of $3.4 million, offset by increases related to stock-based compensation expense of $6.8 million, non-cash interest expense of $0.7 million, and impairment loss on sublease of $0.4 million. There was an additional decrease to net loss of $2.4 million related to the change in operating assets and liabilities primarily due to a reduced bonus and commission accrual related to the reductions in workforce 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 $83.5 million for the year ended December 31, 2022. Net cash used in operating activities consists of net loss of $8.0 million, adjusted for non-cash items and the effect of changes in working capital. Non-cash adjustments primarily include depreciation expense of $0.3 million, stock-based compensation expense of $9.3 million, change in estimated fair value of earn-out liabilities of $82.7 million, and amortization of premium on short-term investments of $0.9 million. There was an additional $2.6 million change in operating assets and liabilities primarily due to an increased prepaid insurance amount in the year ended December 31, 2022.

Net Cash Provided by (Used in) Investing Activities

Years Ended December 31, 2023 and 2022

Net cash provided by investing activities was $83.4 million for the year ended December 31, 2023. The cash was related to $140.0 million of proceeds from maturities of short-term investments, partially offset by $56.4 million of cash used to purchase short-term investments.

Net cash used in investing activities was $81.2 million for the year ended December 31, 2022. The cash was primarily used to purchase short-term investments, partially offset by the proceeds from maturities of short-term investments.

Net Cash Provided by (Used in) Financing Activities

Years Ended December 31, 2023 and 2022

Net cash used in financing activities was $4.5 million for the year ended December 31, 2023 and consisted of $4.4 million of repayment of principal on the note payable and $0.1 million of taxes paid related to net share settlements of share-based awards.

Net cash provided by financing activities was $141.9 million for the year ended December 31, 2022 and consisted primarily of $131.8 million of proceeds from the Business Combination, net of transaction costs and $10.0 million of proceeds from the issuance of a note payable.

Funding Requirements

Based on our current operating plan, we believe that our existing cash and cash equivalents will be sufficient to fund our operations and capital expenses into the second half of 2025. However, we have based this estimate 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 Annual 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 Collaboration Agreement, the Company issued a $5.0 million corporate bond to Shionogi for cash. 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 maturity date of the corporate bond is November 10, 2031 and does not bear interest during its term. The corporate bond is prepayable by the Company at any time without penalty. The repayment of the corporate bond can be accelerated upon the termination of the Collaboration Agreement or upon the occurrence of certain events of default (as set forth in the corporate bond), in both cases without penalty.

Debt Financing and Covenants

At December 31, 2023, the Company had outstanding principal of $10.6 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 December 31, 2023, 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 is secured by substantially all of our personal property assets, including accounts receivable, equipment, license agreement, general intangibles, inventory and investment property, and all of the proceeds and products of the foregoing. The Amended and Restated Loan and Security Agreement with SVB required an exclusive relationship for our operating cash account, however in light of the events and status of SVB, in April 2023 we entered into a Letter Agreement to amend the Amended and Restated Loan and Security Agreement with SVB (now a division of First-Citizens Bank & Trust Company) to allow the Company to establish accounts and move a portion of our cash resources to other financial institutions. The SVB Term Loan contains various affirmative and negative covenants that limit our ability to engage in specified types of transactions. We were in compliance with the covenants under the SVB Term Loan as of December 31, 2023.

See Note 10, *Note Payable*, of the notes to Akili's consolidated financial statements for the years ended December 31, 2023 and 2022, included elsewhere in this Annual 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 elsewhere in this 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 elsewhere in this 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 elsewhere in this 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 while the components are separate performance obligations, they have the same method and pattern of recognition. 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 years ended December 31, 2023 and 2022.

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.

Legacy Akili Common Stock Valuations

The fair value of Legacy Akili's common stock underlying stock awards was determined by the board of directors (the "Board"). Given the absence of a public trading market, the Board considered numerous objective and subjective factors to determine the fair value of Legacy Akili's common stock at each board of directors meeting in which stock awards were approved. These factors included, but were not limited to:

- the prices at which we sold our preferred stock to outside investors in arm's-length transactions;
- our results of operations, financial position, and capital resources;
- contemporaneous third-party valuations common stock;
- rights, preferences, and privileges of convertible preferred stock relative to common stock;
- the lack of marketability of common stock;
- stage and development of Legacy Akili's business;
- the history and nature of our business, industry trends and competitive environment;
- general economic conditions; and
- the likelihood of achieving a liquidity event, such as an initial public offering or sale of Legacy Akili, given prevailing market conditions.

We determined the fair value per share of the underlying Legacy Akili common stock by taking into consideration results obtained from third-party valuations and additional factors that were deemed relevant. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation ("Practice Aid"). The Practice Aid identifies various available methods for allocating the enterprise value across classes of capital stock in determining the fair value of Legacy Akili common stock at each valuation date. Based on our stage of development and other relevant factors, historically, we have considered both the Probability Weighted Expected Return Method ("PWERM") and the option pricing method ("OPM") as appropriate methods for estimating our enterprise value to determine the fair value of Legacy Akili common stock. The PWERM is a scenario-based methodology that estimates the fair value of common stock based upon an analysis of future values for the company, assuming various outcomes. The common stock value is based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes available as well as the rights of each class of stock. The future value of the common stock under each outcome is discounted back to the valuation date at an appropriate risk-adjusted discount rate and probability weighted to arrive at an indication of value for the common stock. The OPM treats the share classes of an enterprise as a series of call options with a claim on the equity value of the company. Exercise prices are determined based on the equity value breakpoints in which the various share classes either receive a liquidation preference or convert, in the case of preferred stock, or exercise, in the case of options and warrants. An option pricing model, such as the Black-Scholes Model, is then utilized to value the call options for the purpose of allocating value to the various share classes of an enterprise. The OPM is a forward-looking analysis in that it considers the liquidation rights and preferences of the share classes as of a future liquidity date.

The assumptions underlying these valuations represented management's best estimates, which involved inherent uncertainties and the application of management's judgment. As a result, if we had used significantly different assumptions or estimates, the fair value of our preferred and common stock and our stock-based compensation expense could be materially different. The fair value of the underlying common stock was determined by the Board until the Company became listed on an established stock exchange.

Item 7A. 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 8. Financial Statements and Supplementary Data.

Our consolidated financial statements, together with the reports of our independent registered public accounting firms, appear beginning on page F-1 of this Annual Report for the year ended December 31, 2023.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. 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 December 31, 2023. 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.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of the effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies and procedures included in such controls may deteriorate. Our management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth in "Internal Control - Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, our management concluded that, as of December 31, 2023, our internal control over financial reporting was effective.

Attestation Report of the Registered Public Accounting Firm

This Annual Report does not include an attestation report of our registered public accounting firm due to an exemption provided by the JOBS Act for "emerging growth companies."

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 December 31, 2023 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 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.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required under this item is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement is expected to be filed with the Securities and Exchange Commission not later than 120 days after the close of the Company's fiscal year ended December 31, 2023.

We have adopted a Code of Ethics that applies to all officers, directors and employees in connection with their work for us. The full text of our Code of Ethics is posted on the investor relations page of our website at https://investors.akiliinteractive.com/governance/governance-documents/default.aspx.

We intend to satisfy any disclosure requirements under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of this Code of Ethics by posting such information on our website, at the Internet address and location specified above.

Item 11. Executive Compensation.

The information required under this item is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement is expected to be filed with the Securities and Exchange Commission not later than 120 days after the close of the Company's fiscal year ended December 31, 2023.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required under this item is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement is expected to be filed with the Securities and Exchange Commission not later than 120 days after the close of the Company's fiscal year ended December 31, 2023.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required under this item is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement is expected to be filed with the Securities and Exchange Commission not later than 120 days after the close of the Company's fiscal year ended December 31, 2023.

Item 14. Principal Accounting Fees and Services.

The information required under this item is incorporated herein by reference to the Company's definitive proxy statement pursuant to Regulation 14A, which proxy statement is expected to be filed with the Securities and Exchange Commission not later than 120 days after the close of the Company's fiscal year ended December 31, 2023.

PART IV

Item 15. Exhibit and Financial Statement Schedules.

(1) For a list of the financial statements included herein, see Index to the Consolidated Financial Statements on page F-1 of this Annual Report, incorporated into this Item by reference.

(2) Financial statement schedules have been omitted because they are either not required or not applicable or the information is included in the consolidated financial statements or the notes thereto.

(3) Exhibits:

Exhibit Number	Description
2.1+	Agreement and Plan of Merger, dated as of January 26, 2022, by and among the Registrant, Karibu Merger Sub, Inc., and Akili Interactive Labs, Inc. (incorporated by reference to Exhibit 2.1 to the Registration Statement on Form S-4 filed on February 14, 2022).
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).
4.2	Description of Registrant's Securities (incorporated by reference to Exhibit 4.2 to Akili, Inc.'s Annual Report on Form 10-K filed on March 9, 2023).
10.1	Amended and Restated Registration Rights Agreement, dated as of August 19, 2022, by and among Akili, Inc., SCS Sponsor I LLC, certain stockholders of Akili Interactive Labs, Inc., as set forth on Schedule 1 thereto and the other parties thereto (incorporated by reference to Exhibit 10.6 to the Registrant's Current Report on Form 8-K filed on August 23, 2022).
10.2	Form of Indemnification Agreement for Executive Officer (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on August 23, 2022).
10.3	Form of Indemnification Agreement for Directors (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on August 23, 2022).
10.4†	Option and Collaboration Agreement, dated as of December 19, 2018, by and between Shionogi & Co., Ltd. and Akili Interactive Labs, Inc., as amended by Amendment No. 1 dated as of January 1, 2020, Amendment No. 2 dated as of May 1, 2020 and Amendment No. 3 dated as of November 15, 2021 (incorporated by reference to Exhibit 10.15 to Amendment No. 1 to the Registration Statement on Form S-4 filed on April 4, 2022).
10.5†	Amended and Restated Loan and Security Agreement, dated as of May 25, 2021, by and among Silicon Valley Bank, SVB Innovation Credit Fund VIII, L.P. and Akili Interactive Labs, Inc. (incorporated by reference to Exhibit 10.17 to Amendment No. 2 to the Registration Statement on Form S-4 filed on May 12, 2022).
10.6	Akili, Inc. 2022 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed on August 23, 2022).
10.7	Form of Incentive Stock Option Agreement under the Akili, Inc. 2022 Stock Option and Incentive Plan (incorporated by reference to Exhibits 99.4 to the Registrant's Registration Statement on Form S-8 filed on October 27, 2022).
10.8	Form of Restricted Stock Award Agreement under the Akili, Inc. 2022 Stock Option and Incentive Plan (incorporated by reference to Exhibits 99.5 to the Registrant's Registration Statement on Form S-8 filed on October 27, 2022).
10.9	Form of Restricted Stock Unit Award Agreement for Company Employees under the Akili, Inc. 2022 Stock Option and Incentive Plan (incorporated by reference to Exhibits 99.6 to the Registrant's Registration Statement on Form S-8 filed on October 27, 2022).
10.10	Form of Restricted Stock Unit Award Agreement for Non-Employee Directors under the Akili, Inc. 2022 Stock Option and Incentive Plan (incorporated by reference to Exhibits 99.7 to the Registrant's Registration Statement on Form S-8 filed on October 27, 2022).
10.11	Form of Non-Qualified Stock Option Agreement for Company Employees under the Akili, Inc. 2022 Stock Option and Incentive Plan (incorporated by reference to Exhibits 99.8 to the Registrant's Registration Statement on Form S-8 filed on October 27, 2022).
10.12	Form of Non-Qualified Stock Option Agreement for Non-Employee Directors under the Akili, Inc. 2022 Stock Option and Incentive Plan (incorporated by reference to Exhibits 99.9 to the Registrant's Registration Statement on Form S-8 filed on October 27, 2022).

10.13	Form of Restricted Stock Unit Award Agreement for Company Employees under the Akili, Inc. 2022 Stock Option and Incentive Plan (Earnout RSUs) (incorporated by reference to Exhibits 99.10 to the Registrant's Registration Statement on Form S-8 filed on October 27, 2022).
10.14	Akili, Inc. 2022 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K filed on August 23, 2022).
10.15	Akili, Inc. Amended and Restated Executive Severance Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on October 27, 2022).
10.16	Akili, Inc. Senior Executive Cash Incentive Bonus Plan (incorporated by reference to Exhibit 10.16 to the Registrant's Quarterly Report on Form 10-Q filed on November 14, 2022).
10.17	Non-Employee Director Compensation Policy of the Company, as amended on August 2, 2023 (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q filed on November 9, 2023).
10.18*	Commercial Sublease, dated as of May 15, 2023, by and between Phoenix American Incorporated and Akili Interactive Labs, Inc.
10.19†	License, Development and Commercialization Agreement, dated as of August 16, 2021, by and between Akili Interactive Labs, Inc. and TALi Digital Limited (incorporated by reference to Exhibit 10.25 to Amendment No. 1 to the Registration Statement on Form S-4 filed on April 4, 2022).
10.20	Joinder and First Loan Modification Agreement, dated December 23, 2022, by and among Silicon Valley Bank, in its capacity as administrative agent and collateral agent, Silicon Valley Bank and SVB Innovation Credit Fund VIII, L.P., as lenders, and Akili, Inc. and Akili Interactive Labs, Inc., as borrowers (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K/A filed on December 27, 2022).
10.21	Letter Agreement, dated as of April 14, 2023, by and among First-Citizens Bank & Trust Company, SVB Innovation Credit Fund VIII, L.P., Akili Interactive Labs, Inc. and Akili, Inc. (incorporated by reference to Exhibit 10.1 to Akili, Inc.'s Form 10-Q filed on May 12, 2023)
10.22†	Advisor Agreement, dated as of October 5, 2023, by and between Akili Interactive Labs, Inc. and Dr. W. Edward Martucci II, Ph.D. (incorporated by reference to Exhibit 10.1 to Akili, Inc. Form 10-Q filed on November 9, 2023).
10.23	Exclusive License Agreement, dated as of October 18, 2013, by and between Akili Interactive Labs, Inc. and The Regents of the University of California, as amended by Amendment No. 1 dated as of May 17, 2018 and Amendment No. 2 dated as of February 25, 2019 (incorporated by reference to Exhibit 10.16 to Amendment No. 1 to the Registration Statement on Form S-4 filed on April 4, 2022).
21.1*	Subsidiaries of the Registrant.
23.1*	Consent of KPMG LLP, independent registered public accounting firm.
24.1*	Power of Attorney (included on signature page to this annual report).
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.
97*	Akili, Inc. Compensation Recovery Policy
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 Annual Report on Form 10-K 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.

+ Schedules and exhibits have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The Registrant agrees to furnish supplementally a copy of any omitted schedule or exhibit to the SEC upon request.

† Portions of this exhibit (indicated by asterisks) have been omitted in accordance with Item 601(b)(10) of Regulation S-K. The Registrant agrees to furnish supplementally a copy of any omitted schedule or exhibit to the SEC upon request.

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Akili, Inc.

Date: February 29, 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)

POWER OF ATTORNEY

Each person whose signature appears below constitutes and appoints Matthew Franklin, as his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitute(s), may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated:

Signature	Title	Date
/s/ Matthew Franklin Matthew Franklin	President, Chief Executive Officer and Director (Principal Executive Officer, Principal Financial Officer, and Principal Accounting Officer)	February 29, 2024
/s/ W. Edward Martucci II, Ph.D. W. Edward Martucci II, Ph.D.	Chairman and Director	February 29, 2024
/s/ Adam Gazzaley, M.D., Ph.D. Adam Gazzaley, M.D., Ph.D.	Director	February 29, 2024
/s/ Mary Hentges Mary Hentges	Director	February 29, 2024
/s/ William “BJ” Jones, Jr. William “BJ” Jones, Jr.	Director	February 29, 2024
/s/ Christine Lemke Christine Lemke	Director	February 29, 2024
/s/ John Spinale John Spinale	Director	February 29, 2024

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INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Akili, Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Akili, Inc. and subsidiaries (the Company) as of December 31, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders' equity (deficit), and cash flows for the years then ended, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for the years then ended, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

We have served as the Company's auditor since 2018.

Boston, Massachusetts
February 29, 2024

AKILI, INC.

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

	December 31,	
	2023	**2022**
Assets		
Current assets:		
Cash and cash equivalents	$ 75,150	$ 54,097
Restricted cash	305	305
Short-term investments	-	82,034
Accounts receivable	300	41
Prepaid expenses and other current assets	2,275	4,565
Total current assets	78,030	141,042
Property and equipment, net	680	919
Operating lease right-of-use asset	1,577	2,596
Prepaid expenses and other long-term assets	96	—
Total assets	**$ 80,383**	**$ 144,557**
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	1,285	2,681
Accrued expenses and other current liabilities	3,326	5,616
Deferred revenue	100	106
Operating lease liability	756	826
Note payable, short term	7,500	4,375
Total current liabilities	12,967	13,604
Note payable, long term	3,445	10,442
Operating lease liability, net of current portion	1,730	2,485
Corporate bond, net of bond discount	2,054	1,834
Earn-out liabilities	1,632	5,513
Other long-term liabilities	23	—
Total liabilities	**21,851**	**33,878**
Commitments and contingencies		
Stockholders' equity		
Common stock, $0.0001 par value: 1,000,000,000 shares authorized; 78,356,527 and 78,022,924 shares issued and outstanding at December 31, 2023 and 2022, respectively	8	8
Additional paid-in capital	358,305	350,980
Accumulated deficit	(299,781)	(240,288)
Accumulated other comprehensive loss	—	(21)
Total stockholders' equity	**58,532**	**110,679**
Total liabilities and stockholders' equity	**$ 80,383**	**$ 144,557**

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

AKILI, INC.

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

	Year Ended December 31,	
	2023	**2022**
Revenues	$ 1,678	$ 323
Cost of revenues	819	441
Gross profit (loss)	859	(118)
Operating expenses:		
Research and development	19,925	28,858
Selling, general and administrative	45,419	61,701
Total operating expenses	65,344	90,559
Operating loss	(64,485)	(90,677)
Other income (expense):		
Other income	4,040	1,482
Interest expense	(2,358)	(1,484)
Change in estimated fair value of earn-out liabilities	3,363	82,734
Total other income	5,045	82,732
Loss before income taxes	(59,440)	(7,945)
Income tax expense	(53)	(19)
Net loss	$ (59,493)	$ (7,964)
Unrealized gain (loss) on short-term investments	$ 21	$ (21)
Comprehensive loss	$ (59,472)	$ (7,985)
Net loss	$ (59,493)	$ (7,964)
Dividends on Series D convertible preferred stock	-	(7,383)
Redemption value of Series D convertible preferred stock	-	(3,692)
Net loss attributable to common stockholders	$ (59,493)	$ (19,039)
Net loss per share attributable to common stockholders - basic and diluted	$ (0.76)	$ (0.64)
Weighted average common stock outstanding - basic and diluted	78,197,107	29,878,041

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

AKILI, INC.

Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)
(In thousands, except share amounts)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Permanent
	Shares	Value	Shares	Value	Capital	Deficit	Loss	Equity (Deficit)
Balance at December 31, 2021	**43,318,218**	**$ 291,876**	**1,674,106**	**$ -**	**$ -**	**$ (226,114)**	**$ -**	**$ (226,114)**
Stock-based compensation expense	-	-	-	-	8,574	-	-	8,574
Exercise of stock options	-	-	116,299	-	149	-	-	149
Stock dividend accrued for Series D preferred stock	1,008,596	7,383	-	-	(4,865)	(2,518)	-	(7,383)
Redemption value of Series D preferred stock	8,472,752	3,692	-	-	-	(3,692)	-	(3,692)
Exercise of Legacy Akili warrants	-	-	8,834	-	-	-	-	-
Vesting of common stock warrants	-	-	-	-	282	-	-	282
Conversion of redeemable preferred stock into common stock	(52,799,566)	(302,951)	52,799,566	5	302,946	-	-	302,951
Issuance of common stock related to Business Combination and PIPE Investment	-	-	23,367,500	3	164,280	-	-	164,283
Reverse recapitalization, net of transaction costs (including ($87,512) of deemed dividends related to Earn-Out Shareholders)	-	-	-	-	(120,386)	-	-	(120,386)
Vesting of RSUs	-	-	56,619	-	-	-	-	-
Other comprehensive loss	-	-	-	-	-	-	(21)	(21)
Net loss	-	-	-	-	-	(7,964)	-	(7,964)
Balance at December 31, 2022	**-**	**$ -**	**78,022,924**	**$ 8**	**$ 350,980**	**$ (240,288)**	**$ (21)**	**$ 110,679**
Stock-based compensation expense	-	-	-	-	7,325	-	-	7,325
Exercise of stock options	-	-	28,224	-	-	-	-	-
Vesting of RSUs	-	-	305,379	-	-	-	-	-
Other comprehensive income	-	-	-	-	-	-	21	21
Net loss	-	-	-	-	-	(59,493)	-	(59,493)
Balance at December 31, 2023	**-**	**$ -**	**78,356,527**	**$ 8**	**$ 358,305**	**$ (299,781)**	**$ -**	**$ 58,532**

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

AKILI, INC.

Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (59,493)	$ (7,964)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	302	308
Reduction in the carrying amount of right-of-use assets	692	489
Impairment loss on sublease	385	-
Stock-based compensation expense	6,807	9,309
Loss on disposal of fixed assets	22	-
Amortization of premium on short-term investments	(1,501)	(881)
Non cash interest expense	723	512
Change in fair value of earn-out liabilities	(3,363)	(82,734)
Changes in operating assets and liabilities:		
Accounts receivable	(259)	(12)
Prepaid expenses and other current assets	2,408	(2,037)
Prepaid expenses and other long-term assets	(96)	11
Accounts payable	(1,396)	387
Accrued expenses and other current liabilities	(2,290)	(310)
Other long-term liabilities	23	(24)
Operating lease liabilities	(825)	(585)
Deferred revenue	(6)	10
Net cash used in operating activities	(57,867)	(83,521)
Cash flows from investing activities:		
Acquisition of property and equipment	(19)	(42)
Capitalized software development costs	(124)	-
Purchases of short-term investments	(56,444)	(111,174)
Proceeds from maturities of short-term investments	140,000	30,000
Net cash provided by (used in) investing activities	83,413	(81,216)
Cash flows from financing activities:		
Proceeds from exercise of stock options	-	149
Proceeds from note payable	-	10,000
Proceeds from Business Combination, net of transaction costs paid	-	131,814
Taxes paid related to net share settlement of share-based awards	(118)	(28)
Repayment of principal on note payable	(4,375)	-
Net cash provided by (used in) financing activities	(4,493)	141,935
Net increase (decrease) in cash, cash equivalents, and restricted cash	21,053	(22,802)
Cash, cash equivalents, and restricted cash at beginning of period	54,402	77,204
Cash, cash equivalents, and restricted cash at end of period	$ 75,455	$ 54,402
Supplementary Information:		
Cash paid for income taxes	$ 16	$ -
Cash paid for interest	1,665	834
Noncash investing and financing activities:		
Deferred asset for fees related to undrawn debt included in accrued expenses	-	51
Common stock warrants issued related to note payable	-	282
Redemption value of Series D preferred stock	-	3,692
Dividends accrued for Series D preferred stock	-	7,383
Recognition of liabilities for Earn-Out Shareholders	-	87,512
Net liabilities assumed in the Business Combination	-	500

The accompanying notes are an integral part of these 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 developing and commercializing 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 commercialize, distribute, and market EndeavorOTC under the COVID-19 Guidance. The Company's efforts are primarily focused on managing and executing its strategic plan to transition from a prescription to a non-prescription model, including obtaining regulatory authorization and commercializing EndeavorOTC in adults with ADHD, pursuing regulatory authorization for over-the-counter labeling of both its EndeavorRx and EndeavorOTC products and continuing to support the distribution and fulfillment of EndeavorRx during the transition. Further development of Akili's programs outside of ADHD will be contingent upon a number of factors, including capital raising and supportive business development activities. 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.

In connection with the Business Combination, SCS completed the sale and issuance of 16,200,000 shares of Akili, Inc. common stock, $0.0001 par value per share (the "Common Stock") in a private placement transaction for a purchase price of $10.00 per share for $162,000 in the aggregate (the "PIPE Investment"). Gross proceeds from the Merger totaled approximately $164,283 which included funds held in SCS's trust account (after giving effect to redemptions). In connection with the Business Combination, approximately $31,438 of transaction costs and other fees were incurred. References to SCS refer to the Company prior to the consummation of the Business Combination and references to "Legacy Akili" refer to Akili Interactive Labs, Inc. (now a wholly-owned subsidiary of Akili, Inc.) prior to the consummation of the Business Combination. Legacy Akili was deemed the accounting acquirer in the Business Combination. This determination was primarily based on Legacy Akili's stockholders prior to the Business Combination having a majority of the voting power in the combined company, Legacy Akili having the ability to appoint a majority of the board of directors of the combined company (the "Board"), Legacy Akili's existing management comprising the senior management of the combined company, Legacy Akili comprising the ongoing operations of the combined company, Legacy Akili being the larger entity based on historical revenues and business operations, and the combined company assuming Legacy Akili's name. Accordingly, for accounting purposes, the Business Combination was treated as the equivalent of Legacy Akili issuing stock for the net assets of SCS, accompanied by a recapitalization. Under this method of accounting, SCS who was the legal acquirer, is treated as the "acquired" company for financial reporting purposes. The net assets of SCS are stated at historical cost, with no goodwill or other intangible assets recorded. The equity structure has been restated in all comparative periods up to the Closing Date to reflect the number of

shares of the Company's Common Stock, $0.0001 par value per share, issued to Legacy Akili stockholders in connection with the Business Combination. As such, the shares and corresponding capital amounts and earnings per share related to Legacy Akili's convertible preferred stock ("Legacy Convertible Preferred Stock") and Legacy Akili common stock prior to the Business Combination have been retroactively restated as shares reflecting the exchange ratio of approximately 1.15 pursuant to the terms of the Business Combination. Legacy Convertible Preferred Stock previously classified as mezzanine was retroactively adjusted, converted into Common Stock, and reclassified to permanent as a result of the reverse recapitalization. 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 as it pursues its strategic goals. The Company's efforts are primarily focused on managing and executing its strategic plan to transition from a prescription to a non-prescription model, including obtaining regulatory authorization and commercializing EndeavorOTC for the adult ADHD market, pursuing regulatory authorization for over-the-counter labeling of both its EndeavorRx and EndeavorOTC products and continuing to support the distribution and fulfillment of EndeavorRx during the transition.

There can be no assurance that the Company's product development and 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 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 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 year ended December 31, 2023 and had an accumulated deficit of $299,781 at December 31, 2023. The Company believes that its cash and cash equivalents at December 31, 2023 of $75,150 will be sufficient to fund the Company's planned operations and existing obligations for at least one year after the date that the consolidated financial statements are issued.

The future viability of the Company is dependent on its ability to generate cash from operating activities, manage liquidity by maintaining reduced operating expenses or 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 pursue its business strategies.

Basis of Presentation

The accompanying 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.

2. Summary of Significant Accounting Policies

Use of estimates: The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of expenses during the reporting periods. Estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, the valuation of the earn-out liability and the valuation of stock-based awards. On an ongoing basis, management evaluates its estimates, including those related to accrued liabilities and stock-based compensation expense. Actual results could differ from the Company's estimates.

Cash and cash equivalents: The Company considers all short-term, highly liquid investments with original maturities of 90 days or less at acquisition date to be cash equivalents. Cash equivalents, which consist of money market accounts, are stated at fair value.

Restricted cash: Restricted cash consists of two savings accounts. One is required as collateral for the business credit cards which remains restricted until the contract is terminated and the obligation is paid in full. The second is a security deposit for an office lease in Larkspur, California and remains in place until the lease ends in 2026.

Investments: The Company considers all investments with original maturities of more than three months but less than one year to be short-term investments. All investments in marketable securities are classified as available for sale. Available-for-sale securities are reported at fair value, with temporary unrealized gains and losses excluded from earnings and reported as a separate component of stockholders' equity, while other-than-temporary gains or losses are included in earnings. The cost of securities sold is determined on a specific identification basis, and realized gains and losses are included in other income (expense) within the consolidated statements of operations and comprehensive loss.

Concentration of credit risk and significant customers: Cash, cash equivalents and investments are the primary exposure for the Company to concentrations of credit risk. The Company maintains deposits in government insured financial institutions in excess of government insured limits. The Company deposits its cash in financial institutions that it believes are financially sound and have not experienced any losses on such accounts and does not believe it is exposed to any significant credit risk on cash. Further, management believes that the financial institutions that hold the Company's investments are financially sound and, accordingly, are subject to minimal credit risk. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

On March 10, 2023, Silicon Valley Bank ("SVB") was closed by the California Department of Financial Protection and Innovation, and the Federal Deposit Insurance Corporation ("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, named Silicon Valley Bridge Bank, N.A. ("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 SVBB and confirmed it would honor existing credit facilities. The Amended and Restated Loan and Security Agreement with SVB required an exclusive relationship for our operating cash account, however in light of the events and status of SVB, we entered into an agreement in April 2023 which allows the Company to establish operating accounts and move an additional portion of our cash resources to another financial institution.

There was no significant concentration in any single customer for the years ended December 31, 2023 and 2022.

Fair value of financial instruments: The Company's financial instruments consist of cash equivalents, short-term investments, accounts payable, accrued expenses, a corporate bond and note payable. The carrying amount of accounts payable and accrued expenses are considered a reasonable estimate of their fair value, due to the short-term maturity of these instruments. The Company's cash equivalents and short-term investments are carried at fair value, determined according to the fair value hierarchy described below (see Note 13).

The Company follows the guidance in Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 820, Fair Value Measurements and Disclosures, or ASC 820, which defines fair value and establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy are described below:

Level 1: Inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date.

Level 2: Valuations based on quoted prices in markets that are not active or for which all significant inputs are observable, either directly or indirectly.

Level 3: Prices or valuations that require inputs that are both significant to the fair value measurement and unobservable.

To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Fair value is a market-based measure considered from the perspective of a market participant rather than an entity-specific measure. Therefore, even when market assumptions are not readily available, the Company's own assumptions are set to reflect those that market participants would use in pricing the asset or liability at the measurement date. The Company uses prices and inputs that are current as of the measurement date, including during periods of market dislocation. In periods of market dislocation, the observability of prices and inputs may be reduced for many instruments. This condition could cause an instrument to be reclassified from Level I to Level 2 or Level 2 to Level 3.

Property and equipment: Property and equipment is stated at cost less accumulated depreciation and any accumulated impairment losses. Cost includes expenditure that is directly attributable to the acquisition of the asset. When parts of an item of property and equipment have different useful lives, they are accounted for as separate items (major components) of property and equipment. Depreciation is calculated using the straight-line method over the estimated useful lives of the related assets:

Furniture and fixtures	5-7 years
Computer equipment and software	3 years
Office equipment	3 years
Leasehold improvements	3-7 years (Or remaining term of the lease, if shorter)
Internal-use software	2-5 years

Depreciation methods, useful lives and residual values are reviewed at least annually and adjusted, if appropriate.

Impairment of long-lived assets: The Company periodically reviews the carrying amount of long-lived assets which consist of property and equipment, to determine whether current events or circumstances indicate that such carrying amounts may not be recoverable. Recoverability of assets held and used is measured by comparison of the carrying amount of an asset or an asset group to estimated undiscounted future net cash flows expected to be generated by the asset or asset group. If the carrying amount of an asset exceeds these estimated future cash flows, an impairment charge is recognized by the amount by which the carrying amount of the assets exceeds the fair value of the asset or asset group, based on discounted cash flows. Management judgment is necessary to estimate the fair value of asset groups. Accordingly, actual results could vary significantly from such estimates.

During the year ended December 31, 2023, the Company recognized an impairment loss of $384 related to the sublease of a portion of its office space in Larkspur, California (see Note 7). The fair value measurement of future cash flows from the sublease agreement were estimated using an income approach to determine the present value. Leasehold improvements related to the subleased area are included in the impairment as the Company no longer receives economic benefits after it discontinues use of the space. The impairment loss was comprised of a write-down of $325 for the right-of-use asset and $59 for the leasehold improvements. The impairment loss is included in general and administrative expenses in the consolidated statements of operations and comprehensive loss.

The Company did not identify any circumstances that would warrant an impairment charge for any long-lived assets on the consolidated balance sheet at December 31, 2023.

Internal-use software development costs: With respect to the Company's software products sold under subscription arrangements with customers, costs incurred in the preliminary design and development stages of a project are expensed as incurred in accordance with FASB ASC 350-40, Internal-Use Software. Once a project has reached the application development stage and it is probable that the software will be completed for its intended function, certain internal, external, direct and indirect costs may be subject to capitalization. Generally, costs are capitalized until the technology is available for its intended use. Subsequent costs incurred for the development of future upgrades and enhancements, which are expected to result in additional functionality, follow the same protocol for capitalization. Capitalized software development costs are recorded in property and equipment on the Company's consolidated balance sheets.

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

Sublease: The Company recognizes sublease income on a straight-line basis over the sublease period. The Company recognizes sublease income as an offset to rent expense within operating expenses in the consolidated statements of operations and comprehensive loss as subleasing is not a primary business activity of the Company and is meant to offset occupancy costs.

Deferred revenue: Deferred revenue represents payment received in advance of revenue being earned and is comprised of fees received in advance of the delivery or completion of the services and amounts received in instances when revenue recognition criteria have not been met. Deferred revenue associated with upfront payments for a subscription to the Company's FDA-authorized video game product is amortized ratably over the subscription period.

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 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.

Transaction Costs: As part of the Business Combination, the Company allocated certain transaction costs to the Earn-out Shares based on the relative fair value of these instruments as compared to the other newly issued instruments. The portion of transaction costs allocated to these instruments was reflected as a reduction to cash and an increase in selling, general and administrative expense. The costs were determined to relate to future share issuances and not to the initial recapitalization and therefore they were expensed on the Closing Date. All costs allocated to the other newly issued instruments, which consisted of Common Stock, were recorded in total permanent equity as a reduction of additional paid-in capital.

Revenue: The Company accounts 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.

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

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 while the components are separate performance obligations, they have the

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

same method and pattern of recognition. 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.

In June 2023, the Company released its EndeavorOTC over-the-counter product under the FDA's COVID-19 Guidance. The Company generates revenue from customers who purchase subscriptions of variable term lengths (currently available as either one month 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 Company has generated revenue from a collaboration agreement with Shionogi. The consideration allocated to each performance obligation is recognized as revenue when control is transferred for the related goods or services. For performance obligations that consist of licenses and other promises, the Company applies judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. The Company has determined that the licenses and other promises under the Collaboration Agreement are a single combined performance obligation satisfied over time. The Company must select a single measure of progress that best depicts the Company's measurement of progress. ASC 606-10-26-33 states that appropriate methods of measuring progress include output methods and input methods and notes that an entity should consider the nature of the good or service that the entity promised to transfer to the customer in determining the appropriate method for measuring progress. Since activities performed to research and validate one phase may be useful in researching and validating subsequent phases, the Company believes that an input method, which tracks the Company's efforts required to perform the contracted activities during the contract term, is more representationally faithful than an output method, which might track the agreed upon deliverables that are not similar to one another.

If an arrangement includes development and regulatory milestone payments or royalties, the Company evaluates whether the milestones or royalties are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone or royalty value is included in the transaction price. Payments that are not within the Company's control or the licensee's control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received.

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

	Year Ended December 31,	
	2023	2022
EndeavorOTC revenue	$ 1,155	$ —
EndeavorRx revenue	523	323
Total	$ 1,678	$ 323

There was no collaboration revenue in either period.

As of December 31, 2023, 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 $106 of product revenue in the year ended December 31, 2023 that was previously included in the December 31, 2022 deferred revenue balance.

Contract Liabilities	Product
Balance at December 31, 2022	$ 106
Revenue recognized	523
Revenue deferred	(529)
Balance at December 31, 2023	$ 100

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 software subscriptions related to our products and hosting fees. Sales of EndeavorRx incurred third-party pharmacy dispense fees and 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 Consolidated Statements of Operations and Comprehensive Loss.

Research and development costs: Research and development costs are expensed as incurred. Research and development costs include personnel and related costs, consulting costs, external contract research and development expenses, as well as depreciation and utilities. The Company has several agreements with non-related entities to conduct research on behalf of the Company. The expenses incurred associated with these agreements are expensed as incurred within research and development costs.

Advertising: The Company expenses advertising costs as incurred. Advertising expenses were $6,580 and $7,861 during the years ended December 31, 2023 and 2022.

Accounting for stock-based compensation: Stock-based compensation made to employees and non-employees, including stock options, restricted stock units ("RSUs") and performance stock units with market conditions ("PSUs"), is measured based on the grant date fair value of the awards and is recognized as compensation expense typically on a straight-line basis over the period during which the share-based award holder is required to perform services in exchange for the award (the vesting period) for stock options and RSUs and on an accelerated attribution basis for each vesting tranche over the respective derived service period for PSUs.

The Company classifies stock-based compensation expense in its consolidated statement of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipients' service payments are classified.

The Company recognizes adjustments to stock compensation expense for forfeitures as they occur. The fair value of each stock option grant is estimated on the date of grant using the Black- Scholes option-pricing model. RSUs are measured based on the fair values of the underlying stock on the date of grant. We use the MCSM to estimate the fair value of PSUs. See Note 12 for further discussion of stock-based compensation.

Income taxes: Deferred tax assets and liabilities are recognized based on temporary differences between the financial reporting and income tax basis of assets and liabilities using rates anticipated to be in effect when such temporary differences reverse. A change in tax rates is recognized in income in the period of the enactment date. A valuation allowance against net deferred tax assets is required if, based upon the available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company also assesses the probability that the positions taken or expected to be taken in its income tax returns will be sustained by taxing authorities. A "more likely than not" (more than 50%) recognition threshold must be met before a tax benefit can be recognized. Tax positions that are more likely than not to be sustained on examination by the taxing authorities, based on the technical merits of the position, are reflected in the Company's consolidated financial statements. Tax positions are measured as the largest amount of tax benefit that is greater than 50% likely of being realized upon settlement with a taxing authority that has full knowledge of all relevant information. The difference between the benefit recognized for a position and the tax benefit claimed on a tax return is referred to as an unrecognized tax benefit. Potential interest and penalties associated with such uncertain tax positions are recorded as a component of income tax expense.

Comprehensive Loss: Comprehensive loss includes net loss as well as other changes in stockholders' equity that result from transactions and economic events other than those with stockholders.

Net Loss Per Share: The Company follows the two-class method when computing net loss per share, or EPS, as the Company has issued shares that meet the definition of participating securities. The two-class method determines net loss per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed.

Basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period. Diluted net loss attributable to common stockholders is computed by adjusting net loss attributable to common stockholders to reallocate undistributed earnings based on the potential impact of dilutive securities. Diluted net loss per share attributable to common stockholders is computed by dividing the diluted net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period, including potential dilutive common shares assuming the dilutive effect of common stock equivalents.

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

Segment and Geographic Information: Operating segments are components of an enterprise about which separate financial information is available that is evaluated regularly by the chief operating decision-maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company's chief operating decision maker is its Chief Executive Officer, or CEO. The Company views its operations as and manages its business in one operating segment operating exclusively in the United States.

Emerging Growth Company Status: The Jumpstart Our Business Startups Act of 2012 permits an emerging growth company, or EGC, such as Akili to take advantage of an extended transition period to comply with the new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. The Company has elected to use this extended transition period under the JOBS Act until such time the Company is no longer considered to be an EGC, which means that when a standard is issued or revised, it has different applications for public or private companies, the Company will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that the Company either (i) irrevocably elect to "opt-out" of such extended transition period or (ii) no longer qualify as an EGC.

Recently adopted accounting pronouncements: In June 2016, the FASB issued ASU No. 2016-13, *Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"), as amended by ASU 2019-10. ASU 2016-13 will change how companies account for credit losses for most financial assets and certain other instruments. For trade receivables, loans and held-to-maturity debt securities, companies will be required to recognize an allowance for credit losses rather than reducing the carrying value of the asset. ASU 2016-13 is effective for the Company for the annual reporting period beginning January 1, 2023. The Company adopted this guidance for the year ended December 31, 2023, however there was no impact to the financial statements.

3. Business Combination

As discussed in Note 1, on August 19, 2022, the Company consummated the Business Combination pursuant to the Merger Agreement. The Business Combination was accounted for as a reverse recapitalization in accordance with GAAP. Under this method of accounting, SCS, who was the legal acquirer, was treated as the "acquired" company for financial reporting purposes. Accordingly, the Business Combination was treated as the equivalent of Akili issuing stock for the net assets of SCS, accompanied by a recapitalization.

Upon the Closing, holders of Legacy Akili common stock received shares of Common Stock in an amount determined by application of the exchange ratio of approximately 1.15 (the "Exchange Ratio"), which was based on Legacy Akili's implied price per share prior to the Business Combination. For periods prior to the Business Combination, the reported share and per share amounts have been retroactively converted by applying the Exchange Ratio. The consolidated assets, liabilities and results of operations prior to the Business Combination are those of Legacy Akili.

In connection with the Business Combination, approximately $31,438 of transaction related expenses and other costs were incurred.

The following table reconciles the elements of the Business Combination to the consolidated statement of cash flows and the consolidated statement of changes in equity:

	Year ended December 31, 2022
Cash - SCS trust and cash (net of redemptions)	$ 2,283
Cash - PIPE investors	162,000
Gross proceeds	164,283
Transaction related expenses and other costs paid at Closing (of which $8,850 represent the Company's transaction costs)	(30,989)
Transaction related expenses and other costs paid after Closing	(449)
Net proceeds from the Business Combination	132,845

In addition to the $8,850 paid at Closing noted in the table above, the Company incurred $4,077 in additional transaction costs related to certain legal, accounting, consulting and other third-party fees incurred. These transaction costs were incurred and paid during the year ended December 31, 2022. Of the Company's total transaction costs of $12,927, $3,046 was allocated to the Earn-Out Shares and expensed upon the Closing, based on the relative fair value of the Earn-Out Shares as compared to the other newly issued instruments as part of the Business Combination. The remaining Company transaction costs were recorded in additional paid-in capital.

The number of shares of Common Stock outstanding immediately following the Closing was as follows:

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

	Common Stock
SCS public stockholders	227,522
SCS sponsor and independent director	6,890,000
Legacy Akili stockholders [(1)]	54,541,224
PIPE investors	16,200,000
Total shares of Common Stock immediately after Closing	77,858,746

(1) The number of Legacy Akili shares was determined from the shares of Legacy Akili shares outstanding immediately prior to the Closing converted at the Exchange Ratio of approximately 1.15. The amount includes the cashless exercise of certain outstanding Akili Interactive Labs, Inc. warrants, which resulted in the issuance of 8,834 shares of Common Stock. All fractional shares were rounded down. Amount excludes the issuance of 7,536,461 Earn-Out Shares (as defined below), as the performance conditions have not yet been satisfied.

Earn-Out Shares:

Earn-Out Shareholders and Earn-Out Service Providers received the contingent right to receive additional shares of Common Stock upon the achievement of certain earn-out targets. Earn-Out Shareholders and Earn-Out Service Providers are eligible to receive up to 7,536,461 shares in the aggregate (the "Earn-Out Shares") of additional Common Stock in three equal tranches upon the Company achieving $15.00, $20.00, or $30.00, respectively, as its volume-weighted average price per share of Common Stock for any 20 trading days within a 30 consecutive trading day period (as adjusted for share splits, reverse share splits, share dividends, reorganizations, recapitalizations, reclassifications, combination, exchange of shares, or the like).

As the Earn-Out Shares to Earn-Out Shareholders contain a settlement provision that precludes them from being indexed to the Company's stock under ASC 815, *Derivatives and Hedging*, they are classified as liabilities. The Company accounts for the potential issuance of the Earn-Out Shares to Earn-Out Shareholders as a contingent consideration arrangement, a liability for which was initially valued and recorded using a MCSM for each earn-out period. Key inputs and assumptions were the Company's stock price, expected term, volatility, the risk-free rate, and dividend yield. Some of these inputs are Level 3 assumptions that are updated each reporting period as the earn-out liabilities are recorded at fair value on a recurring basis. The Company revalued the earn-out liabilities as of December 31, 2023 and the change in the fair value of the earn-out liabilities was recorded in other income (expense) on the statement of operations.

As the Earn-Out Shares to Earn-Out Service Providers are indexed to whether such Earn-Out Service Providers hold qualifying equity instruments when the earn-out targets are achieved, they are classified as a liability under ASC 718, "*Compensation-Stock Compensation*". The Company accounts for the potential issuance of the Earn-Out Shares to Earn-Out Service Providers as the grant of a compensatory award under ASC 718. As there are no continuing service obligations, the awards were expensed on the date of the Business Combination and the fair value is updated each reporting period. The change in fair value is recorded as stock compensation for the period in the same functional category as the grantees' operating expenses.

	Earn-Out Shareholders	Earn-Out Service Providers	Total
Fair value as of December 31, 2022	$ 4,778	$ 735	$ 5,513
Change in fair value	(3,363)	(518)	(3,881)
Fair value as of December 31, 2023	$ 1,415	$ 217	$ 1,632

4. Option and Collaboration Agreements

Shionogi & Co., Ltd.

On December 19, 2018, the Company entered into an Option and Collaboration Agreement (the "Collaboration Agreement") with Shionogi & Co., Ltd ("Shionogi"), whereby the Company granted an option to Shionogi to develop and commercialize licensed digital therapeutic software products in specified territories.

As part of the agreement, Shionogi made an upfront payment to the Company of $10,000 at the date of execution that provided Shionogi up to April 15, 2019 to continue to evaluate the technology. In March 2019, Shionogi exercised its option to license the technology in exchange for another $10,000 cash payment. In connection with Shionogi exercising its option to enter into the Collaboration Agreement, the Company issued a $5,000 corporate bond to Shionogi for cash, with an initial discount estimated to be $3,805 (see Note 9). With the execution of the option, the Company is eligible to receive development and commercial milestones of up to $105,000. In addition, the Company will receive royalties on sales of the licensed products in Japan and Taiwan. In October 2019, the Company and Shionogi entered into a modification scope of work agreement. Shionogi paid the Company an additional fee of $387 as a result of the modification. As all obligations under the Collaboration Agreement were fulfilled, revenue of $24,192 was recognized by the end of 2021. The Company did not recognize any milestones or royalties during the years ended December 31, 2023 and 2022.

TALi Digital Limited

On October 16, 2023, Akili Interactive Labs, Inc., a wholly owned subsidiary of the Company, and TALi Digital Limited mutually agreed to terminate the License, Development and Commercialization Agreement dated as of August 16, 2021 between such parties, effective as of October 16, 2023. As a result of the termination, no additional payments are due to TALi. During the year ended December 31, 2023, the Company did not make any payments for out of pocket costs related to this agreement. As of the termination date, the Company has not made any payments for milestones or royalties related to this agreement.

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

5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	December 31,	
	2023	2022
Prepaid insurance	$ 1,008	$ 1,892
Prepaid clinical trials	-	697
Other current assets	1,267	1,976
Prepaid expenses and other current assets	$ 2,275	$ 4,565

6. Property and Equipment

Property and equipment, net consisted of the following:

	December 31,	
	2023	2022
Furniture and fixtures	$ 116	$ 184
Computer equipment and software	269	477
Office equipment	44	60
Leasehold improvements	885	975
Capitalized internal-use software costs	551	427
Total property and equipment	1,865	2,123
Less: accumulated depreciation and amortization	(1,185)	(1,204)
Property and equipment, net	$ 680	$ 919

Depreciation and amortization expense was $302 and $308 for the years ended December 31, 2023 and 2022, respectively.

7. Commitments and Contingencies

Litigation: From time to time, the Company is a party to or can be threatened with litigation in the ordinary course of business. The Company regularly analyzes current information, including, as applicable, the Company`s defenses and insurance coverage, and, as necessary, provides accruals for probable and estimable liabilities for the eventual disposition of any matters. The Company was not a party to any material legal proceedings as of the years ended December 31, 2023 and 2022.

Office Space: As of December 31, 2023, the Company leases office space under a non-cancelable operating lease in Larkspur, California, which consists of approximately 43,600 square feet pursuant to a lease that will expire in November 2026, in exchange for approximately $74 per month, subject to an annual 4% increase each May. The Company provided a customary letter of credit in the amount of $250 as a security deposit, which is included in restricted cash within the consolidated balance sheets.

In May 2023, the Company entered into a sublease agreement, pursuant to which the Company agreed to sublease approximately 5,716 rentable square feet of the Larkspur, California office space to a third party for a term commencing on June 1, 2023 and ending coterminous with the Larkspur, California lease in November 2026, in exchange for the sum of approximately $23 per month, subject to an annual 4.0% increase.

The lease for office space in Boston, Massachusetts consisting of approximately 4,000 square feet expired in December 2023.

In November 2023, the Company entered into a membership agreement, pursuant to which the Company agreed to pay a monthly membership fee for the sum of approximately $9 per month for access to office space in Boston, Massachusetts, with such access commencing on January 1, 2024. The agreement is for a one-year term and will automatically renew for successive one-year terms, subject to the Company’s right to terminate the agreement upon prior written notice and pursuant to the terms of the membership agreement and is classified as a short-term lease.

These leases do not include any restrictions or covenants that had to be accounted for under the new lease guidance.

During the years ended December 31, 2023 and 2022, the Company recognized $757 of rent expense, net of sublease payments received and $1,026 of rent expense, respectively.

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

Net cash paid for the amounts included in the measurement of the operating lease liability on the consolidated balance sheet and operating activities in the consolidated statement of cash flow was $1,042 for the year ended December 31, 2023. The weighted average remaining lease term and incremental borrowing rate as of December 31, 2023 was 2.9 years and 7.6%, respectively.

Future lease payments for our noncancelable operating leases (excluding short-term leases) as of December 31, 2023 and a reconciliation to the carrying amount of the operating lease liability presented in the consolidated balance sheet as of December 31, 2023 is as follows:

Years Ending December 31,	Amounts
2024	$ 914
2025	950
2026	904
Total undiscounted payments due under operating leases	2,768
Less imputed interest	(282)
Total	$ 2,486
Current operating lease liability	$ 756
Non-current operating lease liability	1,730
Total	$ 2,486

8. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	December 31,	
	2023	2022
Accrued bonus	$ 2,355	$ 2,819
Accrued royalties	150	110
Accrued wages and benefits	200	1,281
Accrued clinical study expenses	12	292
Accrued consulting service expenses	129	401
Other accrued expenses	480	713
Total	$ 3,326	$ 5,616

9. Corporate Bond

In March 2019, in connection with Shionogi exercising its option to enter into the Collaboration Agreement, the Company issued a $5,000 corporate bond to Shionogi for cash. 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 maturity date of the corporate bond is November 10, 2031 and does not bear interest during its term (fixed interest rate of 0.0%). The corporate bond is prepayable by the Company at any time without penalty. The repayment of the corporate bond can be accelerated upon the termination of the Collaboration Agreement or upon the occurrence of an event of default (as defined), in both cases without penalty.

The Company determined that the interest rate on the corporate bond did not reflect a market interest rate that the Company would expect to incur on a similar instrument issued apart from the Collaboration Agreement. As such, the Company estimated the market rate of interest for a similar instrument (as 12.0%) and recorded a discount on the corporate bond at issuance in order to impute interest at this rate over the term of the instrument. The initial discount on the corporate bond was estimated to be $3,805. As the corporate bond was issued in connection with the Collaboration Agreement, the Company also added the estimated initial discount as a component of the transaction price (and an adjustment to revenue recognized) related to the Collaboration Agreement. The Company amortizes the initial discount to interest expense using the effective interest method over the term of the corporate bond.

The Company recognized amortization expense of $220 and $196 related to the discount on the Corporate Bond as a component of interest expense in the consolidated statements of operations and comprehensive loss for the years ended December 31, 2023 and 2022, respectively.

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

The carrying amount of the corporate bond is as follows:

	2023	2022
Corporate Bond	$ 5,000	$ 5,000
Unamortized discount on Corporate Bond	(2,946)	(3,166)
Corporate Bond, net of discount	$ 2,054	$ 1,834

10. Note Payable

Amended and Restated Loan and Security Agreement

On May 25, 2021, the Company entered into an Amended and Restated Loan and Security Agreement with Silicon Valley Bank ("SVB") and SVB Innovation Credit Fund VIII, L.P. ("SVB Innovation Fund") (collectively, the "Lenders"). In December 2022, we entered into a Joinder and First Loan Modification Agreement with SVB (the "Amended SVB Term Loan"). As described in Note 2, First Citizens BancShares, Inc. entered into an agreement to purchase all assets and liabilities of SVBB and will fully honor the existing Amended SVB Term Loan.

The Company borrowed $5,000 in May 2021 and $10,000 in June 2022 and made interest-only payments through May 2023 before beginning to repay the outstanding principal in 24 equal monthly payments on the first day of each month beginning June 1, 2023, plus interest. The maturity date of the Amended and Restated Loan and Security Agreement is May 1, 2025.

The Amended and Restated Loan and Security Agreement accrues interest on each advance at a per annum rate of the greater of (a) the Wall Street Journal prime rate plus 3.75% or (b) 7.0%. The Company can elect to prepay all, but not less than all, of the advances drawn prior to the maturity date. The Company will be required to pay a prepayment fee, calculated by multiplying the outstanding principal balance outstanding immediately prior to such prepayment by 1.0%. The Company will be required to make a final payment equal to 5.0% of the total amounts drawn from each tranche (the "Final Payment"), due upon the earliest of maturity, prepayment or termination of the amounts drawn under the Amended and Restated Loan and Security Agreement.

The Loan and Security Agreement is secured by substantially all of the Company's personal property assets, including accounts receivable, equipment, license agreements, general intangibles, inventory and investment property, and all of the proceeds and products of the foregoing. The Company is also subject to certain financial and non-financial covenants in the Loan and Security Agreement, including requirements to maintain operating and deposit accounts with the lender and restrictions on certain corporate actions.

Upon closing of the Amended and Restated Loan and Security Agreement, the Company entered into warrant agreements with the Lenders ("Warrant Agreements"). As part of the Warrant Agreements, the Company issued fully-vested warrants to purchase 84,350 shares of common stock to the Lenders with an exercise price of $3.82 per share with a fair value of $268 on the date of issuance (see Note 11 for details). As a result of the $10,000 draw in June 2022, warrants to purchase 31,242 shares became available with a fair value of $282.

In relation to the entering into the Amended and Restated Loan and Security Agreement, the Company incurred a total of $559 of debt issuance costs (including the fair value of the warrants granted to the Lenders, plus the $250 Final Payment). The Company incurred an additional $782 of debt issuance costs related to the $10,000 draw in June 2022 (including the fair value of the warrants granted to the Lenders, plus the $500 Final Payment). The Company is amortizing the deferred issuance costs to interest expense on the effective interest method through the maturity date of the Amended and Restated Loan and Security Agreement.

At December 31, 2023, the Company had outstanding principal of $10,625 and there is no remaining available undrawn debt. The Company recognized non-cash interest expense related to debt issuance costs of $503 and $341 for the years ended December 31, 2023 and 2022, respectively. The Company recognized selling, general and administrative expense related to loan commitment fees of $42 and $211 for the years ended December 31, 2023 and 2022 respectively. The interest rate in effect was 12.3% and 11.3% as of December 31, 2023 and 2022, respectively. The weighted average interest rate was 11.9% and 9.2% for the years ended December 31,

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

2023 and 2022, respectively. At December 31, 2023, the carrying amount of the note payable (excluding the current portion of $7,500) is as follows:

Outstanding principal	$	10,625
Note payable, short term		(7,500)
Final payment		750
Unamortized debt issuance costs		(430)
Note payable, long term (net of debt issuance costs)	$	3,445

Future minimum principal payments due under the Amended and Restated Loan and Security Agreement, excluding the Final Payment, are as follows:

Years Ending December 31,		
2024	$	7,500
2025		3,125
Total	$	10,625

11. Capital Stock

The Company's authorized capital stock consists of 1,000,000,000 shares of Common Stock, par value $0.0001 per share and 100,000,000 shares of preferred stock, par value $0.0001 per share. As of December 31, 2023, there were 78,356,527 shares of Common Stock issued and outstanding and 133,578 warrants outstanding to purchase Common Stock. There were no shares of preferred stock issued and outstanding.

The holders of the Common Stock are entitled to one vote for each share of Common Stock. The holders of Common Stock shall be entitled to receive dividends out of funds legally available. In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, the holders of Common Stock shall be entitled to share ratably in the remaining assets of the Company available for distribution. The Board or any authorized committee thereof is authorized to issue shares of preferred stock and to fix the designations, powers, including voting powers, full or limited, or no voting powers, preferences and the relative, participating, optional or other special rights of the shares of each series and any qualifications, limitations and restrictions thereof.

Legacy Convertible Preferred Stock:

Prior to the Business Combination, Legacy Akili had issued Series A-1 convertible preferred stock, Series A-2 convertible preferred stock, Series B convertible preferred stock, Series C convertible preferred stock and Series D convertible preferred stock, collectively referred to as the “Legacy Convertible Preferred Stock.” In connection with the Business Combination, the Legacy Convertible Preferred Stock was retroactively adjusted, converted into Common Stock at an exchange ratio of approximately 1.15, and reclassified to permanent equity as a result of the reverse recapitalization. As of December 31, 2023, there is no Legacy Convertible Preferred Stock authorized, issued or outstanding.

Common Stock Warrants: In May 2021, the Company entered into the Amended and Restated Loan and Security Agreement (see note 10). In conjunction with this modification, the Company issued warrants to the Lenders to purchase a total of 224,938 shares of common stock with an exercise price of $3.82 per share, of which, 84,350 were fully vested and immediately exercisable. These warrants were determined to be a separate freestanding instrument from the Amended and Restated Loan and Security Agreement. The Company also concluded that the remaining warrants that could vest in future periods in connection with additional loan advances will be treated as separate issuances if and when they are issued. In connection with the June 2022 draw, warrants to purchase an additional 31,242 shares of common stock became vested. The Company considered the accounting for the warrants and concluded that they met the requirements for equity classification under ASC 815-40. Upon initial issuance, the vested warrants to purchase the Company’s common stock were recorded at fair value. The Company utilized the Black- Scholes option valuation approach to value the common warrants that were issued, resulting in an estimated fair value of $268 in May 2021 and $282 in June 2022. The Company recorded this amount as an increase to additional paid-in capital and an increase to debt issuance costs (see Note 10).

The Company determined the fair value of the warrants using the Black-Scholes option model with the following assumptions:

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

Amended and Restated Loan and Security Agreement Warrants	May 2021	June 2022
Fair value of common stock	$3.82	$10.06
Expected volatility	95.00%	96.56%
Expected term (in years)	10.00	8.91
Risk-free interest rate	1.56%	3.23%
Expected dividend yield	0.00%	0.00%

In August 2020, the Company entered into the First Loan Modification Agreement with SVB. In conjunction with this modification, the Company issued warrants to the lender, of which, 17,986 are fully vested and outstanding as of December 31, 2023. The warrants have an exercise price of $5.95 per share.

Employee Stock Purchase Plan

In connection with the Closing, the Company adopted the 2022 Employee Stock Purchase Plan (the "2022 ESPP"). The 2022 ESPP is a shareholder-approved plan under which substantially all employees may voluntarily enroll to purchase the Company's Common Stock through payroll deductions at a price equal to 85% of the lower of the fair market values of the stock as of the offering date or the exercise date, provided that no offering shall exceed 27 months. An employee's payroll deductions under the 2022 ESPP are limited to 15% of the employee's compensation and employees may not purchase more than $25,000 of stock during any calendar year.

A total of 1,167,881 shares of our Common Stock are reserved and authorized for issuance under the 2022 ESPP. In addition, the number of shares of Common Stock available for issuance under the 2022 ESPP is automatically increased each January 1 of each calendar year beginning on January 1, 2023, and ending in 2031, by the least of (i) the excess (if any) of (A) 1% of the outstanding shares issued and outstanding on the immediately preceding December 31st (excluding any shares reserved for issuance under equity-based plans of Akili, Inc. including the 2022 Stock Option and Incentive Plan and the 2022 ESPP) over (B) the number of shares of stock then reserved for issuance under the 2022 ESPP as of such date, (ii) 1,167,881 or (iii) such number of shares determined by the administrator. Through December 31, 2023, no shares have been issued under the 2022 ESPP.

12. Stock-Based Compensation

2011 Stock Incentive Plan: Prior to the Business Combination, the Company's 2011 Stock Incentive Plan (the "2011 Plan") allowed the Company to grant incentive stock options, nonqualified stock options, and restricted stock to employees, directors, and nonemployees of the Company. Upon the Closing, the remaining unallocated share reserve under the 2011 Plan was cancelled and no new awards will be granted under such plan. Awards outstanding under the 2011 Plan were assumed by Akili, Inc. upon the Closing and continue to be governed by the terms of the 2011 Plan.

2022 Stock Option and Incentive Plan: In 2022, the Board approved the 2022 Stock Option and Incentive Plan, (the "2022 Plan"), which provides for the grant of incentive stock options, nonqualified stock options, and restricted stock to employees, directors, and nonemployees of the Company up to an aggregate of 12,813,781 shares of the Company's Common Stock.

During the year ended December 31, 2023, the Company incurred cash outflows of $118 related to the payment of withholding taxes for vested RSUs. These cash outflows are presented within net cash provided by financing activities in the consolidated statements of cash flows.

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

	Year Ended December 31,	
	2023	2022
Research and development	$ 2,526	$ 3,493
Selling, general and administrative	4,281	5,816
Total	$ 6,807	$ 9,309

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

Included in the years ended December 31, 2023 and 2022 balances in the table above is $(518) and $735, respectively, of stock-based compensation related to the potential issuance of the Earn-Out Shares to Earn-Out Service Providers, as described in Note 3.

Stock Options: The terms of the stock option grants, including the exercise price per share and vesting periods, are determined by the Board or by the compensation committee of the Board, as applicable.

Stock options are typically granted at exercise prices equal to the fair value of our common stock at the date of grant. Our stock options typically vest at a rate of 25% after one year from the vesting commencement date and then every six months over an additional three-year period. While the vesting schedule noted is typical, stock options have been issued under other vesting schedules. These alternative schedules include, but are not limited to (i) vesting at a rate of 25% every six months for two years, (ii) vesting at a rate of 16.67% every six months for three years, and (iii) vesting at a rate of 12.5% every six months for four years. The stock options expire ten years from the grant date or within 90 days of employee termination.

The following is a summary of stock option activity for the year ended December 31, 2023:

	Number of Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Balance at December 31, 2022	12,190,970	$ 3.98	7.36	
Granted	5,199,280	$ 0.86		
Cancelled	(2,769,719)	$ 3.58		
Exercised	(28,778)	$ 0.03		
Balance at December 31, 2023	14,591,753	$ 2.94	7.31	$ 285
Exercisable December 31, 2023	7,593,913	$ 3.71	5.53	$ 99
Options vested and expected to vest, December 31, 2023	14,591,753	$ 2.94	7.31	$ 285

During the year ended December 31, 2023 the Company extended the exercise period for vested options from three months to two years for 69 terminated employees. Incremental compensation expenses related to this modification recorded during the year ended December 31, 2023 was $208.

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 years ended December 31, 2023 and 2022:

	Year Ended December 31,	
	2023	2022
Fair value of Common Stock	$ 0.86	$ 5.03
Expected volatility	104.32%	99.19%
Expected term (in years)	5.92	5.93
Risk-free interest rate	4.10%	3.34%
Expected dividend yield	0.00%	0.00%

Fair value of Common Stock: The fair value of the underlying common stock was determined by the Board until the Company became listed on an established stock exchange. The fair value was based upon a variety of factors, including the results obtained from independent third-party valuations, the Company's financial position and historical financial performance, the status of technological developments within the Company's products, the composition and ability of the current clinical and management team, an evaluation or benchmark of the Company's competition, the current business climate in the marketplace, the illiquid nature of the common stock, arm's length sales of the Company's capital stock (including preferred stock), the effect of the rights and preferences of the preferred stockholders, and the prospects of a liquidity event, among others.

Expected volatility: As there is not sufficient historical volatility for the expected term of the options, the Company used an average historical share price volatility based on an analysis of reported data for a peer group of comparable companies, which were selected based upon industry similarities.

Expected term (in years): Expected term represents the period that the Company's share option grants are expected to be outstanding. There is not sufficient historical share exercise data to calculate the expected term of the options. Therefore, the Company utilizes the

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

"simplified" method for all options granted to value share option grants. Under this approach, the weighted-average expected life is presumed to be the average of the vesting term and the contractual term of the option.

Risk-free interest rate: The Company determined the risk-free interest rate by using a weighted-average equivalent to the expected term based on the U.S. Treasury yield curve in effect as of the date of grant.

Expected dividend yield: The Company does not anticipate paying any dividends in the foreseeable future.

The weighted average grant-date fair value of stock options granted to employees during the years ended December 31, 2023 and 2022 was $0.70 and $3.94 per share, respectively.

During the years ended December 31, 2023 and 2022, the aggregate intrinsic value of stock option awards exercised was $40 and $504, 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 December 31, 2023 there was $10,219 of unrecognized compensation cost related to unvested stock option grants to employees, which is expected to be recognized over a weighted-average period of 2.2 years.

Restricted Stock Units: The Company began issuing RSUs to its employees in 2022. RSUs are equity awards granted to employees that entitle the holder to shares of the Company's common stock when the awards vest. RSUs granted to newly hired employees typically vest 25% on the first vesting date, which occurs approximately one year after the date of grant, and ratably each six months of the ensuing three year period. RSUs have been issued under other vesting schedules. These alternative schedules include, but are not limited to, (i) vesting at a rate of 16.67% every six months over three years, (ii) vesting at a rate of 12.5% every six months over four years, and (iii) vesting at a rate of 25% every six months over two years. RSUs are measured based on the fair value of the Company's common stock on the date of grant.

The following table summarizes RSU activity for the year ended December 31, 2023:

	Number of RSUs	Weighted-Average Grant Date Fair Value
Balance at December 31, 2022	801,401	$2.30
Granted	3,121,125	$0.82
Vested	(321,739)	$2.08
Forfeited	(601,950)	$1.74
Balance at December 31, 2023	2,998,837	$0.89

As of December 31, 2023 there was $2,435 of unrecognized compensation cost related to unvested RSUs under the 2022 Plan, which is expected to be recognized over a weighted-average period of 2.5 years.

Performance Stock Units:

PSUs are equity awards granted to employees that, upon vesting, entitle the holder to shares of the Company's common stock. Under the 2022 Plan, the Company granted PSUs that will vest, if at all, on a graded basis during the five-year period commencing on November 2, 2022, subject to the achievement of specified performance goals related to the volume-weighted average closing price of the Company's common stock over a 30-trading day period. As such, these awards are considered to contain a market condition. All PSUs are subject to continued employment on the date of vesting.

The following table summarizes PSU activity for the year ended December 31, 2023:

	Number of PSUs	Weighted-Average Grant Date Fair Value
Balance at December 31, 2022	4,554,408	$1.50
Granted	—	n/a
Vested	—	n/a
Forfeited	(2,526,274)	$1.50
Balance at December 31, 2023	2,028,134	$1.50

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

Compensation cost associated with PSUs is recognized on a straight-line basis over the derived service period of each of the three vesting tranches, which vest upon the achievement of three different volume-weighted average closing prices of the Company's common stock. The Company determines the grant-date fair values of PSUs utilizing a MCSM. The Company's use of a MCSM requires the use of the following inputs:

Current stock price: the closing stock price as quoted on Nasdaq as of November 2, 2022 was $2.30.

Risk-free interest rate: the risk-free interest rate of 4.3% was based on the U.S. Treasury rate at the time of grant commensurate with the remaining term of the PSUs.

Expected term: the expected term is the five-year term of the PSUs.

Expected volatility: the volatility rate as of November 2, 2022 was 95.0%. 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.

As of December 31, 2023, there was $1,737 of unrecognized compensation cost related to unvested PSUs, which is expected to be recognized over a weighted average period of approximately 1.6 years.

13. 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 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

	Fair Value Measurements as of December 31, 2022			
Description	Level 1	Level 2	Level 3	Total
Assets				
Cash equivalents:				
Money market funds	$ 32,829	$ -	$ -	$ 32,829
Short-term investments:				
United States treasuries	82,034	-	-	82,034
Total assets	$ 114,863	$ -	$ -	$ 114,863
Liabilities				
Long-term liabilities:				
Earn-out liabilities	-	-	5,513	5,513
Total liabilities	$ -	$ -	$ 5,513	$ 5,513

The Company evaluates transfers between levels at the end of each reporting period. There were no transfers of financial instruments between levels during the years ended December 31, 2023 and 2022.

As of December 31, 2023 and 2022, the Company's cash equivalents consisted of money market funds with original maturities of less than 90 days from the date of purchase. As of December 31, 2023, the Company did not hold short-term investments. As of December 31, 2022, the Company's short-term investments consisted of United States treasuries with original maturities of more than three months but less than one year.

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

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

Company, with the change in fair value recognized in "Change in estimated fair value of earn-out liabilities" in the consolidated statement of operations.

The estimated fair value of the Earn-out Shares was determined using a MCSM using the following assumptions at December 31, 2023:

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 December 31, 2023 was $0.49.

Expected term: the expected term is 3.6 years as of December 31, 2023, which is the remaining term of the earn-out period.

Expected volatility: the volatility rate as of December 31, 2023 was 119.5%. 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.

See Note 3 for a table that reconciles the change in fair value of the earn-out liabilities valued using Level 3 inputs.

14. Income Taxes

The provision for income taxes consists of the following components:

	Years Ended December 31,	
	2023	2022
Current		
Federal	$ —	$ —
State	53	19
Total current expense (benefit)	53	19
Deferred		
Federal	-	-
State	-	-
Total deferred expense (benefit)	$ —	$ —
Total tax recognized	$ 53	$ 19

A reconciliation setting forth the differences between effective tax rate of the Company as well as the U.S. federal statutory tax rate is as follows:

	Years Ended December 31,	
	2023	2022
Benefit at federal statutory rate	21.00%	21.00%
State taxes	4.73%	54.48%
Credits	1.38%	13.63%
Transaction costs	0.00%	(6.22%)
Gain on earn-out shares	1.19%	218.69%
Share-based payment measurement	(0.78%)	(10.45%)
Other	(0.10%)	2.56%
Change in valuation allowance	(27.51%)	(293.93%)
Effective tax rate	(0.09%)	(0.24%)

Significant components of the Company's deferred tax assets and liabilities are as follows:

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

	Years Ended December 31,	
	2023	2022
Deferred tax assets:		
Operating tax losses	$ 67,464	$ 55,350
Research credits	8,586	7,416
Temporary differences	1,240	1,337
Research and development costs	6,799	4,823
Start-up costs	2,075	2,197
Lease liability	617	847
Share based payments	4,484	3,298
Gross deferred tax assets	91,265	75,268
Valuation Allowance	(90,364)	(74,010)
Deferred tax assets, Less: valuation allowance	901	1,258
Deferred tax liabilities:		
Right-of-use asset	(391)	(664)
Other temporary differences	(510)	(594)
Deferred tax liabilities	(901)	(1,258)
Total	$ —	$ —

Deferred income taxes reflect the net tax effect of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amount used for income tax purposes. At December 31, 2023, the Company has federal net operating loss carryforwards totaling $275,482 of which $31,208 begin to expire in 2031 and $244,274 can be carried forward indefinitely. At December 31, 2023, the Company had state net operating loss carryforwards totaling $162,969, which begin to expire in 2031, as well as other temporary differences that will be available to offset regular taxable income during the carryforward period.

Additionally, at December 31, 2023, the Company has federal R&D credit carryforwards totaling $6,330 which begin to expire in 2039, state R&D credit carryforwards totaling $2,856 which begin to expire in 2033.

The net change in the valuation allowance for deferred tax assets was an increase of $16,354 and $27,723 for the years ended December 31, 2023 and 2022, respectively. This increase for the years ended December 31, 2023 and 2022 was primarily due to the generation of net operating loss carryforwards, capitalized R&D expenditures as required by changes to the tax laws from the TCJA as described below, and capitalized start-up costs.

On December 22, 2017, the Tax Cuts and Jobs Act (“TCJA”) was signed into law. Under the TCJA provisions, effective with tax years beginning on or after January 1, 2022, taxpayers can no longer immediately expense qualified research and development (“R&D”) expenditures and are required to capitalize and amortize the costs under section 174. Accordingly, the Company capitalized $13,906 and $20,859 of R&D expenses as of December 31, 2023 and 2022, respectively. These costs will be amortized for tax purposes over 5 years for R&D performed in the U.S. and over 15 years for R&D performed outside the U.S.

Management of the Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets, which are comprised principally of net operating loss carryforwards and research and development credits. Under the applicable accounting standards, management has considered the Company’s history of losses and concluded that it is more likely than not that the Company will not recognize the benefits of domestic deferred tax assets. Accordingly, a full valuation allowance has been established at December 31, 2023 as the Company is in development stage and does not have assurance of future income as the Company expects to generate continued losses while in development.

Under the provisions of the Internal Revenue Code, the net operating loss and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. Net operating loss and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code, respectively, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the value of the Company immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. The Company has completed financings since its inception which may have resulted in a change in control as defined by Section 382 and 383 of the Internal Revenue Code, and it may complete future financings that could result in a change in control in the future. The Company has not, as yet, conducted a study to determine if any such changes have occurred that could limit its ability to use the net operating loss and tax credit carryforward. Also, the Company has undertaken only a preliminary analysis of its research and experimentation credits. In order to substantiate fully such credits it intends to complete a full credit study before such credits are utilized on its tax return.

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

The Company accounts for uncertain tax positions pursuant to ASC 740 which prescribes a recognition threshold and measurement process for financial statement recognition of uncertain tax positions taken or expected to be taken in a tax return. If the tax position meets this threshold, the benefit to be recognized is measured as the largest amount of tax benefit that is greater than 50% likely of being realized upon settlement with a taxing authority that has full knowledge of all relevant information. As of December 31, 2023 and 2022, the Company has not recorded any unrecognized tax benefits. The Company has not, as yet, conducted a study of research and development tax credit carryforwards. This study may result in an adjustment to the Company's research and development credit carryforwards; however, until a study is completed, and any adjustment is known, no amounts are being presented as an uncertain tax position. A full valuation allowance has been provided against the Company's research and development tax credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the consolidated balance sheets or consolidated statement of operations and comprehensive loss if an adjustment was required. The Company does not expect any material changes in the unrecognized tax benefits within the next twelve months.

15. Net Loss Per Share

The following table summarizes the computation of basic and diluted net loss per share attributable to common stockholders of the Company:

	Year Ended December 31,	
	2023	2022
Numerator:		
Net loss	$ (59,493)	$ (7,964)
Dividends on Series D convertible preferred stock	-	(7,383)
Redemption value of Series D convertible preferred stock	-	(3,692)
Net loss attributable to common stockholders - basic and diluted	$ (59,493)	$ (19,039)
Denominator:		
Weighted average common stock outstanding	78,197,107	29,878,041
Net loss per share attributable to common stockholders - basic and diluted	$ (0.76)	$ (0.64)

For periods in which the Company reports a net loss attributable to common stockholders, potentially dilutive securities have been excluded from the computation of diluted net loss per share as their effects would be anti-dilutive. Therefore, the weighted average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at period end, from the computation of diluted net loss per share attributable to common stockholders because including them would have had an anti-dilutive effect:

	Year Ended December 31,	
	2023	2022
Warrants to purchase Common Stock	133,578	242,924
Stock options to purchase Common Stock	14,591,753	12,190,970
Earn-out shares	7,536,461	7,536,461
Unvested RSUs	2,998,837	801,401
Unvested PSUs	2,028,134	4,554,408
Total	27,288,763	25,326,164

16. Employee Benefit Plan

The Company has a 401(k) retirement plan in which substantially all U.S. employees are eligible to participate. Eligible employees may elect to contribute up to the maximum limits, as set by the Internal Revenue Service, of their eligible compensation. The total contribution matching expense for the Company was $689 and $784 for the years ended December 31, 2023 and 2022, respectively.

17. Restructuring Charges

On January 12, 2023, the Company announced a restructuring of its operations and a reduction in workforce. As a result of the restructuring, the Company incurred a restructuring charge of $2,329 associated primarily with severance and other termination-related benefits related to 48 full-time employees, representing approximately 31% of the employee base at the time of the

restructuring. All costs associated with the restructuring were recorded within operating expenses in the same functional category as the employees' operating expenses in the quarter ended March 31, 2023. The restructuring reduced costs related to certain of the Company's pipeline programs in order to prioritize certain of its commercial efforts and its ADHD label expansion programs.

On September 13, 2023, the Company announced a further restructuring of its operations and a reduction in workforce. As a result of the restructuring, the Company incurred a restructuring charge of $2,401 associated primarily with severance and other termination-related benefits related to 47 full-time employees, representing approximately 40% of the employee base at the time of the restructuring. All costs associated with the restructuring were recorded within operating expenses in the same functional category as the employees' operating expenses in the quarter ended September 30, 2023. The restructuring reduced costs related primarily to the Company's field sales force and market access teams in order to implement its announced plan to transition from a prescription to a non-prescription business model.

As of December 31, 2023, there are unpaid restructuring expenses of $94 in accrued expenses and other current liabilities.

CORPORATE INFORMATION

BOARD OF DIRECTORS

Matthew Franklin
President, Chief Executive Officer and Director of the Company

Adam Gazzaley, M.D., Ph.D.
Director and Chief Science Advisor of the Company

Mary Hentges
Director of the Company
Former advising Chief Financial Officer to Noom, Inc.

William "BJ" Jones, Jr.
Director of the Company
Chief Commercial Officer of NewAmsterdam Pharma Company N.V.

Christine Lemke
Director of the Company
Co-Chief Executive Officer and Director of Evidation Health, Inc.

W. Edward Martucci II, Ph.D.
Director and advisor to the Company
Former Chief Executive Officer of the Company

John Spinale
Director of the Company
Managing Director at JAZZ Venture Partners

NON-DIRECTOR EXECUTIVE OFFICERS

Jacqueline Studer, J.D.
Chief Legal Officer and Secretary