2022 Annual Report

Thorne HealthTech

Letter to stockholders

Dear Fellow Shareholders,

2022 was a solid year for Thorne HealthTech, Inc. In our first full year as a public company, we executed our core strategies while navigating a dynamic macroeconomic backdrop to drive strong growth; well above market rates. Our culture of innovation continued to flourish, as we delivered new cutting-edge solutions with first mover advantages that we expect to create significant long-term value in multiple end markets. We saw strong, efficient growth in our base of customers and further expanded our network of health-care practitioners to more than 47,000, capitalizing on long-standing customer satisfaction scores, constantly improving engagement strategies, and evolving go-to-market strategies.

Our performance reflects the trust our customers have in Thorne to support their daily health and wellness journeys because of the personalization we offer, the science behind our portfolio of solutions that includes our health tests and supplements, and our unmatched quality standards. For 2022, record net sales grew 24 percent over 2021, with an impressive compound annual growth rate of more than 30 percent over 2019. In addition, we were again profitable on both a GAAP and an adjusted basis, which extends our long track record of profitable growth and showcases our commitment to protecting the bottom line.

Looking ahead, there are no shortages of opportunities across channels for us to continue extending our leadership position, delivering personalized health and wellness solutions for health goals to customers of any age or life stage, with a seamless and engaging customer journey. Our marketing engine is efficient, with ample room to grow our trusted brand. We are involved in approximately 35 clinical trials with various indications. Our artificial intelligence-powered R&D engine continues to feed our product development pipeline with advanced modeling of human health over time across stages of wellness and disease, with applications in both the natural and biopharmaceutical spaces. Our 2023 production facility expansion will be a major steppingstone in achieving significantly increased scale, that we expect to drive multi-faceted efficiencies, introduce many new and unique production capabilities, and generate highly accretive margins once fully operational in 2024.

Against the backdrop of a consumer-led health revolution focused on personalized wellness, our team knows that the importance of a personalized and scientific approach to achieving critical health goals has never been clearer. We believe the power of our integrated platform at scale, that combines the power of science and artificial intelligence with education, testing, and supplementation will continue enabling customers to achieve their goals, fuel financial success for Thorne HealthTech, and unlock significant long-term value for our shareholders.

I look forward to continuing to share our progress with you. Thank you for your investment and support.

Sincerely,

Paul Jacobson
Chief Executive Officer

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549a

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2022

OR

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

Commission File Number 001-40826

THORNE HEALTHTECH, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**27-2877253**
State or other jurisdiction of incorporation or organization	I.R.S. Employer Identification No.

152 W. 57th Street, New York, NY 10019
Address of principal executive offices, Zip Code

(929) 251-6321
Registrant's telephone number, including area code:

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, $0.01 par value per share	**THRN**	**Nasdaq Global Select 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	☐	Emerging growth company	☒
Non-accelerated filer	☒	Smaller reporting company	☒		

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

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

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

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

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

Based on the closing price as of June 30, 2022, which was the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the common stock held by non-affiliates of the registrant was $65.3 million. For the sole purpose of this calculation, the term "non-affiliate" has been interpreted to exclude directors, officers, and holders of 10% or more of the Company's common stock.

The number of shares of the Registrant's common stock outstanding as of March 30, 2023 was 53,550,928.

DOCUMENTS INCORPORATED BY REFERENCE

Items 10, 11, 12, 13 and 14 of Part III incorporate information by reference from the Registrant's definitive proxy statement relating to its 2022 annual meeting of stockholders to be filed with the Securities and Exchange Commission within 120 days after the close of the Registrant's fiscal year.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (Annual Report) contains statements that are based on our management's expectations, intentions, plans, beliefs and assumptions that constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and are intended to come within the safe harbor protection provided by those sections. All statements other than statements of historical facts contained in this Annual Report, including, without limitation, statements regarding the conditions of our industry, our future results of operations and financial position, business strategy, development plans, expected research and development costs, regulatory strategy, product and service development, sales and marketing activities, international expansion efforts, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "would," "expect," "plan," "anticipate," "could," "intend," "target," "project," "outlook," "contemplate," "believe," "estimate," "forecast," "predict," "potential," "likely" or "continue" or the negative of these terms or other similar expressions.

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements are current only as of the date of this Annual Report, are based upon information available to us as of the date of this Annual Report and are subject to a number of risks, uncertainties and assumptions described in the heading "Summary of Risk Factors" and the risk factors detailed further in Part I, Item 1A and elsewhere in this Annual Report. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not place undue reliance on these statements. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements.

When considering these forward-looking statements, you should keep in mind the cautionary statements in this document and in the Company's other Securities and Exchange Commission ("SEC") filings. These forward-looking statements speak only as of the date on which such statements were made, and the Company undertakes no obligation to update these statements except as required by federal securities laws.

PART I

Item 1. Business

Unless we state otherwise or the context otherwise requires, the terms "we," "us," "our," "Thorne," "the Company," "our business," "our company" refer to Thorne HealthTech, Inc. and its consolidated subsidiaries as a combined entity. Adjusted EBITDA, as used herein, is a non-GAAP measure. For a detailed description of Adjusted EBITDA, please see the discussion under "Management's Discussion and Analysis of Financial Condition and Results of Operations - Key Financial and Operating Data - Adjusted EBITDA and Adjusted EBITDA Margin."

Our Purpose

We believe that a personalized and scientific approach to wellness can lead to happier and healthier lives. Our goal is to transform the consumer's approach to health and wellness and empower our customers to live healthier longer through testing, teaching and proactive measures that help to achieve peak performance and avoid chronic health conditions before they occur.

Who We Are

Thorne is a science-driven wellness company developing innovative solutions for a personalized approach to health and wellness. We seek to bring the scientific rigor of biopharma to the prevention space to help people live longer, healthier lives. Our unique, vertically integrated brands, Thorne and Onegevity, provide actionable insights and personalized data, products and services that empower individuals to take a proactive approach to improve and maintain their health over their lifetime. By combining our proprietary multi-omics database, artificial intelligence (AI) and digital health content with our science-backed nutritional supplements, we deliver a total system for wellness. We believe our integrated solution will redefine the expectations for good health.

Founded in 1984, Thorne Research was a small company dedicated to being a "thorn" in the side of the traditional supplement industry by making the purest and highest quality nutritional supplements to sell to health professionals. With a vision for an unparalleled health ecosystem fueled by innovation and technology, our current Chief Executive Officer, Paul Jacobson, and his management team acquired Thorne Research in 2010 and co-founded Onegevity in 2018. In early 2021, we completed our acquisition of Onegevity and combined these two complementary companies. During the past 12 years, we have evolved to become a transformative consumer brand, trusted by more than 5 million customers, 47,000 healthcare professionals, thousands of professional athletes, more than 100 professional sports teams and multiple U.S. Olympic teams.

We utilize testing and data to create improved product quality and deliver personalized solutions to consumers, health professionals and professional sports teams. We also help pharmaceutical and biotechnology companies repurpose existing drugs and compounds, improve existing medications, and develop new products. Today, consumers are faced with a healthcare system that is focused on the treatment of disease rather than a proactive approach to health and wellness. The supplement market is crowded with confusing products that lack clinical validation or brand equity. We have positioned our brands as a paradigm shift from a focus on the treatment of disease to a proactive approach to health and wellness. The benefits of focusing on health can include enhanced performance in daily life, longer health spans, younger biological ages and reduced reliance on the healthcare system and its associated costs. We have developed a subscription platform that seamlessly combines convenient and comprehensive testing methods, proprietary data, personalized wellness education and premium nutritional solutions to focus on the human body and its unique needs. Through our platform of innovative health solutions and proprietary technology, we are building a new category within the health and wellness market.

Our total addressable market consists of the $358.8 billion global nutritional supplement market (as of 2021 and projected to have a CAGR of 6.3% through 2030 , according to Grand View Research), the $195.1 billion global digital health market (as of 2021 and projected to have a CAGR of 16.1% through 2030, according to FNF Research), the $75.0 billion global drug discovery market (as of 2021 and projected to have a CAGR of 8.9% through 2030, according to Precedence Research) and the $67.3 billion global clinical testing market (as of 2021 and projected to have a CAGR of 6.3% through 2030, according to Straits Research).

Our novel approach seeks to resolve key pain points in the consumer health journey. Our model of test, teach, transform and iterate ensures that consumers are not only active participants in their healthcare, but are also educated and empowered to navigate an overwhelming nutritional supplement marketplace. We help individuals answer the question "what do I take and why?" and are able to personalize nutritional supplement recommendations and protocols because we understand there is no one-size-fits-all solution. Our relentless focus on building a new model of health has resulted in a robust portfolio of science-driven products and high customer satisfaction, as demonstrated by our favorable Net Promoter Score (NPS) of 69 during the year ended December 31, 2022. Our success is not limited to the U.S. market; our Thorne brand was sold in 29 countries in 2022, and we expect to continue to expand internationally.

Our unique go-to-market strategy combines our direct-to-consumer (DTC) and subscription model with an ecosystem of health professionals. We provide customers with direct access to our brand through our mobile, web and Amazon channels. In addition to the DTC channel, our broad range of connected health professionals provides another channel for our products to be marketed and distributed to consumers. We have built our active and growing network to more than 47,000 health professionals, which includes medical doctors, naturopathic doctors, registered dieticians, pharmacists, chiropractors, nutritionists, trainers, acupuncturists and other accredited health professionals.

Thorne: Thorne provides health tests, education, and products that support the optimization of health. We offer health tests to generate comprehensive, personalized molecular portraits for our customers. Our proprietary multi-omics platform, Onegevity, uses the results of these tests to create personalized recommendations, which we believe provide individuals with greater conviction about what actions they need to take, such as consulting with their physician or nutritionist, making a lifestyle change, or using nutritional supplements. All of our tests are performed by reputable third-party clinical laboratories, and the test results and Onegevity-powered AI actionable insights are reviewed by board-certified physicians prior to being delivered to the customer through our website and app.

We have developed premium, high-quality nutritional supplements through our trusted brand, Thorne. We believe that we have established industry leading sourcing, production and testing standards, which are designed to meet or exceed U.S. and international current Good Manufacturing Practice requirements (cGMPs), all of which are subject to third-party certification and audit. We manage nearly all product formulations, ingredients, production processes, documentation, testing and product activities at our facility in Summerville, South Carolina. Our distinguished science and medical teams are advancing an innovative pipeline of products, including a series of next-generation products with nicotinamide riboside (NR), a compound involved in cellular metabolism, which we believe contains properties that support healthy aging at the cellular level.

Health Intelligence: Health Intelligence combines Onegevity's AI and data with professional assistance to map, integrate and understand the billions of dynamic biological features that precisely describe the state of an individual’s health. The platform can be used by customers to manage their own health, and by practitioners and professionals to support patient health and advance their scope of practice. The platform can also be used in the research and development of nutritional supplements and pharmaceuticals by business-to-business (B2B) customers.

Our fast-growing and scaling wellness platform has experienced significant recent growth. Our compelling financial profile is characterized by accelerated year-over-year sales growth, including a focus on steady profitable growth, efficient customer acquisition and strong customer retention.

For the years ended December 31, 2021 and 2022:

- we generated net sales of $184.3 million and $228.7 million, respectively, representing 33.1% and 24.1% year-over-year growth, respectively;
- we generated gross profit of $96.4 million and $114.9 million, respectively, representing 52.3% and 50.2% of net sales, respectively;
- we generated net income of $6.8 million in 2021 and net income of $14.9 million in 2022; and
- we generated Adjusted EBITDA of $20.6 million in 2021 and $24.5 million in 2022.

See the section titled “Selected Consolidated Financial and Other Data—Adjusted EBITDA and Adjusted EBITDA Margin” for information regarding our use of Adjusted EBITDA and a reconciliation of net loss to Adjusted EBITDA.

The recent key customer metrics of our business included:

- customer acquisition costs (CAC) of $39 and life-time value (LTV) of $177, resulting in a 4.5x LTV-to-CAC during the year ended December 31, 2021; compared to a CAC of $38 and LTV of $175, resulting in a 4.6x LTV-to-CAC during the year ended December 31, 2022;
- active subscriptions of 257,070 and 375,185, as of December 31, 2021 and 2022, respectively, representing year-over-year growth of 45.9%; and
- average orders per customer of 3.0 during each of the years ended December 31, 2021 and 2022, respectively.

Our management team has decades of experience in the health and wellness industry and several members of our executive team have been with Thorne for more than 10 years. Our scientific team has authored more than 2,800 peer-reviewed publications in top-tier technical journals and hundreds of years of combined scientific industry and research experience.

Recent Developments

Nutrativa Acquisition. In February 2022, we completed the acquisition of Nutrativa LLC (Nutrativa), a company leveraging two-dimensional high-speed printing technology that provides healthier, environmentally superior alternatives to traditional beverages and gummies via dissolvable supplement discs. Following the acquisition, we launched our dissolvable supplement disc product line, beginning with a comprehensive daily multi-vitamin for children. We have also entered into a partnership agreement to produce the supplement discs for private label. We intend to further deploy the innovative technology to address consumer needs in a more sustainable manner and to expand our portfolio of products and services to new health areas and markets.

OneDraw™ Blood Collection Device (OneDraw). OneDraw is currently approved by the U.S. Food and Drug Administration (FDA) as a Class II medical device and has a European Conformity mark for supervised use by health-care professionals to collect blood samples to measure HbA1c for monitoring the long-term control of blood sugar in diabetic individuals. In May 2022, we reported the results of a large-scale surveillance study of more than four thousand participants who repeatedly self-administered COVID-19 serologic testing at 3-month time intervals. Over the 12-month study period, 99.9% of the samples taken with the OneDraw device received by the independent laboratory were successfully processed, demonstrating the reliability of OneDraw's approach in remote blood sample collection. In addition, the majority of the study participants reported preferring the ease-of-use and near pain-free experience of OneDraw over other collection methods. From more recent development efforts, the device now leverages advanced technology that enables cold-chain-free sample preservation at room temperature. OneDraw can also extract higher volumes than other common collection methods, resulting in more sample material available for testing and storage relative to other methods.

In August 2022, OneDraw was certified in Japan as a medical device, having been cleared by the Pharmaceutical and Medical Devices Agency (PMDA). Most recently, OneDraw was selected for use in the Department of Defense's Cancer Moonshot 2.0 Project as part of a President Biden initiative to drive a renewed focus on preventative health and early disease detection. We are currently working with the FDA to clear OneDraw for medical use in unsupervised settings, which would provide us with first mover status in at-home blood sample collection and the ability to extend the offering into our established DTC customer base. We believe these recent developments significantly enhance OneDraw's value proposition and will accelerate strategic partnership opportunities in our numerous end markets, positioning us well to capitalize on projected industry growth rates.

Gut Health Test with Microbiome Wipe. In May 2022, we reported the results of an initial study that validated the performance of our novel wipe-based stool microbiome collection method, when compared to commercially available DNA collection and preservation kits. Following that study, we relaunched our proprietary Gut Health Test with the first-to-market wipe technology that we believe revolutionizes the user experience. We also believe that awareness of the importance of microbiome health and the "gut-brain axis" is growing exponentially on a global stage, and that our first-mover advantage with proprietary technology creates lasting competitive advantages in the DTC space and other end markets such as telehealth, clinical research, and corporate wellness.

New Products. In addition to our new children's multi-vitamin/mineral supplement and health test advancements, we continued to launch innovative, high-value supplement products with clinically backed ingredients, including:

- Metabolic Health, a combination of bergamot and curcumin, that targets healthy metabolism and supports healthy cholesterol and blood sugar levels;
- Collagen Fit, a formula combining collagen and NR, intended to support joint and muscle health, cellular energy production, training, recovery, and healthy aging;
- Ovarian Care, a blend of nutrients and botanical extracts for women seeking support for menstrual regularity and various aspects of reproductive health by balancing hormones, supporting a healthy insulin response, and providing antioxidant support; and
- Daily Greens Plus, a unique powder formula targeting healthy aging, energy, and focus that combines the highest-quality sources of green nutrition with NR, adaptogens that support a healthy stress response and adrenal function, an antioxidant blend that boosts the body's defenses against oxidative damage, a mushroom blend that promotes optimal immune function, as well as prebiotic and enzyme support for healthy digestion and gut function.

PreCon Acquisition. In January 2023, we completed the acquisition of PreCon Health, Inc. (PreCon), a company focused on scientific discovery, innovation, and advancing safe and effective products that support healthy brain function. We initially partnered with PreCon in 2021 to bring to market the first multi-ingredient nutritional supplement formulated to support pre- and post-impact brain health, SynaQuell ™ and SynaQuell+ ™. In addition to strengthening our brain health portfolio, this acquisition provides us with the requisite intellectual property for continued development, as well as access to PreCon's top-tier medical and scientific advisory board. We recently completed clinical trials related to the effect of SynaQuell on brain function and subconcussive brain impact, each conducted at the Mayo Clinic. Current details of the clinical trials can be found at clinical trials.gov, and preliminary study results for the completed study are expected to be made available in the first half of 2023.

Thorne HealthTech Platform

Our Technology

We seek to transform the health and wellness market by combining (i) our proprietary technology platform, Onegevity, a comprehensive multi-omics database that uses powerful AI platform, digital twin simulations, and machine learning to map, integrate, and understand the vast numbers of dynamic biological features that describe the state of an individual's health and provides actionable recommendations of how to improve it. Onegevity provides a comprehensive molecular portrait and personalized recommendations for an individual's health, based on integrated analysis of longitudinal blood, genetics and gut microbiome profiles.

Our AI model and multi-omics database improves our product formulations and makes our recommendations to customers more precise. Using Onegevity across our product portfolio creates an unparalleled ecosystem where data collected from customers and our network of health professionals strengthens our AI model. We collect and analyze hundreds of personalized tests, evaluations and surveys per day and are able to develop actionable insights from that data on our platform. The data collected from consumers, combined with a powerful AI engine enhances our ability to provide personalized recommendations and education to our customers, driving higher conversion and retention. This system enables us to create better products because we have access to multi-omics datasets, while also helping other businesses, such as those in the pharmaceutical, food and skin care industries, to develop more personalized solutions with our data analytics. The availability of this data may open further opportunities for us in the future to drive revenue by providing data services as a health intelligence provider.

Our Biological Age test is designed to be a simple, quick, and affordable evaluation to determine one's biological age versus chronological age and to assess the age of an individual's organs system. The straightforward, easily understood results are designed to guide the recommendations made to optimize wellness and decrease biological age.

Our Products

Nutritional Supplements: We offer premium, high-quality nutritional supplements that are developed with rigorous science and comprehensive testing from start to finish. This includes a suite of nutritional supplement products centered around a novel ingredient, NR, which we believe contains properties that support healthy aging at the cellular level. Onegevity fuels our evidence-based nutritional product development. Our confidence that each product we formulate and manufacture will deliver the intended outcome is based on extensive clinical evidence and medical literature. Our research and development for the formulation of new products is conducted in-house, in collaboration with leading research institutions from around the world. We have a robust product pipeline focused on future high market growth indications and personalization. No single nutritional supplement represented more than 6% of total sales during the year ended December 31, 2022.

Our formulas are of the highest quality offered in the nutritional supplement market, and our manufacturing processes have received among the highest possible ratings in the industry, which is aligned with our unparalleled commitment and adherence to cGMPs and quality throughout our entire supply chain. The quality control and quality assurance for all products are performed in-house in our two state-of-the-art laboratories. We manufacture our products in our 272,000-square-foot Summerville, South Carolina facility which is third-party certified as complying with Good Manufacturing Practice guidelines. To ensure supply chain consistency and to meet the highest quality standards, we thoroughly and frequently test our ingredients for contaminants. We manufacture approximately 25 products certified by NSF International (NSF) as NSF Certified for Sport products. The NSF certification gives athletes complete confidence that our nutritional supplements do not include any banned substances.

We approach the formulation and manufacturing of each product in a scientific, data-driven way, using clinical evidence and medical literature to support the inclusion of each ingredient in individual formulas. Since our inception, we have built and continue to maintain a database of technical evidence, scientific literature, and industry research that we use to substantiate the structure and function claims we make in support of the indications of use, safety, and efficacy of our nutritional supplement products. We focus on using ingredients in our products that are supported by clinical trial data or other credible scientific research.

Moreover, we have conducted additional clinical studies on a significant number of ingredients in our product portfolio either by ourselves, in concert with our strategic partner Indena S.p.A. (Indena), and other research partners like the Mayo Clinic. This includes studies on botanical extracts and small molecule products, including vitamin analogs, such as nicotinamide riboside, and conjugated materials, such as ketogenic esters. Currently, we are participating in more than 20 ongoing clinical trials by supplying products, offering technical advisement or participating as the principal investigators. We do not view the clinical studies on any one of our products as being material to our business.

Health Tests: Customers uncover insights about their health through our tests, which are powered by our proprietary, multi-omic platform. We turn those insights into a personalized plan for how to eat, exercise and choose supplements, based on unique test results. Customers can have our tests delivered to their doorstep, collect biological samples at home, and then can drop their free return envelope in nearly any mailbox. Alternatively, customers can go to a diagnostic laboratory, such as Quest Diagnostics, to have their samples collected and tests performed. After a licensed professional reviews the results, customers receive their comprehensive Onegevity-powered results and evidence-based recommendations online. Our extensive portfolio of health tests includes tests focused on sleep, stress, weight management, gut health, heavy metals, biological age and more.

Our Services

Our platform combines the AI developed by Onegevity with professional assistance to map, integrate and understand the vast numbers of dynamic biological features that precisely describe the state of an individual's health. The platform is used by customers to manage their own health, and by practitioners and professionals to support patient health and advance their scope of practice. We leverage a portfolio of enterprise-ready models and a proprietary, rapidly expanding multi-omics database to model various stages of health and disease and to help improve health outcomes. Our platform can be used in the development of nutritional supplements and pharmaceuticals by our business-to-business customers.

Health Intelligence: Our Health Intelligence platform provides insights and personalized recommendations as a part of an individual's health test results. The underlying technology uses pattern recognition, deep neural networks, bioinformatics and our multi-omics database to provide these recommendations. Designed as a multi-tenant capable service, Health Intelligence powers our testing and nutritional supplement channel and also has third-party applications. Pharmacies, health professionals and lifestyle companies can use Health Intelligence to engage, educate and empower their patients and users to make smarter decisions about their health. We put individuals at the center of control of their health journey with direct access to convenient molecular diagnostics and intelligent digital analytics to develop personalized and highly actionable plans to achieve desired health goals.

Discovery: Our Discovery platform is designed to help identify and develop new nutritional and pharmaceutical products. This capability is achieved through predictive algorithms deployed across our multi-omics database, which are further informed by an array of biological and chemical factors, that can identify pharmaceutical agents or natural products likely to have the targeted result. In addition to fueling our internal supplement product research and development, our Discovery platform is able to serve clients in diverse fields, including pharmaceuticals, biotechnology, consumer packaged goods (CPGs) and research clinics. In the past, we have helped clients repurpose existing drugs and compounds, improve existing medications and develop new products.

Thorne Lab: Our new Thorne Lab provides comprehensive wellness assessments that leverage our deep multi-omic datasets and technology to provide a first-of-its-kind, in-person clinical experience that embodies the personalized scientific wellness paradigm. Thorne Lab empowers patients to track their health over time by providing one of the most comprehensive health assessments currently available. As part of a precision wellness programs, a trained independent clinician will guide patients through comprehensive, personalized health assessments that include focus on highly critical but less commonly understudied modules of health, such as cognitive function, grip strength and balance, which are all leading indicators in long-term health, but rarely evaluated when a patient is healthy. We believe that by giving individuals a 360-degree snapshot of their health through our platform, we can identify opportunities that preserve their health and optimize performance. Thorne Lab also equips scientists with longitudinal multi-scale health data and a testbed environment to develop, validate and deploy new products and services. As a result, Thorne Lab creates a virtuous cycle of innovation that radically accelerates the pace at which wellness can be optimized and promising ideas can potentially become clinical practice.

Powerful Health Professional Network

Our network of more than 47,000 health professionals includes medical doctors, naturopathic doctors, registered dieticians, pharmacists, chiropractors, nutritionists, trainers, acupuncturists, and other accredited healthcare professionals. Our annual retention rate with these health professionals was 88% in 2022. Backed by this strong network, we offer convenient testing and data-driven, personalized nutrition, clinically studied supplements and pre- and pro-biotics designed to lower healthcare costs and improve wellness for health professionals and consumers.

Vertically Integrated Product Development Platform

We have built our brand on the core pillars of safety, credibility, quality, and user experience. The foundation for these pillars comes from our vertically integrated capabilities. We believe we are one of the only vertically integrated science-based wellness companies in the world, which enables us to provide our customers with premium products made with the highest quality ingredients. Our platform also provides fixed-cost leverage on increased volumes and optimizes our ability to efficiently monitor and manage our inventory.

Bringing high-quality products to market starts at the source. Our research and development team searches worldwide to find only the highest-quality ingredients to use in our nutritional supplements. We source high-quality ingredients that have been clinically tested, allowing us to better understand each ingredients' safety and quality profile. To us, "clean" describes supplements that do not contain any harmful, banned, or unnecessary ingredients. Our "No List" guides us every day in choosing which ingredients to source and how to formulate new products. We partner with suppliers whose practices emphasize quality, science, and environmental responsibility. Our single largest provider of botanical materials is Indena, a company based in Milan, Italy, which is well-known for its identification, development, and production of high-quality actives derived from plants. We have access to Indena's comprehensive botanical compound libraries, which enables throughput functional molecule screening.

Our vertical integration spans from sourcing the highest quality ingredients, research and development activities, product delivery and continued customer engagement. Our product formulation is driven completely in-house by a team of scientists and engineers utilizing proprietary technologies, health intelligence systems, and our Onegevity Discovery AI Platform. This capability drives our data-centric approach to evidence-based nutritional product formulations. The Onegevity Discovery AI Platform delivers molecular insights and personalized health mapping. This system has a one-of-a-kind gene expression library and is one of the world's most comprehensive multi-omics databases for precision wellness. It has been used to track one of the largest microbiome datasets from skin and gut health covering multiple key diseases. These databases are integrated with product targets and statistical and analytical methods that have been published in top peer-reviewed journals, including *Nature, Science,* and *Proceedings of the National Academy of Sciences*.

We develop the optimal product formula to meet the needs of our customers and have the proper facility to maintain control of the manufacturing process. In 2019, we opened our state-of-the-art 272,000-square-foot facility in Summerville, South Carolina. This facility provides significant enhancements to our manufacturing capacity and production efficiencies, research and development platform and in-house laboratory and testing capabilities. This facility demonstrates our commitment to manufacturing all our products in the United States and ensures a quality product is delivered to our growing and loyal customer base. To meet anticipated demand, we are expanding our manufacturing and fulfillment operations in Summerville, South Carolina, with significant incremental capacity coming online in 2023. Please refer to additional discussion within Item 7 Liquidity and Capital Resources of Management's Discussion and Analysis.

Our vertically integrated platform has also enabled the development of a suite of nutritional supplement products centered around a novel ingredient, NR, which we believe contains properties that support healthy aging at the cellular level. Whether it be older consumers looking to stay healthy longer, or younger consumers focusing on their wellness earlier in life, many individuals are seeking new ways to promote healthy aging. We believe NR addresses these demands and presents a significant market opportunity. Through our integrated platform, we have leveraged the trust and manufacturing expertise of Thorne and the power of Onegevity's engine and multi-omics database to develop and launch our NR-based suite of products.

We believe it is crucial to form relationships with leading industry participants in order to continue to provide innovative products to our customers. Our development ecosystem is comprised of research partners like Mayo Clinic, Legacy Health, Tetra Biopharma, Kyowa Hakko Bio, and a global pharmaceutical company; sponsorship of UFC, Human Powered Health cycling, USA Rugby, Penske Racing, Roush Fenway Racing, and the U.S. Army World Class Athlete Program; and high-profile customers such as individual Navy SEALs, professional teams in the NFL, MLB and NBA and other major athletic organizations.

Our products are subject to four rounds of testing in our state-of-the-art, in-house laboratories. This process includes testing of raw materials and components, which screens for contaminants; in-process testing, which ensures the correct amount of ingredients are used in our formulations; finished product testing, which confirms the identity, potency, and purity of the ingredients, and that no microbiological contamination occurred during manufacturing; and in-house stability testing, which confirms each product will meet its label claims at its expiration date.

During the year ended December 31, 2022, approximately 90% of our nutritional supplement sales were generated by products that we manufactured in-house. We make strategic decisions to use outside contract manufacturers for products like probiotics that cannot be made in the same facility as all our other supplements due to the risk of cross-contamination.

Sales Channel Strategy

Our go-to-market strategy leverages numerous sales channels. Across these channels, a common philosophy guides what we do; put the customer first, meet them on their terms, and cultivate meaningful relationships that grow over time.

Consumers (DTC). We provide consumers with direct access to our brand through our mobile and web channels as well as through Amazon.com via our authorized reseller. Our consumers are 60% female and 40% male, ages 25 to 65 with high household income. We will continue to reach these consumers through our marketing efforts, while also looking for new ways to reach consumers in a brand-aligned way, such as through independent pharmacies and other specialty retail venues.

Athletes. We reach athletes, gyms, professional sports teams, and performance organizations through our world-class partnerships, our Sports Sales Team, and through our web and mobile channels using digital marketing tactics. We will continue to invest in these efforts to reach athletes, while also expanding our reach through strategic initiatives, such as our partnership with CrossFit, where we plan to deploy physical kiosks into a portion of its affiliate gyms.

Health professionals. We have approximately 47,000 healthcare professionals in our network, including medical doctors, naturopaths, registered dieticians, nutritionists, chiropractors, and other accredited healthcare professionals. We reach these professionals through our education programs, such as webinars and conferences, publications and white papers, our Professional Sales Team, as well as through our web and mobile channels.

International. Through joint ventures and distributors, we strive to extend our reach effectively and efficiently outside the United States and capture demand in international markets, including the Asia Pacific, the Middle East and throughout Europe.

B2B. We reach pharmaceutical companies, CPG brands, research clinics, distributors, and other wholesalers with our Business Development Team.

Our Industry and Opportunity

Industry

We participate in the large and growing multi-billion dollar global health and wellness industry. The market is highly fragmented, and no company holds a significant market share. We are redefining consumers' expectations and approach to health and wellness through our portfolio of science-backed personalized solutions that meet the highest standards of quality, safety and efficacy.

Opportunity

We have a significant opportunity to continue to penetrate the product categories and channels we compete in today. In addition, we believe we benefit from several consumer trends.

Consumerization of Healthcare and an Increase of Healthcare in the Home: We believe that in the last 10 years there has been a shift from individuals viewing themselves as patients to viewing themselves as consumers in the healthcare market. This has been demonstrated by the growth of the home healthcare market and increased competition in the healthcare provider marketplace. In an always-connected world of data, individuals expect and demand from healthcare what they are accustomed to in their everyday lives. They demand a personalized and holistic approach to daily wellness and long-term health combined with the convenience of products and services being available at their fingertips, all from the comfort and safety of their home. We believe successfully achieving this approach is only possible through the convergence of medicine and technology. The COVID-19 pandemic has accelerated the trend of healthcare moving to the home, placing a greater impetus on individuals to find new ways to protect their health and fueling resiliency with limited person-to-person interaction.

Shift to Personalized Health: Personalized health tailors interventions for preventing and treating disease to the individual characteristics of each patient. The complete sequencing of the human genome, which was completed in 2003, ushered in the era of personalized medicine by providing a greater understanding of how an individual’s unique molecular and genetic profile makes him or her predisposed to certain diseases. As demonstrated by the rise in targeted gene therapies and cancer treatments, health care is evolving from a reactive, “one-size-fits-all” approach to a distinctively proactive, personalized and integrative approach. We believe the dietary supplement market can be personalized in the same way. Such an approach will focus on the optimal selection of treatments and preventative measures that best address a patient’s unique medical attributes, vulnerabilities and predispositions.

Increased Demand for Safe Nutritional Supplements Driven by Increased Consumer Education and Expanding Datasets: Physicians and other health professionals are motivated to help patients, and increasingly, are measured by patient outcomes. Traditional practitioners are now more and more likely to study and prescribe nutritional supplements due to the growing evidence of the positive impact of supplement use and their safety profile. For example, traditional medical doctors have become an increased focus and now account for more than one-third of our customer base in 2022, thanks to our continued growth initiatives and increased demand from their patients.

In a recent study conducted by the Council for Responsible Nutrition (CRN), it was observed that 80% of Americans are using dietary supplements, up 7% from 2020, and of the respondents surveyed, 79% viewed the dietary supplements industry as trustworthy, versus 74% in 2020. Further, the same study noted that 16.7% of supplement purchases were made online in 2020, up 64% from 2019.

Demand for Convenience: Consumers are increasingly placing more value on an exceptional user experience and a demonstrated willingness to invest in bringing premium products and services into their daily lives. Preferences for digital platforms and subscription-based products and services have increased in demand in recent years. Customers want simplicity and an easily available online option from a trusted and clinically validated brand. Our offerings are built to provide an unmatched user experience and provide information to consumers in a way they can easily understand and manage. Consumers can complete personalized testing, create and update their subscription and learn more about their recommended product suite, all from the comfort of their own home. Our omni-channel distribution model can deliver products to most U.S. consumers within two days or allow them to leverage our network of healthcare professionals to receive their products at their local healthcare practitioner's office. We make our test results and recommendations easy to understand. For example, our Biological Age test and resulting recommendations provide consumers with one easily understood number and an actionable plan with the goal of helping consumers reduce their biological age and extend their health span.

What Sets Us Apart

Our Differentiated Consumer Journey

We believe we provide consumers with one of the world’s most innovative solutions for a personalized approach to health and wellness, delivered through our integrated platform of testing, supplements, and digital health content. Our proprietary platform is redefining consumer health through a model of test, teach, transform, and iterate to address the consumer pain points that exist in the market today. Consumers struggle to navigate confusing supplement categories and the market is crowded with ineffective, low-grade products. Personalization has been shown to deliver better health outcomes, yet current health solutions continue a “one-size-fits-all” approach. The current healthcare system focuses on the treatment of disease, but consumers need and want a proactive, empowered approach to health and wellness focused on maintaining and supporting health and promoting wellness.

We teach individuals about their health and wellness and what is occurring in their bodies and why we recommend specific supplement choices. We aim to address an individual’s health needs and deficiencies with our nutritional supplements, as needed. This is an iterative process and provides a differentiated and simplified journey for our customers to navigate the complicated supplement market and improve their health over time.

Trusted Brand, Products and Services

We believe we are a leader in developing high-quality nutritional supplements in a variety of unique forms. We presently sell more than 300 supplements and health tests. Our network of tens of thousands of health professionals, trainers, and world-class athletes deepens the credibility of our product portfolio. Our offerings are further differentiated by conducting all manufacturing and quality management in the United States. We have strong relationships with our suppliers, predominantly located in Europe and United States, who assist in our product innovation cycle and share our commitment to bringing the highest quality products to our customers.

NSF International evaluates product and ingredient safety through its accredited certification and testing services. The NSF Dietary Supplement Certification Program certifies dietary supplements that meet the requirements of the official American National Standard for Dietary Supplements (NSF/ANSI Standard 173). The certification process includes a toxicology and label review to verify product formulation, testing to identify and quantify dietary ingredients declared on the product label, testing to ensure the product does not contain unacceptable levels of contaminants and annual current Good Manufacturing Practices (cGMP) facility inspections. Our facility has been cGMP certified through NSF since 2015. As part of this certification, our Quality Management system, which includes onsite and third-party laboratory operations, is audited to ensure compliance to cGMPs.

This commitment to quality has contributed to our position as one of the most comprehensive NSF Certified For Sport tested supplement manufacturers in the United States and Canada, with approximately 25 NSF Certified For Sport tested supplement products. The NSF For Sport program in the United States and Canada each certify our nutritional supplements to be free from substances banned by major sporting organizations and enables athletes, dietitians, coaches and consumers make more informed decisions when choosing sports supplements. We believe our supplements line is one of the most extensive NSF Certified For Sport product lines based on publicly available data for the number of certified products by manufacturer, regardless of whether the products are currently on the market; however, there is no publicly available volume or revenue data regarding our competitors' NSF Certified For Sport supplement products. Although we plan to continue to seek and maintain NSF Certified For Sport certification for certain of our trusted brand of products, we face competition from other manufacturers that have similarly broad lines of NSF Certified For Sport supplement products and target the professional athlete market.

Powerful Data and AI engine

Our AI model and multi-omics database improve our product formulations and make our recommendations to consumers more precise. We collect and process hundreds of personalized tests, evaluations and surveys per day and are able to develop actionable insights from that data with our Onegevity platform. The data collected from customers, combined with a powerful AI engine, enhances our ability to provide personalized recommendations and education to our customers, thereby driving higher conversion and retention. Our platform captures this information which is utilized by our algorithms to create better nutritional supplements with optimal safety and quality and also helps our B2B customers develop more personalized solutions. The availability of this data may open further opportunities for us in the future to drive revenue by providing data services as a health intelligence provider.

Scalable Platform

The large number of highly engaged consumers who trust our Thorne brand and Onegevity platform provide a strong foundation for developing new products that extend across the health and wellness markets. This ecosystem uniquely positions us to create and capture value along the continuum of a consumer's life with safe and innovative formulas that provide support for prenatal development, healthy adult lifestyles and healthy aging. We have achieved a demonstrated ability to develop innovative new products and successfully integrate acquired companies and assets.

Founder-Led, Science-Oriented Team

Our team of pioneers brings expertise in science-backed wellness, precision health, systems biology and AI-for-health, and has a proven track record of driving profitable growth. Co-Founder Paul Jacobson built this team with a commitment to redefine what it means to be healthy and to push the limits of human potential. Our experienced and highly regarded team of scientists spans fields such as molecular medicine, neuroscience, immunology and genetics.

Growth Strategies

Grow Brand Awareness

We have a significant opportunity to continue to grow our brand awareness and generate new customers. We intend to invest in brand campaigns, full-funnel marketing tactics, and thought leadership initiatives to drive awareness and new customer growth. Once acquired, our customers have demonstrated brand loyalty, so we are well positioned in the market to expand our customer base and effectively retain customers.

Launch New Products and Expand Content Offerings

We intend to launch new products focused on unmet clinical needs. We will continue to invest in evidence-based nutritional supplement development powered by Onegevity's proprietary AI engine and multi-omics database. For example, through Onegevity's compound delivery platform, we were able to identify the highly efficacious compound from bergamot extract to formulate our recently launched Metabolic Health product.

Leverage Our Multi-Omics Database and AI with B2B Partners

Our longitudinal multi-omics database is proprietary, difficult to replicate, and generates unprecedented data insights. We will seek to monetize our database and unique analysis model with a diverse set of enterprise clients.

Continue to Improve Personalization for a Better Consumer Experience

Our personalized approach to health, delivered through a customized platform of testing, supplements and digital health content continues to contribute to our favorable NPS score and subscription retention rates. We will seek to improve our outstanding track record by further enhancing our AI solutions and consumer engagement to provide tailored, personalized solutions to our customers.

Invest in Our Platform

We will continue to invest in technology and the infrastructure to support the growth of our integrated Thorne and Onegevity platform.

Further Expand into International Markets

We will continue to build on our network of distributors across Asia, Europe, the Middle East, and South America. We believe we have the regulatory expertise to execute this initiative and to accelerate international growth.

Selectively Pursue Acquisitions

Our comprehensive platform will enable us to selectively pursue strategic and complementary assets that support our customers' needs. We have a track record of successfully identifying and integrating acquisitions. Our March 2021 acquisition of Onegevity Health strategically expanded our testing and education offerings. We intend to augment and scale the breadth of our platform and offerings through continued strong organic growth opportunities and the acquisition of complementary products and services.

Sales and Marketing

We have been able to turn the luxury aspect of Thorne into a competitive advantage by tapping into consumers' aspiration to be more, where health is the new measure of wealth. To deliver an exceptional brand experience, we focus on:

- *Content*: Developing and sharing engaging, research-driven educational information,
- *Community*: Engaging our brand ambassadors, influencers, and loyal consumers around their self-optimization and self-investment; and
- *Commerce*: Delivering a first-class, frictionless experience for customers.

We will continue to invest in these pillars of our brand experience, while also scaling our brand partnerships and influencers to further grow brand equity. We have a holistic, full-funnel strategy that balances long-term brand objectives with performance marketing goals using a mix of paid, owned, and earned media. Our paid media budget is generally split, with approximately 60% focused on brand tactics and 40% focused on performance marketing tactics. We use large-reach vehicles to provide ample scale and exposure for our audience, such as TV streaming advertising, display, and out-of-home. We also use highly targeted tactics, such as paid social and paid search to build frequency of our product solutions against the right audiences and prompt them to convert.

We maintain a balance between unpaid and paid acquisition, and we prioritize our successful unpaid acquisition strategies and channels. We believe the economics of paid acquisition degrades over time, which is why we have focused on unpaid acquisition. We actively invest in search engine optimization (SEO), improving the user interface and user experience (UI/UX) on our website and mobile application (app), growing our organic social presence, and building new digital products to drive customer engagement. We also are focused on bolstering our earned media efforts to augment our paid and owned strategies by increasing word of mouth and garnering more media placements.

We believe we are well positioned in the market and there is significant room to expand our customer base and convert them into active, recurring customers. Our efficient customer acquisition combined with strong repeat purchase behavior to generate an attractive ratio of customer lifetime value (LTV) to customer acquisition costs (CAC), which was 4.6x in 2022.

Omni-Channel Sales Model

Customers can purchase our products through our omni-channel model consisting of both our DTC platform and our large network of health professionals.

There are two typical consumer pathways to purchasing our supplement products for the first time through our DTC channel. The first common pathway is through our educational platform, where a consumer searches for a specific ingredient, health concern or product, and due to targeted advertising or positive media content, they land on our website to learn more. Once on our site, the consumer may read our Take 5 Daily blog articles or take a product quiz to help determine the best product to meet his or her needs. An interested consumer typically purchases one to two nutritional supplement products on average, with an average unit price of $34.37, either through our website, app or third-party site such as Amazon. We have an average rating of 4.6 stars across our products on Amazon, which we believe to be among the highest in the industry. Our platform also enables customers to easily choose personalized plans through our subscription service.

The second pathway occurs when a consumer searches for a data-driven approach to determine the best product to meet his or her needs. These consumers typically find our website due to targeted advertising or positive media content and purchase one health test for an average price of $159.00 through our website or app. This consumer then collects a bio sample, mails the sample to a third-party laboratory, and receives his or her test results on Thorne.com within seven to ten business days. Within the results, the consumer can review his or her health insights and personalized recommendations on diet, lifestyle and supplementation. From there, the consumer converts and purchases on average one to two of our supplement products. For customers in this second pathway, we receive revenue from the testing fee and from our supplement product sales. As a result of our merger with Onegevity, we expect the traffic to our websites through this second pathway to continue to increase and to realize increasing revenue as a result of the synergy with our supplement products.

Our platform enables customers to easily choose personalized plans through our subscription service. Customers may also choose to subscribe through Total subscriptions grew from 257,070 in 2021 to 375,185 in 2022, a 45.9% year-over-year growth rate. We plan to further expand this channel in order to continue building a strong recurring revenue stream. We have made significant investments in our supply chain logistics in order to offer shipping anywhere in the United States within two days.

In addition to our robust DTC channel, we have also grown our network of more than 47,000 health professionals across the world who recommend our products to their patients when appropriate. We are a trusted brand by top health professionals all over the world. According to the Holistic Primary Care's 2016 Practitioner Survey Report, we are the most dispensed brand by health professionals with 30- to 40-year-old patients. This ecosystem provides a separate channel to reach our customers. Our team of more than 25 sales professionals continue to expand this network, educating health professionals of the benefits to using our products. As we continue to see more and more patients seeking safe, effective nutritional supplements for their health, our products have become increasingly popular through this channel. Thousands of our trusted health professionals recommend our products to their patients through "online dispensing," whereby consumers can avoid going to a retailer and instead purchase any recommended products directly through our website using their health professional's trusted recommendations and unique code. Health professionals also have the option to buy our products directly to resell in their offices. This continues to increase our brand awareness while also benefiting patients who are being treated by our network of health professionals. We continue to see the adoption through this channel, demonstrated by continued year-over-year sales growth of 18.4% in 2021 and 18.5% in 2022.

Our selling efforts are accelerated and supported by an in-house U.S.-based customer service team. Our customer service representatives are available for live online chat, as well as live phone support from 9 a.m. to 7 p.m. Eastern Standard Time, Monday through Friday. We also make our licensed medical professionals available to answer non-disease related questions to both health professionals and consumers.

Clinical Laboratory Partners

We partner with independent certified clinical laboratories, such as ZRT Laboratory, CosmosID, and Quest Diagnostics, to process, and in some cases, produce, the tests that we offer. These laboratories are responsible for receiving and logging samples, preparing samples for processing, processing samples, and performing quality assurance and quality control to assure the validity of all test results before returning results to our network of physicians for assessment. The samples these laboratories process on our behalf include saliva-, blood-, stool- and urine-derived samples.

Competition

We are building a new health category to develop personalized nutritional solutions to improve health with the same degree of scientific rigor that pharmaceutical and biotechnology companies are using for disease treatment. We are at the intersection of and compete against companies that offer DTC subscriptions, digital health services, personalized consumer products, and data-enabled wellness solutions. Due to our comprehensive approach to health and wellness, we currently compete with different health and wellness companies in different markets, such as Nestle Health Science and Metagenics in the nutritional supplement market, Hims, 23and Me, and Livongo in the health services and online testing market, and companies in the AI-driven healthcare market. The market for our products and services is highly fragmented, with many global players participating across category segments in which no single company has obtained more than a 5% market share. We believe no single competitor offers a similarly comprehensive, vertically integrated platform combining product efficacy with personalized health and wellness solutions to consumers, health professionals and corporations.

We believe the principal competitive factors in our market are product quality, customer experience, brand awareness and loyalty, reliability and trust. We believe we differentiate ourselves from our competitors by our relentless pursuit of science-based, personalized health and wellness solutions.

Research and Development

We plan to continue to devote significant resources to research and development. Our research and development organization is responsible for the design, architecture, and operation of our personalized testing platform and nutritional supplement products. Our personalized testing platform includes more than 10, such as the Biological Age test and Gut Health test. We develop new nutritional products through evidence-based product development in areas such as healthy aging and cognition. We pioneered a drug-supplement mapping system that, through AI, helps develop a new B2B pipeline to support product development of our B2B partners, such as pharmaceutical and CPG companies.

We continue to innovate in many areas, such as the development of Thorne Lab. Our Thorne Lab assessments provide an in-person clinical experience powered by AI, which we believe will help expand the personalized scientific wellness paradigm. By enabling individuals to obtain a 360-degree snapshot of their well-being, we believe Thorne Lab empowers individuals to identify opportunities that preserve their health and optimize performance. Thorne Lab also equips scientists with longitudinal multi-scale health data and a testbed environment to develop, validate and deploy new products and services. As a result, Thorne Lab creates a virtuous cycle of innovation that radically accelerates the pace at which wellness can be optimized and promising ideas can potentially become clinical practice.

We are also developing two new advanced tests. The first is our brain health test that will combine blood testing, health histories and cognitive assessments. The second is a metabolomics-based test that will provide our most comprehensive information to date, providing deep health insights and informing personalization around the majority of our product portfolio.

Intellectual Property

We believe that our intellectual property rights are valuable and important to our business. We rely on trademarks, trade secrets, intellectual property assignment agreements, confidentiality procedures, non-disclosure agreements and employee non-disclosure and invention assignment agreements to establish and protect our proprietary rights. In addition, we rely at least in part on trade secrets to protect some aspects of our business, including the sourcing and methods of manufacturing for our nutritional supplement products, the multi-omics database and the algorithm of our AI models. Though we rely in part upon these legal and contractual protections, we believe that factors such as the skills and ingenuity of our employees and the functionality and frequent enhancements to our solutions are larger contributors to our success in the marketplace.

As of December 31, 2022, we held 72 active registered trademarks in the United States, primarily for product names, tag lines, and several THORNE marks; we have been issued one pending Notice of Allowance by the U.S. Patent and Trademark Office (USPTO), and we have several active trademark applications pending at the USPTO. Internationally, we received trademarks for THORNE in one or more classes in the following jurisdictions: Canada, China, European Union (27 member states), Hong Kong, Indonesia, Japan, Mexico, New Zealand, Philippines, Russia, Kingdom of Saudi Arabia, United Arab Emirates, and United Kingdom. We have trademark applications for THORNE in one or more international classes currently pending in the following jurisdictions: Australia, Brazil, Brunei, China, India, Malaysia, Qatar, Russia, Serbia, Singapore, South Korea, Taiwan, Thailand, Ukraine, and Vietnam.

We intend to pursue additional intellectual property protection, including patent protection in the future, to the extent we believe it will be beneficial and cost-effective. Despite our efforts to protect our intellectual property rights, they may not be respected in the future or may be invalidated, circumvented or challenged. For example, third parties may have blocking patents that could be used to prevent us from commercializing our products and practicing our proprietary technology, and any patent applications we pursue that may issue in the future may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products or could limit the term of patent protection that otherwise may exist for our products. In addition, the scope of the rights granted under any issued patents may not provide us with protection or competitive advantages against competitors with similar products. Furthermore, our competitors may independently develop similar technologies that are outside the scope of the rights granted under any issued patents that we own or in-license. For these reasons, we may face competition with respect to our products and services.

Our industry is characterized by the existence of many patents and frequent claims and related litigation based on allegations of patent infringement or other violations of intellectual property rights. We believe that competitors will try to develop products that are similar to ours and that may infringe our intellectual property rights. Our competitors or other third parties may also claim that our solutions infringe their intellectual property rights. Some companies in our industry have extensive patent portfolios. From time to time, third parties have in the past and may in the future assert claims of infringement, misappropriation and other violations of intellectual property rights against us or our customers or partners, with whom our agreements may obligate us to indemnify against these claims. Successful claims of infringement by a third-party could prevent us from offering certain products or features, require us to develop alternate, non-infringing technology, which could require significant time and during which we could be unable to continue to offer our affected products or solutions, require us to obtain a license, which may not be available on reasonable terms or at all, or force us to pay substantial damages, royalties or other fees. Moreover, our solutions incorporate software components licensed to the general public under open source software licenses. We obtain many components from software developed and released by contributors to independent open source components of our solutions. Open source licenses grant licensees broad permissions to use, copy, modify and redistribute our platform. As a result, open source development and license practices can limit the value of our software copyright assets. For additional information, see the section titled “Risk Factors—Risks Related to our Business – Risks Related to our Intellectual Property.”

Data Protection

We are committed to the security and privacy of our customers’ data. The data we collect and process is an integral part of our products and services, allowing us to ensure our products are safe and effective, to provide an engaging consumer experience, to recommend the most relevant products and services and to reach opted-in consumers with timely information. We collect and may use personal information to help operate our business, including for analytical purposes, and to communicate and otherwise reach our consumers. In some instances, we use third-party service providers to assist us in these activities.

We attempt to control access to and distribution of our proprietary information, including our algorithms, source code and customer data through enterprise-grade security measures. We utilize various technology and process-based methods, such as multi-layer firewalls, intrusion detection systems, content filtering, endpoint security, centralized logging and alerting, email security mechanisms and access control mechanisms. Our platform offers powerful data security from our cloud infrastructure to the application layer, end-to-end data encryption, as well as fine grain authorization controls and sensitive field data masking. In addition, we continue to pursue independent third-party assessments and validations of our security and compliance capabilities, including an examination conducted under Statement on Standards for Attestation Engagements (SSAE) No. 16 (Reporting on Controls at a Service Organization), commonly referred to as Service Organization Controls (SOC) reports.

Culture and Values

Our culture is driven by empowering our employees. By ensuring employees enjoy their jobs and believe they are challenged and treated fairly, we believe they will work hard to deliver our premium products for our customers and strong results for our investors.

We pride ourselves on the fact that our manufacturing and customer service takes place in our facilities in the United States. During 2020, we developed protocols to deal with the COVID-19 pandemic and were forced to adjust to a workforce that was split between those who could work from home and those who could not.

We used the COVID-19 pandemic as an opportunity to learn from our employees. We established the Thorne United Committee, an action committee derived from all of our departments, which examined how we paid people, our role in the community, the diversity of our staff, the childcare issues facing employees, the potential for adult education programs, mentoring by senior staff and opportunities for college and trade school scholarships.

We believe that talented and engaged employees create trust and a bond with our customers that no senior management team can achieve alone. We engineer and produce complex products to solve the complex problems of health and wellness and believe that if our customers are to trust our brand, our employees must lead the messaging and be trusted to make decisions that do not compromise the quality of our products. To that end, we have long had policies that senior management cannot overrule decisions made by our quality control and quality assurance teams, nor can senior management overrule decisions taken by our adverse event review team about reporting Serious Adverse Events to the U.S. Food and Drug Administration (FDA) or the safety of our products. We are a product-driven company, built around a culture that empowers employees to make the right decisions and rewards them for doing the right things for the company and our customers.

The key to our success lies in the four tenets of our culture that have driven our innovation and ingenuity from the very start. These tenets define our legacy and propel us toward a future where we are the leader in solving the complex problems of health and wellness. These four tenets are:

A belief in our purpose. We are a team united behind a common purpose: educating, inspiring and improving the health and wellness of people around the world. Being part of a larger purpose is what drives and unites us. It is this shared passion and belief in our mission that has helped us earn the trust of thousands of health professionals, United States Olympic Teams, Mayo Clinic and customers around the world.

A belief in the power of our people. Our culture empowers our employees. From our distinguished researchers to our elite customer-care team, every individual has the opportunity to make a difference firsthand. Every individual has the opportunity to lead, to bring ideas to the table and to be an instrument of change in our workplace culture. We encourage candor, collaboration and communication within our company.

Our culture is built on equality, where people of all backgrounds and experiences are both celebrated and encouraged. As of December 31, 2022, women constitute 40% of the leadership roles across our company and minorities represent 38% of our total employees. This group of leaders operates across multiple departments, including research and development, finance, marketing, bioinformatics, product development and customer service.

We give our employees the tools required to succeed. We offer competitive compensation, fully paid employee benefits, employee training and development, childcare benefits and monthly product credits for personal and immediate family use. We also provide unique growth opportunities dedicated to the ongoing training and professional development of our employees. To better achieve this objective, we draw together internal and external resources to develop and deliver the very best training, development and enrichment programs for our employees.

A belief in our communities. We create opportunities for employees to give back to their communities and support causes of their choosing. We are an active supporter of communities in South Carolina through charitable donations and programs. We encourage employees to support these activities with employer-sponsored paid time off for volunteer work. Our company does not make contributions to any political causes. Instead, we encourage our employees to take an active role in good government without management intervention.

Our Thorne United Committee champions a work environment that promotes the values of diversity, equality, inclusiveness and community. Its work supports programs that address cultural diversity, education and development, community outreach, dependent care support and employee wellness. Specific examples of these programs include tuition support for employees and a tuition grant award program for employees' dependents, a company-sponsored 529 college savings plan with a company contribution, internship and mentoring options for employees' children, community support programs and comprehensive childcare support.

A belief to lead from the front. Our mission is to be the world's leader in scientific wellness. This is the bedrock of our organization's culture and it drives us to become the market leader in research and development, bringing innovative new products to market that address unmet clinical needs. Our goal is to innovate and provide new ways to think about health, performance and wellness.

Human Capital

We are extremely proud of our team, which embodies a diverse mix of backgrounds, industries and levels of experience, united in the shared belief that we can help people lead healthier, happier lives with longer health spans. As of December 31, 2022, we had 544 full-time employees across our company. Of these employees, 281 were in manufacturing, 48 were in sales and marketing, 68 were in customer service and shipping, 59 were in medical, research and development and 88 were in general and administrative functions. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We have not experienced any work stoppages, and we believe the relationship between management and employees is one that has developed over mutual trust and is in good standing.

Sustainability

We care deeply about the origins of our ingredients. We only partner with suppliers whose practices emphasize quality, science and responsibility. Higher quality ingredients that meet our stringent specifications of potency, purity and absorption ultimately translate into better health and wellness. We believe that the environment should not be compromised for the sake of profits. To us, doing our part to protect the environment and its resources goes hand-in-hand with our quality standards. We take pride in being a steward of the botanical ingredients we use in our products. If we happen to learn a botanical ingredient is becoming endangered or over sourcing is diminishing its supply, we will discontinue its use in our product line.

As our sustainability efforts evolve, we are working on long-term solutions to eliminate unnecessary paper waste, including an innovative paperless “pick, pack, and ship” system. Nearly all of our shipping supplies are made from recycled materials, including our shipping boxes, fill-air pillows and padded packs. We are also heavily invested in introducing innovative products, such as Effusio by Thorne, that align with our sustainability mission and help solve the complex problems we face today with plastic pollution. Effusio by Thorne leverages proprietary printing technology to develop dissolvable supplement beverage discs that provide healthier alternatives to traditional beverages, while also providing sustainable packaging alternatives and reducing packaging waste and emissions during shipping. Effusio by Thorne packaging is plastic free and the carton is fully recyclable.

Facilities

We currently lease three industrial facilities located in Summerville, South Carolina, which house our warehouse, production and primary distribution operations and a fourth industrial facility located in Benicia, California for regional distribution operations. We also lease and operate two administrative and support locations in New York, New York, and Madison, Wisconsin.

Our primary manufacturing and administrative facility is located in Summerville, South Carolina. The 272,000 square-foot facility is located on 25.8 acres and houses our manufacturing and production, research and development, medical affairs, engineering, quality management, laboratory testing, brand marketing, inside sales, customer service, finance, legal, human resources, warehousing and materials management, procurement and safety functions. The lease expires in October 2037. We have the right to renew for two additional terms of five years each.

We also operate a 115,500 square-foot warehouse facility in Summerville, South Carolina, within close proximity to our primary manufacturing and administrative facility. This facility expands our finished goods warehousing and shipping capabilities to the eastern United States and international markets. This facility is under a lease which terminates in July 2026. We have the right to renew for two additional terms of three years each.

On July 28, 2021, we entered into a lease for a to-be-constructed 360,320 square-foot industrial facility in Summerville, South Carolina, directly adjacent to our primary facility. This lease will commence upon the completion of construction of the facility, which is currently estimated to be during the second quarter of 2023 and will terminate upon the thirteenth anniversary of the commencement date. We have the right to renew for one additional term of five years. Upon commencement of this lease, we plan to relocate certain warehousing and certain materials-processing production activities from our primary manufacturing facility to provide additional space for expansion of our current manufacturing and production capabilities in support of our continued growth.

We also maintain a 16,896 square-foot warehouse in Benicia, California that services Midwest and West Coast product fulfillment operations. This lease terminates in January 2025. We have the right to renew for one additional term of five years.

Our corporate headquarters in New York, New York consists of 3,500 square-feet of space and primarily houses executive management, business development, corporate marketing and Onegevity personnel. The leases for this office space expire in 2027.

In addition, our information management and digital marketing staff, including our Chief Technology Officer, occupy a 2,500 square-foot facility in Madison, Wisconsin. The lease for this office expires in October 2024.

We intend to procure additional space as we add employees, grow production and expand geographically. We believe, however, that our facilities are adequate to meet our needs for the immediate future and suitable additional space will be available to accommodate any expansion of our operations as needed.

Government Regulation

Products that promote health and wellness, as well as payment for such products, are regulated by various federal, state and local agencies, including but not limited to the following: (i) the FDA, which administers the Federal Food, Drug and Cosmetic Act (FDCA), as well as other relevant laws; (ii) the Federal Trade Commission (FTC); (iii) the Consumer Product Safety Commission (CPSC); (iv) the Office for Civil Rights, which administers the privacy aspects of the Health Insurance Portability and Accountability Act of 1996; and (v) various state regulatory bodies. The FDA in the course of enforcing the FDCA may subject a company to various sanctions for violating FDA regulations or provisions of the FDCA, including requiring or requesting recalls, issuing Warning Letters, seeking to impose civil money penalties, seizing products that the agency believes are non-compliant, seeking to enjoin distribution of a specific product, seeking disgorgement of profits and seeking to criminally prosecute a company and its officers and other responsible parties.

Dietary Supplements

The Dietary Supplement Health and Education Act of 1994 (DSHEA), amended the FDCA to establish a new framework governing the composition, safety, labeling, manufacturing and marketing of dietary supplements. Generally, under DSHEA, dietary ingredients (i.e., vitamins; minerals; herb or other botanical; amino acids; or dietary substances for use by humans to supplement diet by increasing total dietary intake; or any concentrate, metabolite, constituent, extract or combination of any of the above) that were marketed in the United States prior to October 15, 1994 as a dietary supplement may be used in dietary supplements without notifying the FDA. "New" dietary ingredients (i.e., dietary ingredients that were "not marketed in the United States before October 15, 1994") must be the subject of a new dietary ingredient notification submitted to the FDA unless the ingredient has been "present in the food supply as an article used for food" without being "chemically altered." A new dietary ingredient notification must provide the FDA evidence of a "history of use or other evidence of safety" establishing that use of the dietary ingredient "will reasonably be expected to be safe." A new dietary ingredient notification must be submitted to the FDA at least 75 days before the initial marketing. The FDA may determine that a new dietary ingredient notification does not provide an adequate basis to conclude that a dietary ingredient is reasonably expected to be safe. In addition, manufacturers of dietary supplements must ensure that ingredients in their products that are not defined as dietary ingredients comply with all the requirements applicable to conventional foods. For example, fillers and other constituents of the product must be approved as food additives or must be deemed generally recognized as safe for the conditions of use in order to be sold.

The FDA generally prohibits the marketing of a dietary supplement with any "disease claim," including claims that the product is intended to treat, cure, mitigate or prevent disease or other health-related conditions or correlating use of the product with a decreased risk of disease, unless the claim constitutes a "health claim" that is authorized by the FDA. The FTC has imposed stringent, claim-specific substantiation standards on certain dietary supplement manufacturers, to settle charges that they deceptively advertised their supplements' efficacy. However, "statements of nutritional support," including so-called "structure/function claims," are permitted to be included in labeling for dietary supplements. Such statements may describe how a particular dietary ingredient affects the structure, function or general well-being of the body, or the mechanism of action by which a dietary ingredient may affect the structure, function or well-being of the body, but such statements may not state that a dietary supplement will reduce the risk or incidence of a disease unless such claim has been reviewed and approved by the FDA. A company that uses a statement of nutritional support in labeling must possess evidence substantiating that the statement is truthful and not misleading. Such statements must be submitted to the FDA no later than thirty days after first marketing the product with the certification that they possess the necessary evidence and must be accompanied by an FDA mandated label disclaimer that "This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease."

The FDA has published detailed current Good Manufacturing Practice (cGMP), regulations that govern the manufacturing, packaging, labeling and holding operations of dietary supplement manufacturers. The cGMP regulations, among other things, impose significant recordkeeping requirements on manufacturers and require dietary supplements to be of appropriate potency, purity and identity. The cGMP requirements are in effect for all dietary supplement manufacturers, and the FDA conducts inspections of dietary supplement manufacturers pursuant to these requirements.

The FDA has broad authority to enforce the provisions of federal law applicable to dietary supplements, including powers to issue a public warning or notice of violation letter to a company, publicize information about illegal products, detain products intended for import, require the reporting of serious adverse events, require a recall of illegal or unsafe products from the market, and request the Department of Justice to initiate a seizure action, an injunction action or a criminal prosecution in the United States courts.

The Food Safety Modernization Act (FSMA), expands the reach and regulatory powers of the FDA with respect to the production and importation of food, including dietary supplements. The expanded reach and regulatory powers include the FDA's ability to order mandatory recalls, administratively detain domestic products, and require certification of compliance with domestic requirements for imported foods associated with safety issues. FMSA also gave FDA the authority to administratively revoke manufacturing facility registrations, effectively enjoining manufacturing of dietary ingredients and dietary supplements without judicial process.

Hemp-Derived Substances

On December 20, 2018, the Agriculture Improvement Act of 2018 also known as the "Farm Bill" was signed into law. The Farm Bill removed hemp from the definition of marijuana under the Controlled Substances Act, and granted the U.S. Department of Agriculture the ability to regulate hemp defined as the cannabis plant (Cannabis sativa L.), and derivatives of cannabis, with extremely low (less than 0.3 percent on a dry weight basis) concentrations of the compound delta-9-tetrahydrocannabinol (THC), The Farm Bill did not alter, and explicitly preserved, the authority of the FDA to regulate dietary supplements, foods, and other products containing cannabis or cannabis-derived compounds including hemp or hemp-derived compounds under the FDCA.

Our hemp oil product is derived from the seeds and mature stalks of the Cannabis Sativa plant and, in accordance with the definition of hemp, contains a THC concentration that is less than 0.3 percent on a dry-weight basis. Hemp-containing products may also be subject to state registration requirements depending on where such products are marketed. We are also subject to state laws and regulations for our hemp oil product, which may limit where we can sell and market hemp-derived products.

Laboratory Developed Tests

The health and wellness tests we offer are considered laboratory developed tests (LDTs), and are designed, manufactured, and used within a single laboratory that is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), a federal law that regulates clinical laboratories that perform testing on specimens derived from humans and under which our partner laboratories are certified. Laboratory testing is currently under the purview of the U.S. Centers for Medicare and Medicaid Services (CMS) and state agencies that provide oversight of the safe and effective use of clinical laboratory tests, including LDTs.

Our partner clinical laboratories' operations are subject to CLIA regulations, which are designed to ensure the quality and reliability of clinical laboratories by mandating specific standards in the areas of personnel qualifications, administration and participation in proficiency testing, patient test management, quality control, quality assurance and inspections. Laboratories must undergo on-site surveys at least every two years, which may be conducted by CMS under the CLIA program or by a private CMS approved accrediting agency. The sanction for failure to comply with CLIA requirements may be suspension, revocation or limitation of a laboratory's CLIA certificate, which is necessary to conduct business, as well as significant fines and/or criminal penalties. Our partner laboratories are also subject to regulation of laboratory operations under state clinical laboratory laws. State clinical laboratory laws may require that laboratories and/or laboratory personnel meet certain qualifications, specify certain quality controls or require maintenance of certain records. Certain states, such as New York, California, Maryland, Pennsylvania, and Rhode Island, each require that laboratories obtain licenses to test specimens from patients residing in those states and additional states may require similar licenses in the future. Only Washington and New York State are exempt under CLIA, as these states have established laboratory quality standards at least as stringent as CLIA's quality standards. Potential sanctions for violation of these statutes and regulations.

Our partner clinical laboratories' operations are subject to complex laws, regulations and licensure requirements relating to billing and payment for laboratory services, sales and marketing interactions with ordering physicians and other health care providers, security and confidentiality of health information, and environmental and occupational safety, among others. Changes in regulations often increase the cost of testing or processing claims. Also, these laws may be interpreted or applied by a prosecutorial, regulatory or judicial authority in a manner that could require our partner laboratories and, consequently us, to make changes in operations, including in pricing, billing and/or marketing practices in a manner that could adversely affect operations.

In addition, the FDCA defines a medical device to include any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals. The health tests we offered may be considered by the FDA to be subject to regulation as medical devices. Among other things, pursuant to the FDCA and its implementing regulations, the FDA regulates the research, testing, manufacturing, safety, labeling, storage, recordkeeping, pre-market clearance or approval, marketing and promotion, and sales and distribution of medical devices in the United States to ensure that medical products distributed domestically are safe and effective for their intended uses. In addition, the FDA regulates the export of medical devices manufactured in the United States to international markets.

Although the FDA has statutory authority to assure that medical devices are safe and effective for their intended uses, the FDA has generally exercised its enforcement discretion and not enforced applicable regulations with respect to LDTs, which the FDA considers to be in vitro diagnostics that are designed, manufactured, and used within a single laboratory for use only in that laboratory. As a result, we believe the health tests that we offer are currently subject to the FDA's enforcement discretion and are not subject to the FDA's oversight.

Legislative and administrative proposals proposing to amend the FDA's oversight of LDTs have been introduced in recent years and we expect that new legislative and administrative proposals will continue to be introduced from time to time. It is possible that legislation could be enacted into law or regulations or guidance could be issued by the FDA which may result in new or increased regulatory requirements for us to continue to offer our health tests or to develop and introduce new tests.

For example, in recent years, FDA has stated its intention to modify its enforcement discretion policy with respect to LDTs. On July 31, 2014, the FDA notified Congress of its intent to modify, in a risk-based manner, its policy of enforcement discretion with respect to LDTs. On October 3, 2014, the FDA issued two draft guidance documents entitled "Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)," or the Framework Guidance, and "FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)," or the Reporting Guidance. The Framework Guidance stated that FDA intends to modify its policy of enforcement discretion with respect to LDTs in a risk-based manner consistent with the classification of medical devices generally in Classes I through III. The Reporting Guidance would have further enabled FDA to collect information regarding the LDTs currently being offered for clinical use through a notification process, as well as to enforce its regulations for reporting safety issues and collecting information on any known or suspected adverse events related to the use of an LDT. On November 18, 2016, the FDA announced that it would not finalize either guidance document to allow for further public discussion on an appropriate oversight approach to LDTs and to give Congressional authorizing committees the opportunity to develop a legislative solution, and the FDA issued a discussion paper on possible approaches to LDT regulation in January 2017. Moreover, in August 2020, the U.S. Department of Health and Human Services announced that FDA will not require premarket review of LDTs absent notice-and-comment rulemaking, as opposed to through guidance documents and other informal issuances.

Medical Devices

LDTs, which are currently subject to FDA's enforcement discretion and for which the U.S. Department of Health and Human Services (HHS) has announced the FDA may not impose its authority without notice and comment rulemaking, the FDA may decide in the future to regulate LDTs and do not qualify for enforcement discretion at present. If this occurs, or if the FDA determines that certain of our other offerings, such as low-risk health and wellness products, including software, are subject to regulation as medical devices, our health tests and/or these other product offerings could become subject to the FDA's authority applicable to medical devices, including the requirement for premarket review. Unless an exemption applies, each new or significantly modified medical device we seek to commercially distribute in the U.S. will require either a premarket notification to the FDA requesting permission for commercial distribution under Section 510(k) of the FDCA, also referred to as a 510(k) clearance, or approval from the FDA of a Premarket Approval (PMA) application.

Classification

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 each medical device and the extent of control needed to provide reasonable assurances with respect to safety and effectiveness. Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be reasonably assured by adherence to a set of FDA regulations, referred to as the General Controls for Medical Devices, which require compliance with the applicable portions of the FDA's quality system regulation (QSR), facility registration and product listing, reporting of adverse events and malfunctions, and appropriate, truthful and non-misleading labeling and promotional materials. Some Class I devices also require premarket clearance by the FDA through the 510(k) premarket notification process described below. Most Class I products are exempt from the premarket notification requirements.

Class II devices are those that are subject to the General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, patient registries, FDA guidance documents and post-market surveillance. Most Class II devices are subject to premarket review and clearance by the FDA. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) premarket notification process. Our subsidiary, Drawbridge Health, Inc., has developed a blood draw device that is regulated as a Class II medical device and received 510(k) clearance in 2019.

Class III devices include devices deemed by the FDA to pose the greatest risk such as life-supporting or life-sustaining devices, or implantable devices, in addition to those deemed novel and 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. Therefore, these devices are subject to the PMA application process, which is generally more costly and time-consuming than the 510(k) process. Through the PMA application process, the applicant must submit data and information demonstrating reasonable assurance of the safety and effectiveness of the device for its intended use to the FDA's satisfaction. Accordingly, a PMA typically includes, but is not limited to, extensive technical information regarding device design and development, preclinical and clinical trial data, manufacturing information, labeling and financial disclosure information for the clinical investigators in device studies. The PMA application must provide valid scientific evidence that demonstrates to the FDA's satisfaction a reasonable assurance of the safety and effectiveness of the device for its intended use.

510(k) Clearance

Under the 510(k) clearance process, the manufacturer must submit to the FDA a premarket notification, demonstrating that the device is "substantially equivalent" to a legally marketed predicate device. A predicate device is a legally marketed device that is not subject to a PMA, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was previously found substantially equivalent through the 510(k) process. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data is sometimes required to support substantial equivalence.

After a 510(k) premarket notification is submitted, the FDA determines whether to accept it for substantive review. If it lacks necessary information for substantive review, the FDA will refuse to accept the 510(k) notification. If it is accepted for filing, the FDA begins a substantive review. By statute, the FDA is required to complete its review of a 510(k) notification within 90 days of receiving the 510(k) notification. As a practical matter, clearance often takes longer, and clearance is never assured. Although many 510(k) premarket notifications are cleared without clinical data, the FDA may require further information, including clinical data, to make a determination regarding substantial equivalence, which may significantly prolong the review process. If the FDA agrees that the device is substantially equivalent, it will grant clearance to commercially market the device.

If the FDA determines that the device is not "substantially equivalent" to a predicate device, or if the device is automatically classified into Class III, the device sponsor must then fulfill the much more rigorous premarketing requirements of the PMA approval process, or seek reclassification of the device through the de novo process. The de novo classification process is an alternate pathway to classify medical devices that are automatically classified into Class III but which are low to moderate risk. A manufacturer can submit a petition for direct de novo review if the manufacturer is unable to identify an appropriate predicate device and the new device or new use of the device presents a moderate or low risk. De novo classification may also be available after receipt of a "not substantially equivalent" letter following submission of a 510(k) to FDA.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, will require a new 510(k) clearance or, depending on the modification, could require a PMA application. The FDA requires each manufacturer to determine whether the proposed change requires a new submission in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. Many minor modifications are accomplished by a letter-to-file in which the manufacturer documents the change in an internal letter-to-file. The letter-to-file is in lieu of submitting a new 510(k) to obtain clearance for such change. The FDA can always review these letters to file in an inspection. If the FDA disagrees with a manufacturer's determination regarding whether a new premarket submission is required for the modification of an existing 510(k)-cleared device, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or approval of a PMA application is obtained. In addition, in these circumstances, the FDA can impose significant regulatory fines or penalties for failure to submit the requisite application(s).

Over the last several years, the FDA has proposed reforms to its 510(k) clearance process, and such proposals could include increased requirements for clinical data and a longer review period, or could make it more difficult for manufacturers to utilize the 510(k) clearance process for their products. For example, in November 2018, FDA officials announced steps that the FDA intended to take to modernize the premarket notification pathway under Section 510(k) of the FDCA. Among other things, the FDA announced that it planned to develop proposals to drive manufacturers utilizing the 510(k) pathway toward the use of newer predicates. These proposals included plans to potentially sunset certain older devices that were used as predicates under the 510(k) clearance pathway, and to potentially publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. These proposals have not yet been finalized or adopted, although the FDA may work with Congress to implement such proposals through legislation.

More recently, in September 2019, the FDA published revised final guidance describing an optional "safety and performance based" premarket review pathway for manufacturers of "certain, well-understood device types" to demonstrate substantial equivalence under the 510(k) clearance pathway by showing that such device meets objective safety and performance criteria established by the FDA, thereby obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. The FDA maintains a list device types appropriate for the "safety and performance based" pathway and continues to develop product-specific guidance documents that identify the performance criteria for each such device type, as well as the recommended testing methods for such device types.

PMA Approval

Following receipt of a PMA application, the FDA conducts an administrative review to determine whether the application is sufficiently complete to permit a substantive review. If it is not, the agency will refuse to file the PMA. If it is, the FDA will accept the application for filing and begin the review. The FDA has 180 days to review a filed PMA application, although the review of an application more often occurs over a significantly longer period of time. During this review period, the FDA may request additional information or clarification of information already provided, and the FDA may issue a major deficiency letter to the applicant, requesting the applicant's response to deficiencies communicated by the FDA.

Before approving or denying a PMA, an FDA advisory committee may review the PMA at a public meeting and provide the FDA with the committee's recommendation on whether the FDA should approve the submission, approve it with specific conditions, or not approve it. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Prior to approval of a PMA, the FDA may conduct inspections of the clinical trial data and clinical trial sites, as well as inspections of the manufacturing facility and processes to ensure compliance with the QSR. PMA devices are also subject to the payment of user fees, and an annual establishment registration fee.

If the FDA evaluation of a PMA is favorable, the FDA will issue either an approval letter, or an approvable letter, the latter of which usually contains a number of conditions that must be met in order to secure final approval of the PMA. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA approval letter authorizing commercial marketing of the device, subject to the conditions of approval and the limitations established in the approval letter. If the FDA's evaluation of a PMA application or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. The FDA also may determine that additional tests or clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and data is submitted in an amendment to the PMA, or the PMA is withdrawn and resubmitted when the data are available. The PMA process can be expensive, uncertain and lengthy and a number of devices for which the FDA approval has been sought by other companies have never been approved by the FDA for marketing.

New PMA applications or PMA supplements are required for modification to the manufacturing process, equipment or facility, quality control procedures, sterilization, packaging, expiration date, labeling, device specifications, ingredients, materials or design of a device that has been approved through the PMA process. PMA supplements often require submission of the same type of information as an initial PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the approved PMA application and may or may not require as extensive technical or clinical data or the convening of an advisory panel, depending on the nature of the proposed change.

In approving a PMA application, as a condition of approval, the FDA may also require some form of post-approval study or post-market surveillance, whereby the applicant conducts a follow-up study or follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional or longer term safety and effectiveness data for the device. The FDA may also approve a PMA application with other post-approval conditions intended to ensure the safety and effectiveness of the device, such as, among other things, restrictions on labeling, promotion, sale, distribution and use. New PMA applications or PMA supplements may also be required for modifications to any approved diagnostic tests, including modifications to our manufacturing processes, device labeling and device design, based on the findings of post-approval studies.

Clinical Trials

Clinical trials are almost always required to support a PMA and are sometimes required to support a 510(k) submission. All clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA's investigational device exemption (IDE), regulations which govern investigational device labeling, prohibit promotion of the investigational device, and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk," to human health, as defined by the FDA, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials. A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical trial to proceed under a conditional approval.

In addition, the study must be approved by, and conducted under the oversight of, an Institutional Review Board (IRB), for each clinical site. The IRB is responsible for the initial and continuing review of the IDE, and may pose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements. Acceptance of an IDE application for review does not guarantee that the FDA will allow the IDE to become effective and, if it does become effective, the FDA may or may not determine that the data derived from the trials support the safety and effectiveness of the device or warrant the continuation of clinical trials. An IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan or the rights, safety or welfare of human subjects.

During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are also subject to FDA's regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device, and comply with all reporting and recordkeeping requirements. Additionally, after a trial begins, the sponsor, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits.

Post-Market Regulation

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of investigational products, or the promotion of ''off-label'' uses of cleared or approved products;
- requirements related to promotional activities;
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices, or approval of certain modifications to PMA-approved devices;
- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;

- correction, removal and recall 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;
- the FDA's recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and
- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Device manufacturing processes are required to comply with the applicable portions of the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, device history file, and complaint files. As a manufacturer, will be subject to periodic scheduled or unscheduled inspections by the FDA. Failure to maintain compliance with the QSR requirements could result in the shut-down of, or restrictions on, manufacturing operations and the recall or seizure of products. The discovery of previously unknown problems with any marketed medical device products, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or off-label by a physician in the practice of medicine, could result in restrictions on a medical device, including the removal of the product from the market or voluntary or mandatory device recalls.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that a manufacturer has failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in any of the following sanctions:

- warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- recalls, withdrawals, or administrative detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for 510(k) marketing clearance or PMA approvals of new products or modified products;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export approvals; or
- criminal prosecutions.

Telehealth Regulation

The practice of health care professions is subject to various federal, state and local certification and licensing laws, regulations and approvals, relating to, among other things, the adequacy of health care, the practice of medicine and other health professions (including the provision of remote care and cross-coverage practice), equipment, personnel, operating policies and procedures and the prerequisites for prescribing medication. In addition, the provision of health care services through any kind of clinic, facility, storefront or other location open to the public is often subject to state clinic licensure laws akin to those that health facilities like hospitals, surgery centers and urgent care clinics must obtain and maintain. We do not operate or promote any physical place to obtain healthcare and therefore do not believe we are subject to any clinic licensure requirements, but the application of some of these laws to the telehealth we facilitate is unclear and subject to differing interpretation.

Some states have enacted regulations specific to providing services to patients via telehealth. Such regulations include informed consent requirements that some states require providers to obtain from their patients before providing telehealth services. Health professionals who provide professional services using telehealth modalities must, in most instances, hold a valid license to practice the applicable health profession in the state in which the patient is located. In addition, certain states require a physician providing telehealth to be physically located in the same state as the patient. Any failure to comply with these laws and regulations could result in civil or criminal penalties against us.

State Corporate Practice of Medicine and Fee Splitting Laws

Our relationships with physicians and other health professionals are subject to various state laws, which are intended to prevent unlicensed persons from interfering with or influencing the physician's professional judgment and prohibiting the sharing of professional services income with non-professional or business interests. These laws vary from state to state and are subject to broad interpretation and enforcement by state regulators. A determination of non-compliance could lead to adverse judicial or administrative action against us and/or our providers, civil or criminal penalties, receipt of cease-and-desist orders from state regulators, loss of provider licenses, or a restructuring of our arrangements with our affiliated professional entities.

Healthcare Fraud and Abuse Laws

Although none of our offerings are currently covered by any third-party payor, including any commercial payor or government healthcare program, we may nonetheless be subject to a number of federal and state healthcare regulatory laws that restrict business practices in the healthcare industry. These laws include, but are not limited to, federal and state anti-kickback, false claims, and other healthcare fraud and abuse laws.

The U.S. federal Anti-Kickback Statute prohibits, among other things, any person or entity from knowingly and willfully offering, paying, soliciting, receiving or providing any remuneration, directly or indirectly, overtly or covertly, to induce or in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any good, facility, item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare 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. The majority of states also have antikickback laws, which establish similar prohibitions, and in some cases may apply to items or services reimbursed by any third-party payor, including commercial insurers and self-pay patients.

The federal false claims, including the civil False Claims Act, prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false, fictitious or fraudulent claim for payment to, or approval by, the federal government, knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government, or knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. Actions under the civil False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Moreover, a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

In addition, the civil monetary penalties statute, subject to certain exceptions, prohibits, among other things, the offer or transfer of remuneration, including waivers of copayments and deductible amounts (or any part thereof), to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of services reimbursable by Medicare or a state healthcare program.

The federal Health Insurance Portability and Accountability Act of 1996 created additional federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, 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.

The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to CMS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals beginning in 2022, and teaching hospitals, and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members.

Violations of fraud and abuse laws, including federal and state anti-kickback and false claims laws, may be punishable by criminal and civil sanctions, including fines and civil monetary penalties, the possibility of exclusion from federal healthcare programs (including Medicare and Medicaid), disgorgement and corporate integrity agreements, which impose, among other things, rigorous operational and monitoring requirements on companies. Similar sanctions and penalties, as well as imprisonment, also can be imposed upon executive officers and employees of such companies.

Data Privacy and Security Laws and Regulations

Numerous state, federal and foreign laws, including consumer protection laws and regulations, govern the collection, dissemination, use, access to, confidentiality and security of personal information, including health related information. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws and federal and state consumer protection laws and regulations (e.g., Section 5 of the FTC Act), that govern the collection, use, disclosure, and protection of health related and other personal information could apply to our operations or the operations of our partners. For example, the privacy and security regulations under HIPAA establish comprehensive federal standards with respect to the uses and disclosures of PHI by health plans, healthcare clearinghouses and certain health care providers referred to as covered entities, and the business associates with whom such covered entities contract for services, as well as their covered subcontractors, in addition to setting standards to protect the confidentiality, integrity and availability of electronic PHI. HIPAA requires covered entities and business associates to develop and maintain policies with respect to the protection of, use and disclosure of electronic PHI, including the adoption of administrative, physical and technical safeguards to protect such information, and imposes certain notification requirements in the event of a data breach.

As we launch commercial diagnostic tests, we must ensure that our use and disclosure and protection of PHI comply with requirements under the HIPAA privacy and security regulations. Violations of HIPAA may result in significant fines and other penalties for wrongful use or disclosure of PHI, including potential civil and criminal fines and penalties.

In addition, certain state and non-U.S. laws, such as the GDPR, govern the privacy and security of personal data, including health-related data in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. For example, California enacted the CCPA, which went into effect on January 1, 2020. Pursuant to the CCPA, certain businesses are required, among other things, to make certain enhanced disclosures related to California residents regarding the use or disclosure of their personal information, allow California residents to opt-out of certain uses and disclosures of their personal information without penalty, provide Californians with other choices related to personal data in our possession, and obtain opt-in consent before engaging in certain uses of personal information relating to California residents under the age of 16. The California Attorney General may seek substantial monetary penalties and injunctive relief in the event of our non-compliance with the CCPA. The CCPA also allows for private lawsuits from California residents in the event of certain data breaches. Moreover, the CPRA recently passed in California. The CPRA significantly modifies the CCPA, creating obligations relating to consumer data including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, with enforcement beginning July 1, 2023. Aspects of the CCPA and CPRA remain uncertain, and we may be required to make modifications to our policies or practices in efforts to comply.

In Europe, the GDPR went into effect in May 2018 and imposes strict requirements for processing the personal data of individuals within the EEA. In addition, the GDPR increases the scrutiny of transfers of personal data from the EEA to the United States and other jurisdictions that the European Commission does not recognize as having “adequate” data protection laws. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. Additionally, from January 1, 2021, companies have to comply with the GDPR and the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, e.g. fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, and it is unclear how United Kingdom data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the United Kingdom will be regulated in the long term.

Privacy and security laws, self-regulatory schemes, regulations, standards, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Federal Trade Commission

The advertising and promotion of our products in the United States is subject to regulation by the FTC, under the Federal Trade Commission Act (FTC Act). The FTC Act requires that an advertiser possess, at a minimum, a "reasonable basis" to substantiate all product claims before the claims are made, and competent and reliable scientific evidence to substantiate health and therapeutic claims. A lack of adequate substantiation may render such claims deceptive and/or misleading. The FTC Act also governs the appropriate use and necessary disclosures relating to promotional statements made by social media influencers as well as product testimonials.

In recent years, the FTC has initiated numerous investigations of and actions against companies that sell dietary supplements. The FTC has issued guidance to assist companies in understanding and complying with its substantiation requirement. We believe that we have adequate substantiation for all material advertising claims that we make for our products in the United States, and we believe that we have organized the documentation to support our advertising and promotional practices in compliance with these guidelines. However, no assurance can be given that the FTC would reach the same conclusion if it were to review or question our substantiation for our advertising claims in the United States.

The FTC may enforce compliance with the law in a variety of ways, both administratively and judicially, using compulsory process, cease and desist orders, and injunctions. FTC enforcement can result in orders requiring, among other things, limits on advertising, corrective advertising, customer redress, restitution, divestiture of assets, rescission of contracts, and such other relief as the agency deems necessary to protect the public. Violation of these orders could result in substantial financial or other penalties. Although we have not been the subject of any action by the FTC, no assurance can be given that the FTC will not question our advertising or other operations in the United States in the future. Any action in the future by the FTC could materially and adversely affect our ability to successfully market our products in the United States.

In addition, state attorneys general and local district attorneys also have jurisdiction to enforce similar state and local consumer protection laws. Our policy is to use advertising that complies with applicable regulations. Nevertheless, there can be no assurance that inadvertent failures to comply with the applicable regulations will not occur. Failure by us to comply with applicable regulations could result in substantial penalties, which could have a material adverse effect on our financial condition or results of operations and adversely affect our ability to successfully market our products in the United States.

Environmental Matters

Our manufacturing processes and those of our suppliers involve the use of hazardous materials and chemicals and produce waste products. We and our suppliers are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials and waste products. For example, the U.S. Environmental Protection Agency (EPA), regulates the generation and disposal of certain hazardous wastes. Additionally, the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended, and other state, local or foreign laws may impose liabilities for the costs of remediating contaminated real property. We may also be subject to environmental, health and safety claims and proceedings. While we believe we are in compliance with applicable environmental regulations, the failure to fully comply with any such regulations could result in the imposition of significant penalties, fines and/or sanctions which could have a material adverse effect on our business.

Proposition 65

We are also subject to regulation under various state, local, and international laws that include provisions governing, among other things, the formulation, manufacturing, packaging, labeling, advertising, and distribution of dietary supplements. For example, California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65), in the state of California is a list of substances deemed to pose a risk of carcinogenicity or birth defects at or above certain levels. If any such listed ingredient exceeds the permissible levels in a marketed product distributed in the state of California, the product must be accompanied by a prominent warning label alerting consumers that the product contains an ingredient linked to cancer or birth defect risk. Private attorney general actions as well as California attorney general actions may be brought against non-compliant products and can result in substantial costs and penalties.

Other Government Regulation

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Biden Administration may impact our business and industry. The Biden Administration could significantly increase the federal government's willingness to engage in regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. Any of these could substantially affect any of our regulated products or services.

Available Information

We maintain a website with the address of https://www.thorne.com. You may obtain at our website, free of charge, copies of our reports filed with, or furnished to, the Securities and Exchange Commission (the "SEC") on Forms 10-K, 10-Q and 8-K. The SEC also maintains a website, with the address of www.SEC.gov, which contains reports, proxy and information statements, and other information filed electronically or furnished to the SEC.

In addition, you may view and obtain, free of charge, at our website, copies of our corporate governance materials, including: Certificate of Incorporation, Amended and Restated Bylaws, Code of Business Conduct and Ethics, Audit Committee Charter, Compensation Committee Charter, and the Nominating and Corporate Governance Committee Charter. Unless specifically incorporated by reference, the information contained on our website is not a part of this Annual Report on Form 10-K.

Item 1A. Risk Factors.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Annual Report, including our consolidated financial statements and the related notes and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this Annual Report, before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations and the market price of our common stock.

Risk Factors Summary

The following is a summary of the principal risks that could materially adversely affect our business, results of operations, and financial condition. Additional discussion of the risks included in this summary, and other risks that we face, can be found below and should be read together with other information in this Annual Report on Form 10-K and other filings we make with the SEC. This summary should not be relied upon as an exhaustive summary of the material risks facing our business.

- We have grown rapidly in recent years and have limited operating experience at our current scale of operations. If we are unable to manage our growth effectively, our brand, company culture and financial performance may suffer.
- Our operating results may fluctuate significantly in the future, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide.
- If the market for our products and services does not continue to grow, grows more slowly than we expect, or fails to grow as large as we expect, our business, financial condition and operating results may be adversely affected.
- If we fail to maintain adequate quality standards for our products and services, our business may be adversely affected and our reputation harmed.
- Our success depends on our ability to maintain the value and reputation of our brand.
- Unfavorable publicity or customer perception of our products and any similar products distributed by other companies could have a material adverse effect on our business. Additionally, adulterated or counterfeit products appearing on the market under the Thorne brand may subject us to costs or liabilities or damage our reputation and brand.
- We may fail to attract, acquire or retain health professionals and consumers as customers at our current or anticipated future growth rate, or may fail to do so in a cost-effective manner, which would adversely affect our business, financial condition and results of operations.
- Our business depends on the effectiveness of our advertising and marketing programs, including the strength of our social media presence, to attract and retain customers.
- If we are unable to anticipate health professional and consumer preferences and successfully develop new and innovative products and services in a timely manner or effectively manage the introduction of new or enhanced products and services, then our business may be adversely affected.
- If we are unable to sustain pricing levels for our products and services, our business could be adversely affected.
- We operate in a highly competitive market and we may be unable to compete successfully against existing and future competitors.
- Any additional fundraising efforts may divert our management from day-to-day activities, which may adversely affect our ability to develop and commercialize our products and services, and we can provide no assurance that such funding will be available on terms that are acceptable to us, or at all.
- Failure to comply with any of the financial covenants under the Company's credit agreement could result in an event of default which may accelerate our outstanding indebtedness or other obligations and have a material adverse impact on our business, liquidity position and financial position.
- Unfavorable U.S. or global economic conditions as a result of the COVID-19 pandemic, international conflicts, or otherwise, could adversely affect our ability to raise capital and our business, results of operations and financial condition.
- An economic downturn, economic uncertainty or inflation may adversely affect customer discretionary spending and demand for our products and services.
- Our nutrition-oriented educational activities may be impacted by government regulation or our inability to secure adequate professional liability insurance.
- If our products do not have the effects intended or cause undesirable side effects, our business may suffer.

- Increases in ingredient costs, long lead times, supply shortages and supply changes could disrupt our supply chain and have an adverse effect on our business, financial condition and operating results.
- Our operating results could be adversely affected if we are unable to accurately forecast customer demand for our products and services and adequately manage our inventory.
- We acquire ingredients for our products from foreign suppliers and may be negatively affected by the risks associated with international trade and importation issues.
- Our success will depend on our ability to use the data our Onegevity platform collects and the ability of our proprietary algorithm and network of medical doctors to interpret test results accurately and consistently, and our failure to do so would have an adverse effect on our operating results and business, harm our reputation and could result in substantial liabilities that exceed our resources.
- We depend on key personnel, the loss of any of which could negatively affect our business.
- Our future success depends on our ability to attract and retain highly skilled personnel and senior management.
- We plan to expand into international markets, which will expose us to significant risks.
- A substantial portion of our sales are through distributors and health professionals, and we do not have direct control over the efforts these distributors and health professionals may use to sell our products. If our relationships with these third-party distributors or health professionals deteriorate, or if these third-party distributors or health professionals fail to sell our products or engage in activities that harm our reputation, or fail to adhere to applicable regulations, our financial results may be adversely affected.
- Our business depends on network and mobile infrastructure and our ability to maintain and scale our technology. Any significant interruptions or delays in service on our apps or websites or any undetected errors or design faults, including flaws in security design, could result in limited capacity, reduced demand, processing delays and loss of customers.
- Our ability to use our net operating loss to offset future taxable income may be subject to certain limitations.
- We may engage in merger and acquisition activities, which could require significant management attention, disrupt our business, dilute stockholder value and adversely affect our operating results.
- We have identified material weaknesses in our internal control over financial reporting. If our remediation measures are ineffective, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to report our financial condition or results of operations accurately or on a timely basis, which may adversely affect investor confidence in us and, as a result, the value of our common stock.
- If we fail to maintain an effective system of disclosure controls and internal control over financial reporting, we may not be able to accurately report our financial results in a timely manner or prevent fraud, which would harm our business.
- If our estimates or judgments relating to our critical accounting policies are based on assumptions that change or prove to be incorrect, our results of operation could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.
- We are subject to regulation by various federal, state and foreign agencies that require us to comply with a wide variety of regulations, including those regarding the manufacture of products, advertising and product label claims, the distribution of our products and environmental matters. Failure to comply with these regulations could subject us to fines, penalties and additional costs.
- Changes in the way that the FDA and other agencies regulate the tests and other products and services we offer, or the FDA's disagreement as to the regulatory classification of our tests or other products, could result in the delay or additional expense in offering the tests or products, or otherwise impact our business.
- After clearance or approval of any of our products, we are subject to continuing regulation by the FDA, and if we fail to comply with FDA regulations, our business could suffer.
- If we modify our 510(k)-cleared products without FDA clearance, the FDA could retroactively determine that the modifications were improper and require us to stop marketing and recall the modified products.
- We and our suppliers are subject to numerous laws and regulations that apply to the manufacture, sale and marketing of nutritional supplements, and compliance with these laws and regulations, as they currently exist or as modified in the future, may increase our costs, limit or eliminate our ability to sell certain products, subject us or our suppliers to the risk of enforcement action, or otherwise adversely affect our business, results of operations and financial condition.
- Our use, disclosure, and other processing of personal information, including health information, is subject to the Health Insurance Portability and Accountability Act (HIPAA), and other federal, state, and foreign data privacy and security laws and regulations, and our failure to comply with those laws and regulations or to appropriately secure the information we hold could result in significant liability or reputational harm and, in turn, a material adverse effect on our client base, customer base and revenue.

- We are dependent on our relationships with healthcare professionals to provide healthcare services, and our business would be adversely affected if those relationships were disrupted.
- 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.
- We may not be able to protect our intellectual property rights throughout the world.
- The market price of our common stock may be volatile, and you could lose all of part of your investment.
- If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about us, our business, or our market, or if they change their recommendations regarding our common stock adversely, the market price and trading volume of our common stock could decline.
- Sales, directly or indirectly, of a substantial amount of our common stock in the public markets by our existing security holders may cause the price of our common stock to decline.

Risks Related to Our Business and Industry

We have grown rapidly in recent years and have limited operating experience at our current scale of operations. If we are unable to manage our growth effectively, our brand, company culture and financial performance may suffer.

We have expanded our operations rapidly and have limited operating experience at our current size and expect to continue to hire additional personnel to support our finance, legal, investor relations, and compliance departments, as we adapt to operating as a public company.

As we grow, our business will become increasingly complex. To effectively manage and capitalize on our growth, we must also continue to expand our sales and marketing capabilities, focus on innovative products and services, upgrade our information management systems and other processes and expand our facilities. Our continued growth could strain our existing resources, and we could experience ongoing operating difficulties in managing our business across numerous geographies, including difficulties in hiring, training and managing a decentralized and growing employee base. Failure to scale and preserve our company culture during this high-growth period could harm our future success, including our ability to retain and recruit personnel and to effectively focus on and pursue our corporate objectives. Moreover, the vertically integrated nature of our business, where we design and manufacture most of our products, develop our own software services and sell our products through our own sales teams and e-commerce sites, exposes us to risk and disruption at many points that are critical to successfully operating our business and may make it more difficult for us to scale our business. If we do not adapt to meet these evolving challenges, or if our management team does not effectively scale with our growth, we may experience erosion to our brand, the quality of our products and services may suffer, and our company culture may be harmed.

Our growth strategy anticipates a significant increase in our advertising and other marketing costs. Successful implementation of our growth strategy will require significant expenditures and we cannot guarantee that these increased investments will result in corresponding and offsetting revenue growth. Because we have a limited history operating our business at its current scale, it is difficult for us to evaluate our current business and future prospects, including our ability to plan for and model future growth. Our limited operating experience at this scale, combined with the rapidly evolving nature of the health and wellness market in which we sell our products and services, substantial uncertainty concerning how these markets may develop, and other economic factors beyond our control, reduces our ability to accurately forecast quarterly or annual revenue. Failure to manage our future growth effectively could have an adverse effect on our business, financial condition and operating results.

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

Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to:

- our ability to successfully commercialize our products and services on our anticipated timelines;
- the timing and cost of, and level of investment in, new marketing initiatives, research and development and commercialization activities relating to our products and services, which may change from time to time;
- our ability to drive adoption of our products and services in our health and wellness market and our ability to expand into any future target markets or geographies;
- the prices at which we will be able to sell our products and services;
- the timing and amount of expenditures that we may incur to develop, commercialize or acquire additional products or

expand our facilities or enter into different geographies;

- seasonal spending patterns of our customers;
- any new laws and regulations that become applicable to us;
- future accounting pronouncements or changes in our accounting policies;
- the outcome of any future litigation or governmental investigations involving us, our industry or both;
- the impact of force majeure events, including pandemics, international wars, on the economy, investment in the health and wellness industry, our business operations, and resources and operations of our customers, suppliers and distributors;
- supply chain delays and shortages, inflation and decreased financial liquidity; and
- general industry, economic and market conditions, including inflation, and other factors, including factors unrelated to our operating performance or the operating performance of our competitors.

The cumulative effects of the factors discussed above could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

The variability and unpredictability of our operating results could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our operating results fall below the expectations of analysts or investors or below any guidance we may provide, or if the guidance we provide is below the expectations of analysts or investors, it could cause the market price of our common stock to decline.

If the market for our products and services does not continue to grow, grows more slowly than we expect, or fails to grow as large as we expect, our business, financial condition and operating results may be adversely affected.

Our success depends substantially on the continued willingness of consumers to adopt health and wellness products and, in particular, to place value in the personalized nature of our platform and scientific evidence we use to market our products and services. To be successful, we will have to continue to significantly invest in educating consumers about our products and services, and provide high-quality products and services that are superior to those offered by our competitors. For example, our customers use our Onegevity platform and take our tests in order to benefit from our nutritional supplement product offerings. The personalized health and wellness market has only recently adopted the use of digital platforms like Onegevity, and it is uncertain whether such service models will sustain high levels of demand or achieve widespread market acceptance. If our customers do not have confidence in our Onegevity platform or the results of the tests they take, they may not act on our recommendations or purchase our products and our revenues will be negatively impacted as a result. In addition, the health and wellness market is heavily saturated, and the demand for and market acceptance of new products and services in the market is uncertain. While we predict that the overall health and wellness market will continue to grow, it is difficult to predict the future growth rates, if any, to the size of our market. We cannot assure you that our market will continue to develop, that the public's interest in personalized health and wellness will continue or that our products and services will become widely adopted. If our market does not further develop, develops more slowly than expected or becomes saturated with competitors or if our products and services do not achieve market acceptance, our business, financial condition and operating results could be adversely affected.

If we fail to maintain adequate quality standards for our products and services, our business may be adversely affected and our reputation harmed.

Our products, including nutritional supplements and health tests, may contain defects or errors and may not perform as intended. These defects or errors could result in a product recall, market withdrawal, negative publicity or other events that would result in harm to our reputation, loss of customers or revenue, refunds, order cancellations, subscription terminations and lack of market acceptance of our products and services. In addition, Onegevity offers health-related services through Thorne's digital platform as well as directly to business customers. Our Onegevity engine relies on third-party testing facilities to process the customer tests and generate patient data and physicians to interpret these results. These services may contain undetected defects, errors or vulnerabilities currently or when new versions or enhancements are released. These defects and errors may also result in Onegevity's engine providing inaccurate recommendations to our customers. As the use of our Onegevity technology grows and we add new features, we may be subject to increased scrutiny, reputational risk and liability should there be a data breach or if our platform fails to perform as anticipated. Any such defects, errors or vulnerabilities would require us to take remedial action, which could require us to allocate significant research and development and customer support resources to address any such problems. Further, as we make acquisitions, we may encounter difficulties in integrating acquired technologies into our services and in augmenting those technologies to meet the quality standards that are consistent with our brand and reputation.

Our agreements with customers, distribution partners and other third parties may include indemnification provisions under

which we agree to indemnify or otherwise be liable to them for losses suffered or incurred in connection with any such defects or errors of our products or services, or other liabilities relating to or arising from our products or services. Some of these indemnity agreements provide for uncapped liability for which we would be responsible, and some indemnity provisions survive termination or expiration of the applicable agreement. Large indemnity payments could harm our business, financial condition and results of operations. Although we attempt to contractually limit our liability with respect to such indemnity obligations, we are not always successful and may still incur substantial liability related to such claims. In addition, although we carry general liability insurance, our insurance against this liability may not be adequate to cover a potential claim, and such coverage may not be available to us on acceptable terms, or at all. Any dispute with a customer or other third-party with respect to such obligations could have adverse effects on our relationship with such customer or other third-party, our reputation and demand for our platform. Any of the foregoing could adversely affect our business, financial condition and results of operations.

Our success depends on our ability to maintain the value and reputation of our brand.

We believe that our customers associate our name with quality products and services and that the strength of our brand is important to attracting and retaining customers. We rely on our trusted brand to differentiate our products and services from those of our competitors in a crowded and saturated market for nutritional supplements and personalized health services. Maintaining, protecting and enhancing our brand depends largely on the success of our marketing efforts, ability to provide consistent, high-quality products, services, features, content and support, and our ability to successfully secure, maintain and defend our rights to use the "Thorne" and "Onegevity" marks and other trademarks important to our brand. We believe that the importance of our brand will increase as competition further intensifies. Accordingly, brand promotion activities aimed at bolstering our brand may require substantial expenditures. Our brand could be harmed if we fail to achieve these objectives or if our public image were to be tarnished by negative publicity. Our brand could also be harmed if any of our key influencers or professional athlete endorsers receive negative publicity, or if our products and services do not perform as intended.

Unfavorable publicity or customer perception of our products and any similar products distributed by other companies could have a material adverse effect on our business. Additionally, adulterated or counterfeit products appearing on the market under the Thorne brand may subject us to costs or liabilities or damage our reputation and brand.

We believe the nutritional supplement market is highly dependent upon customer perception regarding the safety, efficacy and quality of nutritional supplements generally, as well as of products distributed by us specifically. Customer perception of our products can be significantly influenced by scientific research or findings, regulatory investigations, litigation, national media attention and other publicity regarding the consumption of nutritional supplements. We cannot assure you that future scientific research, findings, regulatory proceedings, litigation, media attention or other research findings or publicity will be favorable to the nutritional supplement market or any product, or consistent with earlier publicity. Future research reports, findings, regulatory proceedings, litigation, media attention or other publicity that are perceived as less favorable than, or that question, such earlier research reports, findings or publicity could diminish confidence in our products and services and could result in a material decrease in the demand for our products and consequently harm our business, results of operations, financial condition and cash flows.

Our dependence upon customer perceptions means that adverse scientific research reports, findings, regulatory proceedings, litigation, media attention or other publicity could have a material adverse effect on the demand for our products, the availability and pricing of our ingredients and our business, results of operations, financial condition and cash flows. Further, adverse public reports or other media attention regarding the safety, efficacy and quality of nutritional supplements in general, or our products specifically, or associating the consumption of nutritional supplements with illness, could have a material adverse effect on our business. Any such adverse public reports or other media attention could arise even if the adverse effects associated with such products resulted from consumers' failure to use such products as directed and the content of such public reports and other media attention may be beyond our control.

Additionally, we are aware of a limited number of adulterated or counterfeit supplement products sold under our brand that did not contain the labeled ingredients intended to be present, did not perform as intended, and may have been placed on the market in an attempt to damage our reputation and brand. Although the ingredients contained in the supplements were harmless, adulterated or counterfeit supplements sold under our brand in the future could contain harmful ingredients or may not perform as intended. Furthermore, a counterfeit test sold may not produce accurate test results. In the future, we could become involved in investigations with the FDA or other federal and state agencies as a result of adulterated or counterfeit supplements or tests. We may incur costs or liabilities resulting from an investigation or become involved in product liability litigation resulting from adulterated or counterfeit supplements or tests. Even if there is no customer harm, adulterated or counterfeit products that do not perform as intended could damage our reputation and brand and lead to a loss of customer sales as a result.

We may fail to attract, acquire or retain health professionals and consumers as customers at our current or anticipated future

growth rate, or may fail to do so in a cost-effective manner, which would adversely affect our business, financial condition and results of operations.

Our continued growth depends, in part, on our ability to attract, acquire and retain consumers and health professionals as customers in a cost-effective manner. Numerous factors, however, may impede our ability to attract, acquire or retain consumers and health professionals as customers, including our failure to attract, effectively train, retain and motivate sales and marketing personnel, our failure to educate customers and health professionals about the benefits of our products, our failure to develop or expand relationships with our distribution partners, our inability to convert initial adoption into ongoing recurring revenue and our failure to provide customer support once products are delivered.

Our DTC success depends, in part, on our existing customers continuing to purchase our products and purchase our subscription services. Our customers have no obligation to purchase our products or renew their subscriptions, and in the normal course of business, some customers may decide to purchase less or none of our products or may decide not to renew their product subscriptions. If we acquire fewer customers than expected, or fewer customers purchase our existing products, try our new products or renew their subscriptions, then our business, financial condition and results of operations would be adversely affected.

In addition, our ability to expand our relationship with our health professional customers depends in large part on our ability to provide new and innovative products and train these professionals on the utility of such products. We believe that our health professional customers place a premium on the efficacy of our products and may not continue to recommend our products to their patients if we do not continue to provide scientific evidence of efficacy for new products and services or if our products fail to achieve the intended patient results. If we are unable to successfully develop new products, educate and train our health professional customers on the benefits of our products and demonstrate a successful value proposition for these health professional customers, then our business, financial condition and results of operations would be adversely affected.

Our business depends on the effectiveness of our advertising and marketing programs, including the strength of our social media presence, to attract and retain customers.

Our business success depends on our ability to attract and retain customers. Our ability to attract and retain customers depends significantly on the effectiveness of our advertising and marketing practices. From time-to-time, we use the success stories of our customers, and utilize brand ambassadors, spokespersons and social media influencers, including in some cases celebrities, in our advertising and marketing programs to communicate on a personal level with consumers. Any actions taken by these individuals that harm their personal reputation or image, or their decision to stop using our products and services, could have an adverse impact on the advertising and marketing campaigns in which they are featured. We and our brand ambassadors, spokespersons and social media influencers also use social media channels as a means of communicating with customers. Unauthorized or inappropriate use of these channels could result in harmful publicity or negative consumer experiences, which could have an adverse impact on the effectiveness of our marketing in these channels. In addition, substantial negative commentary by others on social media platforms could have an adverse impact on our brand, reputation and ability to attract and retain customers. If our advertising and marketing campaigns do not generate a sufficient number of customers, our business, financial condition and results of operations will be adversely affected.

If we are unable to anticipate health professional and consumer preferences and successfully develop new and innovative products and services in a timely manner or effectively manage the introduction of new or enhanced products and services, then our business may be adversely affected.

Part of our success is our ability to innovate and introduce new products focused on our health professional and consumer demands. To maintain our success and increase our customer base, we must continue to develop products and services and anticipate and react to changing health professional and consumer demands in a timely manner. Our products and services are subject to changing consumer preferences that cannot be predicted with certainty. If we are unable to introduce new or enhanced products in a timely manner, or our new or enhanced products are not accepted by our customers, then our competitors may introduce competitive products faster than us, which could negatively affect our rate of growth. Moreover, our new products may not receive customer acceptance because preferences could shift rapidly to alternative nutritional supplements, and our future success depends in part on our ability to anticipate and respond to these changes. Failure to anticipate and respond in a timely manner to changing customer preferences could lead to, among other things, lower sales and subscriptions, pricing pressure, lower gross margins, and excess inventory. Even if we are successful in anticipating consumer preferences, our ability to adequately react to and address them will partially depend upon our continued ability to develop and introduce innovative, high-quality product and services offerings. Development of new or enhanced products and services may require significant time and financial investment, which could result in increased costs and a reduction in our profit margins.

If we are unable to sustain pricing levels for our products and services, our business could be adversely affected.

The prices for our nutritional supplement products reflect their high quality, safety and efficacy. If we are unable to sustain pricing levels for our products and services, whether due to competitive pressure or otherwise, then our gross profits could be reduced. Further, our decisions regarding the development of new products and services are based on assumptions about future pricing. If there is price compression in the market after these decisions are made, then it could lower our gross profits and have a negative effect on our results of operations.

We operate in a highly competitive market and we may be unable to compete successfully against existing and future competitors.

We face significant competition in the health and wellness market. Due to our comprehensive approach to health and wellness, we currently compete with different health and wellness companies in different markets, such as Nestle Health Science and Metagenics in the nutritional supplement market, Hims, 23andMe and Livongo in the health services and online testing market, and companies like Schrodinger and SEMA4 in the AI-driven healthcare market. We believe that the principal competitive factors in our market are product quality, consumer experience, brand awareness and loyalty, reliability and trust in the quality of our products and services.

Some of our current competitors are large publicly-traded companies, or are divisions of large publicly-traded companies, and may enjoy a number of competitive advantages over us, including:

- greater name and brand recognition;
- greater financial and human resources;
- broader and deeper product lines and services;
- larger sales forces and more established distributor networks;
- substantial intellectual property portfolios;
- larger and more established customer bases and relationships;
- greater research and development capacity; and
- better established, larger scale and lower cost manufacturing capabilities.

Our competitors may develop, or have already developed, products, features, services and technologies that are similar to ours or that achieve greater acceptance. They may undertake more successful product development efforts, create more compelling employment opportunities or marketing campaigns and may adopt more aggressive pricing policies. Our competitors may also develop or acquire, or have already developed or acquired, intellectual property rights that significantly limit or prevent our ability to compete effectively in the public marketplace. In addition, our competitors may have significantly greater resources than us, allowing them to identify and capitalize more efficiently upon opportunities in new markets and consumer preferences and trends, quickly transition and adapt their products and services, devote greater resources to marketing and advertising and be better positioned to withstand substantial price competition. We cannot assure investors that our products will compete favorably or that we will be successful in the face of increasing competition from products, services and technologies introduced by our existing or future competitors, or developed by our distributors or healthcare professionals. In addition, we cannot assure investors that our competitors do not have or will not develop products or services with better outcomes or at lower costs than ours. Any failure to compete effectively could materially and adversely affect our business, financial condition and operating results.

We may choose to raise additional funding in order to develop future products, acquire other companies or technologies or expand into other geographies.

We expect that our existing cash as of the date of this Annual Report will be sufficient to fund our operating expenses and capital expenditures for at least the next 12 months. Our future capital requirements will depend on and could increase significantly as a result of many factors, including:

- the number and type of products we develop and commercialize;
- the cost of intellectual property proceedings and any intellectual property litigation involving us;
- the success of any collaborations and joint ventures that we enter into with third parties and the ability to maintain them thereafter;
- the extent to which we acquire or invest in businesses, products and technologies;
- the rate at which we expand internationally and offer our products in additional geographies;
- our headcount growth and associated costs as we expand our business operations and our research and development and manufacturing activities;
- the impact of any business interruptions to our operations or to operations of our manufacturers, suppliers or other vendors resulting from the COVID-19 pandemic or a similar public health crisis or other force majeure event, such as the

ongoing war in the Ukraine; and

- the costs of operating as a public company.

We may need to access additional financing to achieve our business objectives and additional financing may or may not be available to us at the time we need it. The inability to raise additional capital when needed would have a material and adverse effect on our business, financial condition and results of operations.

Any additional fundraising efforts may divert our management from day-to-day activities, which may adversely affect our ability to develop and commercialize our products and services, and we can provide no assurance that such funding will be available on terms that are acceptable to us, or at all.

If we need additional financing in the future, we cannot guarantee that it will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our common stock to decline. To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest will be diluted, and the terms of those securities may include liquidation or other preferences that materially adversely affect your rights as a common stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to make capital expenditures, declare dividends or otherwise conduct our business. If we are unable to obtain any funding we need on a timely basis, we may be required to significantly curtail, delay or discontinue research or development of new products or our digital platform and the commercialization of our products or expansion into new geographies, any of which could materially affect our business, financial condition, and results of operations.

Failure to comply with any of the financial covenants under the Company's credit agreement could result in an event of default which may accelerate our outstanding indebtedness or other obligations and have a material adverse impact on our business, liquidity position and financial position.

On December 21, 2022, the Company entered into a Credit Agreement (the "2022 Credit Agreement") with Fifth Third Bank, N.A. which provides for a $12 million term promissory note and a $45 million revolving credit promissory note, each with a maturity date of December 21, 2027. The 2022 Credit Agreement fully replaces our $15 million revolving line of credit issued under the April 8, 2022 loan agreement with Bank of America, N.A.

The 2022 Credit Agreement includes customary representations, warranties and covenants, and acceleration, indemnity and events of default provisions, including, among other things, certain non-financial covenants and two financial covenants. One financial covenant requires the Company to maintain, at all times, a senior net leverage ratio of not more than (a) 3.0:1.0 as of the end of the Fiscal Quarters ending March 31, 2023; June 30, 2023; and September 30, 2023; (b) 2.75:1.0 as of the end of the Fiscal Quarters ending December 31, 2023; March 31, 2024; June 30, 2024; and September 30, 2024; (c) 2.50:1.0 as of the end of the Fiscal Quarters ending December 31, 2024; March 31, 2025; June 30, 2025; and September 30, 2025; (d) 2.25:1.0 as of the end of the Fiscal Quarters ending December 31, 2025; March 31, 2026; June 30, 2026; and September 30, 2026; and (e) 2.0:1.0 as of the end of the Fiscal Quarters ending December 31, 2026; March 31, 2027; June 30, 2027; and September 30, 2027. The other financial covenant requires the Company to maintain, at all times, a fixed charge coverage ratio of no less than 1.20:1.0, as of the end of any fiscal quarter ended, commencing with the fiscal quarter ending March 31, 2023.

The Company was in compliance with its non-financial and financial covenants as of December 31, 2022. Failure to comply with the foregoing non-financial and financial covenants, if not cured or waived, will result in an event of default that could trigger acceleration of our indebtedness, which would require us to repay all amounts owed under the 2022 Credit Agreement and could have a material adverse impact on our business, liquidity position and financial position.

We cannot be certain that our future operating results will be sufficient to ensure compliance with the financial covenants in our 2022 Credit Agreement or to remedy any defaults. In addition, in the event of any event of default and related acceleration, we may not have or be able to obtain sufficient funds to make the accelerated payments required under the 2022 Credit Agreement.

Unfavorable U.S. or global economic conditions as a result of the COVID-19 pandemic, international conflicts, or otherwise, could adversely affect our ability to raise capital and our business, results of operations and financial condition.

While the potential economic impact brought by, and the duration of, the COVID-19 pandemic and the war in the Ukraine are difficult to assess or predict, these conditions have resulted in, and may continue to result in, extreme volatility and disruptions in the

capital and credit markets, reducing our ability to raise additional capital through equity, equity-linked or debt financings, which could negatively impact our short-term and long-term liquidity and our ability to operate in accordance with our operating plan, or at all. Additionally, our results of operations could be adversely affected by general conditions in the global economy and financial markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including weakened demand for our products and services our ability to raise additional capital when needed on favorable terms, if at all. A weak or declining economy could strain our customers' budgets or cause delays in their payments to us. Additionally, inflation, rising wages and surging oil and gas prices could increase our cost of production. While we would attempt to offset any increases in production costs through cost savings measures within our business and price increases to our customers, our ability and success in doing so is uncertain. Any of the foregoing could harm our business, and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our ability to raise capital, business, results of operations and financial condition.

Inflation and weakness in general economic conditions and recessions could negatively affect our financial condition and results of operations.

Our operations and financial performance may be affected by general macroeconomic conditions, consumer confidence and discretionary spending habits. Consumer spending habits are affected by, among other things, inflation, weakness in general economic conditions, recessions, pandemics, wars and military actions, levels of employment, salaries and wage rates, debt obligations, discretionary income, interest rates, volatility in capital markets, consumer confidence and consumer perception of current and future economic conditions. Declines in, or uncertain economic outlooks for, the U.S. or certain international economies could adversely affect consumer spending habits which may, among other things, result in a decreased demand for our nutritional supplements and health tests, which could materially adversely affect our revenues and operating results. Inflation increases domestic and international shipping costs, raw material prices, and labor rates. The continued increase in fuel prices could also have an effect on consumer spending and on our costs of producing, procuring and shipping our products. We may be unable to, or choose not to, recover our increase in costs from our customers leading to a reduction in operating results. In situations where we attempt to pass our increased costs on to our customers, our ability to recover these cost increases through price increases may lag, resulting in delayed operating results. Any attempts to offset cost increases with price increases may result in greater reductions in sales, increased customer dissatisfaction with our products or otherwise harm our reputation. We are also unable to predict the impact of efforts by central banks to combat elevated levels of inflation. Increases in lending rates may reduce economic activity. If downward pressures continue due to these economic factors, this may lead to a recession. If a recession occurs, economies weaken, fuel prices continue to increase or inflationary trends continue, our business and operating results could be materially and adversely affected.

An economic downturn, economic uncertainty or inflation may adversely affect customer discretionary spending and demand for our products and services.

Some customers may consider our products and services to be discretionary. Factors affecting the level of consumer spending for such discretionary items include current economic conditions, including inflation, customer confidence in future economic conditions, fears of recession, the availability and cost of customer credit, levels of unemployment and tax rates. In recent years, the United States and other significant economic markets have experienced cyclical downturns and worldwide economic conditions remain uncertain. As global economic conditions continue to be volatile or economic uncertainty remains, trends in customer discretionary spending also remain unpredictable and subject to reductions. To date, our business has operated almost exclusively in a relatively strong economic environment or in the COVID-19 pandemic where healthcare has been a priority and, therefore, we cannot be sure the extent to which we may be affected by recessionary conditions without a pandemic. Unfavorable economic conditions may lead customers to delay or reduce purchases of our products and services and customer demand for our products and services may not grow as we expect. Sensitivity to economic cycles and any related fluctuation in customer demand for our products and services could have an adverse effect on our business, financial condition and operating results.

Our nutrition-oriented educational activities may be impacted by government regulation or our inability to secure adequate professional liability insurance.

We provide nutrition-oriented education and supplement plans to our customers, and these activities may be subject to state and federal regulation and oversight by professional organizations. In the past, the FDA has expressed concerns regarding summarized health and nutrition-related information that (i) does not, in the FDA's view, accurately present such information, (ii) diverts a consumer's attention and focus from FDA-required nutrition labeling and information or (iii) impermissibly promotes drug-type disease-related benefits. If our employees, consultants or the other third parties we engage to provide this information do not act in accordance with regulatory requirements, we may become subject to penalties that could have a material adverse effect on our business. We believe we are currently in compliance with relevant regulatory requirements, and we maintain professional liability insurance in order to mitigate risks associated with this nutrition-oriented education. However, we cannot predict the nature of, and changes to, future government regulation and oversight, including the potential impact of any such regulation on this activity. Furthermore, the availability of professional liability insurance or the scope of such coverage may change, or our insurance coverage

may prove inadequate, which may adversely impact the ability of our customer educators to provide some information to our customers. The occurrence of any such developments could negatively impact the perception of our brand, our sales and our ability to attract new customers.

We may initiate product recalls or withdrawals, may be subject to regulatory enforcement actions or incur material product liability claims, any of which could increase our costs and adversely affect our reputation and our results of operations.

As a manufacturer, marketer and retailer of products designed for human consumption, we may initiate product recalls or withdrawals, or may be subject to seizures and adverse public relations if our products are contaminated, adulterated, mislabeled, misbranded or fail to achieve expected stability or shelf life, are alleged to cause injury or illness, or if we are alleged to have violated governmental regulations in the manufacture, labeling, promotion, sale or distribution of any of our products, whether caused by us or someone in our manufacturing or supply chain. Our products primarily consist primarily of nutritional supplements and, in most cases, are not necessarily subject to pre-market regulatory review or approval in the United States. The raw materials used to make certain of our products may be vulnerable to spoilage and contamination by naturally occurring molds and pathogens. Additionally, some of our products contain ingredients that do not have long histories of human consumption. Previously unknown adverse reactions resulting from human consumption of these ingredients could occur. Some of the products we sell are produced by third-party manufacturers.

A product recall, withdrawal or seizure could result in destruction of product inventory and inventory write-off, negative publicity, temporary facility closings for us or our contract manufacturers, supply chain interruption, fines and substantial and unexpected expenditures, any of which would reduce operating profit and cash flow. In addition, a product recall, withdrawal or seizure may require significant management attention. Product recalls may materially and adversely affect consumer confidence in our brands, hurt the value of our brands and lead to decreased demand for our products. Product recalls, withdrawals or seizures also may lead to increased scrutiny by federal, state or international regulatory agencies of our operations and increased litigation and could have a material adverse effect on our business, results of operations, financial condition and cash flows.

We have been in the past, and may be in the future, be subject to various product liability claims, including, among others, that our products include inadequate instructions for use or inadequate warnings concerning possible side effects and interactions with other substances. Any such product liability claims may also include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection laws. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our existing products. As a marketer of products manufactured by third parties, we also may be liable for various product liability claims for products we do not manufacture. Even successful defense would require significant financial and management resources.

Regardless of the merits or eventual outcome, liability claims may result in any of the following:

- decreased demand for our products or products that we may develop in the future;
- decline in price charged for our products;
- loss of revenue;
- injury to our reputation;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants;
- product recalls or withdrawals;
- labeling, packaging, marketing or promotional modifications or restrictions;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize our existing or future products; and
- a decline in our stock price.

The cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. In addition, our inability to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims could prevent or inhibit the development and commercial production and sale of our products, which could adversely affect our business, financial condition, results of operations, and prospects. Insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no or inadequate coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate

collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

If our products do not have the effects intended or cause undesirable side effects, our business may suffer.

Although many of the ingredients in our current dietary supplement products are vitamins, minerals and other substances for which there is a long history of human consumption, they also contain innovative ingredients or combinations of ingredients. Although we believe all of such products and the combinations of ingredients in them are safe when taken as directed, the products could have certain undesirable side effects if not taken as directed or if taken by a consumer that has certain medical conditions. In addition, such products may not have the effect intended if they are not taken in accordance with certain instructions, which include certain dietary restrictions. Furthermore, there can be no assurance that any of the products, even when used as directed, will have the effects intended or will not have harmful side effects in an unforeseen way or affect populations differently. If any of our products or products we develop or commercialize in the future are shown to be harmful or generate negative publicity from perceived harmful effects, our business, financial condition, results of operations and prospects would be harmed significantly.

Increases in ingredient costs, long lead times, supply shortages and supply changes could disrupt our supply chain and have an adverse effect on our business, financial condition and operating results.

Meeting customer demand partially depends on our ability to obtain timely and adequate delivery of ingredients for our nutritional supplement products. Certain ingredients that get incorporated into our nutritional supplement products are sourced from a limited number of third-party suppliers, and some of these ingredients are provided by a single supplier. These suppliers may breach or otherwise terminate our supply agreements, or their capabilities to deliver adequate ingredients to us may be affected by other factors such as fluctuations in the market, supply chain issues, litigation or regulatory issues or force majeure events, including the COVID-19 pandemic and international conflicts such as those affecting the Ukraine, and in any of the cases, the sourcing and commercialization of our products can be adversely affected. For example, there is considerable patent and other intellectual property development activity in the personalized health and wellness products industry, and litigation, based on allegations of infringement or other violations of intellectual property, is frequent in this industry. If our suppliers are sued, their capabilities to deliver adequate ingredients to us may be adversely affected. We are therefore subject to the risk of shortages and long lead times in the supply of these ingredients and the risk that our suppliers discontinue or modify ingredients. In addition, the lead times associated with certain ingredients are lengthy and preclude rapid changes in quantities and delivery schedules. We have experienced supply shortages and resulting longer lead-times in the past and may in the future experience ingredient shortages, and the predictability of the availability of these ingredients may be limited. In the event of an ingredient shortage or a supply interruption from suppliers of these ingredients, we may not be able to develop alternate sources of supply in a timely manner. Developing alternate sources of supply for these ingredients may be time-consuming, difficult and costly and we may not be able to source these ingredients on terms that are acceptable to us, or at all, which may undermine our ability to fill our orders in a timely manner. Any interruption or delay in the supply of any of these ingredients, or the inability to obtain these ingredients from alternate sources at acceptable prices and within a reasonable amount of time, would harm our ability to meet our scheduled product deliveries to our customers. In addition, increases in our ingredient costs could have a material effect on our gross margins. The loss of a significant supplier, an increase in ingredient costs, or delays or disruptions in the delivery of ingredients, could adversely impact our ability to generate future revenue and earnings and have an adverse effect on our business, financial condition and operating results.

Our operating results could be adversely affected if we are unable to accurately forecast customer demand for our products and services and adequately manage our inventory.

To ensure adequate inventory supply, we must forecast inventory needs and expenses and place orders sufficiently in advance with our suppliers, based on our estimates of future demand for particular products and services. Failure to accurately forecast our needs may result in manufacturing delays or increased costs. Our ability to accurately forecast demand could be affected by many factors, including changes in customer demand for our products and services, changes in demand for the products and services of our competitors, widespread acceptance of personalized health recommendations and nutritional supplements, unanticipated changes in general market conditions and the weakening of economic conditions or consumer confidence in future economic conditions. This risk may be exacerbated by the fact that we may not carry a significant amount of inventory and may not be able to satisfy short-term demand increases. If we fail to accurately forecast customer demand, we may experience excess inventory levels or a shortage of products available for sale. Inventory levels in excess of customer demand may result in inventory write-downs or write-offs and the sale of excess inventory at discounted prices, which would cause our gross margins to suffer and could impair the strength and our brand. Further, lower than forecasted demand could also result in excess manufacturing capacity or reduced manufacturing efficiencies, which could result in lower margins. Conversely, if we underestimate customer demand, our suppliers and manufacturers may not be able to deliver products to meet our requirements or we may be subject to higher costs in order to secure the necessary production capacity. An inability to meet customer demand and delays in the delivery of our products to our customers could result in reputational harm and damaged customer relationships and have an adverse effect on our business, financial condition and operating

results.

We acquire ingredients for our products from foreign suppliers and may be negatively affected by the risks associated with international trade and importation issues.

We acquire ingredients for a number of our products from suppliers outside of the United States. Accordingly, the acquisition of these ingredients is subject to the risks generally associated with importing raw materials, including, among other factors, delays in shipments, changes in economic and political conditions, including the current instability caused by the outbreak of war in Ukraine, quality assurance, health pandemics affecting the region of such suppliers, including COVID-19, nonconformity to specifications or laws and regulations, tariffs, trade disputes and foreign currency fluctuations. While we audit and inspect our suppliers' and manufacturers' facilities as necessary both in the United States and internationally, we cannot assure you that raw materials received from suppliers or finished products from manufacturers outside of the United States will conform to all specifications, laws and regulations or our internal standards. There have in the past been quality and safety issues in our industry with certain items imported from overseas. We may incur additional expenses and experience shipment delays due to preventative measures adopted by the U.S. governments, our suppliers and our company.

Our success will depend on our ability to use the data our Onegevity platform collects and the ability of our proprietary algorithm and network of medical doctors to interpret test results accurately and consistently, and our failure to do so would have an adverse effect on our operating results and business, harm our reputation and could result in substantial liabilities that exceed our resources.

Our success depends on our ability to provide reliable, high-quality tests that incorporate rapidly evolving information about the role of various risk factors in disease and aging. Errors, including if our tests fail to perform with high accuracy, or mistakes in the interpretation of those results, could have a significant adverse impact on our business. A substantial amount of judgment is required in order to interpret testing results for an individual patient and to develop appropriate, customized customer recommendations. We also rely on medical doctors to interpret the data that we collect and to incorporate specific information about an individual customer into their profile.

We do not provide recommendations regarding disease. The marketing, sale and use of our Onegevity platform testing service could subject us to liability for errors in, misunderstandings of, or inappropriate reliance on information we provide, and could lead to claims against us if someone were to allege that our tests failed to perform as it was designed or if our medical doctors failed to correctly interpret the data. A product liability or professional liability claim could result in substantial damages and be costly and time-consuming for us to defend. Although we maintain liability insurance, including for errors and omissions, we cannot assure you that our insurance would fully protect us from the financial impact of defending against these types of claims or any judgments, fines or settlement costs arising out of any such claims. Any liability claim, including an errors and omissions liability claim, brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any liability lawsuit could cause injury to our reputation or cause us to suspend the use of the Onegevity platform or sales of our products and tests. The occurrence of any of these events could have an adverse effect on our business, reputation and results of operations.

We depend on key personnel, the loss of any of which could negatively affect our business.

We depend greatly on our executive team, including Paul F. Jacobson, our Chief Executive Officer, Will C. McCamy, our President, Tom P. McKenna, our Chief Operating Officer, Michelle L. Crow, our Chief Marketing Officer, Stephen M. Phipps, our Chief Innovation Officer, Bodi Zhang, our Chief Strategy Officer, Nathan D. Price, Chief Scientific Officer, Scott R. Hurth, our Chief Technology Officer and Daniel McEvoy, our President of Onegevity. We rely heavily on the continued service and performance of our senior management team, which provides leadership, contributes to the core areas of our business and helps us to efficiently execute our business. We also depend greatly on other key employees, including key scientific personnel and health professionals. In general, only highly qualified and trained scientists and health professionals have the necessary skills to develop and market our products and provide our services. In addition, some of our manufacturing, quality control, safety and compliance, information technology, sales and e-commerce related positions are highly technical as well. If the senior management team, including any new hires that we make, fails to work together effectively and to execute our plans and strategies on a timely basis, then our business and future growth prospects could be harmed. Also imperative to our success are our influencers who we rely on to market our products and services, and who act as brand ambassadors.

Additionally, the loss of any key personnel could make it more difficult to manage our operations and research and development activities, reduce our employee retention and revenue, and impair our ability to compete. Although we have entered into employment offer letters with our key personnel, these agreements have no specific duration and constitute at-will employment. We do not maintain key person life insurance policies on any of our employees. The loss of services of our senior management team or

key employees that may be hired in the future may have a material and adverse effect on our business.

Our future success depends on our ability to attract and retain highly skilled personnel and senior management.

Our future success depends, in part, on our ability to continue to identify, attract, develop, integrate and retain qualified and highly skilled personnel, including senior management, engineers, scientists, product managers, logistics and supply chain and quality control personnel. Competition for highly skilled personnel is often intense and such highly skilled personnel have increasingly been changing jobs and seeking promotions as demand for their services increases. We may not be successful in attracting, integrating or retaining qualified personnel to fulfill our current or future needs. We have from time to time experienced, and we expect to continue to experience, difficulty in hiring highly skilled employees with appropriate qualifications. In addition, job candidates and existing employees often consider the value of the equity awards they receive in connection with their employment. If the perceived value of our common stock declines, it may adversely affect our ability to hire or retain highly skilled employees. In addition, we may periodically change our equity compensation practices, which may include reducing the number of employees eligible for equity awards or reducing the size of equity awards granted per employee. If we are unable to attract, integrate, or retain the qualified and highly skilled personnel required to fulfill our current or future needs, our business and future growth prospects could be harmed.

We face intense competition for these professionals from our competitors, customers, marketing partners and other companies throughout the industries in which we compete. Our success will depend, in part, upon our ability to attract and retain additional skilled personnel, which may require substantial additional funds. There can be no assurance that we will be able to find and attract additional qualified employees or retain any such personnel. Our inability to hire qualified personnel may have a material and adverse effect on our business.

Our passion and focus on delivering a high-quality consumer experience may not maximize short-term financial results, which may yield results that conflict with the market's expectations and could result in our stock price being negatively affected.

We are committed to our focus on producing high-quality products and engaging our customers through personalized recommendations and investment in our platform, which may not necessarily maximize short-term financial results. We frequently make business decisions that may reduce our short-term financial results, such as sourcing higher quality ingredients and investing substantially in product research and development, if we believe that the decisions are consistent with our goals. We believe this will improve our financial results over the long term as we deliver actionable recommendations and quality products to our customers. These decisions may not be consistent with managing costs and the short-term expectations of our stockholders and may not produce the long-term benefits that we expect, in which case our growth and consumer engagement, and our business, financial condition and operating results could be harmed.

We plan to expand into international markets, which will expose us to significant risks.

We are currently expanding our operations to other countries, which requires significant resources and management attention and subjects us to regulatory, economic, and political risks in addition to those we already face in our primary markets of the United States, Canada, the United Kingdom, Australia, China, and the European Union. There are significant risks and costs inherent in doing business in international markets, including:

- difficulty establishing and managing international operations and the increased operations, travel, infrastructure, including establishment of local delivery service and customer service operations and legal compliance costs associated with locations in different countries or regions;
- the need to vary pricing and margins to effectively compete in international markets;
- marketing and brand recognition costs;
- the need to adapt and localize products for specific countries, including obtaining rights to third-party intellectual property used in each country;
- increased competition from local providers of similar products and services;
- the ability to protect and enforce intellectual property rights abroad;
- the need to offer customer support in various languages;
- the challenges of negotiating with foreign distributors;
- difficulties in understanding and complying with local laws, regulations and customs in other jurisdictions;
- compliance with anti-bribery laws, such as the U.S. Foreign Corrupt Practices Act (FCPA), and the U.K. Bribery Act 2010 (U.K. Bribery Act), by us, our employees and our business partners;
- complexity and other risks associated with current and future legal requirements in other countries, including legal requirements related to consumer protection, consumer product safety and data privacy and data protection frameworks,

such as the E.U. General Data Protection Regulation (GDPR);

- tariffs and other non-tariff barriers, such as quotas and local content rules, as well as tax consequences;
- fluctuations in currency exchange rates and the requirements of currency control regulations, which might restrict or prohibit conversion of other currencies into U.S. dollars; and
- political or social unrest or economic instability in a specific country or region in which we operate, including, for example, the effects of "Brexit," which could have an adverse impact on our operations in the United Kingdom and E.U.

We have limited experience with international regulatory environments and market practices and may not be able to penetrate or successfully operate in the markets we choose to enter. In addition, we may incur significant expenses as a result of our international expansion, and we may not be successful. We may face limited brand recognition in certain parts of the world that could lead to non-acceptance or delayed acceptance of our products and services by customers in new markets. We may also face challenges to acceptance of our health and wellness content in new markets. Our failure to successfully manage these risks could harm our international operations and have an adverse effect on our business, financial condition and operating results.

A substantial portion of our sales are through distributors and health professionals, and we do not have direct control over the efforts these distributors and health professionals may use to sell our products. If our relationships with these third-party distributors or health professionals deteriorate, or if these third-party distributors or health professionals fail to sell our products or engage in activities that harm our reputation, or fail to adhere to applicable regulations, our financial results may be adversely affected.

Our sales model depends on our ability to sell our products through health professionals and through distributors. Our network of health professionals typically receive a discount from list price or rebate on the products their patients purchase from us. We can provide no assurance that these health professionals will continue to recommend our products at their current levels, or at all. Additionally, we may be unable to continue to grow our network of health professionals and therefore may not continue to achieve revenue growth through this channel.

In the United States, we have select strategic distributors in addition to our DTC and health professional channels. We also rely on a third-party reseller to manage our sales and fulfillment through the Amazon platform for operational convenience. We do not control the operational decisions of Amazon or this third-party provider, such as the amount of warehousing and inventory space to make available for our products. We have experienced instances in the past where Amazon has prioritized warehousing space to other products on a seasonal basis, which may cause an order backlog for our products if there is not a sufficient quantity of our products ready to ship from these facilities. If a backlog on orders through Amazon became frequent, it may reduce our revenue and harm our reputation. The loss of these third-party providers in the United States may result in delayed revenue as we seek alternative providers or transition those activities to a direct model.

A significant portion of our international sales are through distributors. We believe that our reliance on distributors internationally improves the economics of our business, as we do not carry the high fixed costs of a direct sales force in any of the countries in which our products are sold, with the exception of Canada. It is part of our strategy to partner with local distributors in foreign countries, such as Australia, New Zealand, United Kingdom, among others, to resell our products as those distributors are most familiar with the local market and regulations.

If we are unable to maintain or enter into such distribution arrangements on acceptable terms, or at all, we may not be able to successfully commercialize our products in certain countries. Furthermore, distributors can choose the level of effort that they apply to selling our products relative to others in their portfolio. The selection, training and compensation of employees of our distributors are within their control rather than our own and may vary significantly in quality from distributor to distributor.

In addition, although our contract terms require our distributors to comply with all applicable laws regarding the sale of our products, including anti-competition, anti-money laundering, sanctions laws and FDA regulations, we may not be able to ensure proper compliance. If our distributors fail to effectively market and sell our products to our expectations or in full compliance with applicable laws, our results of operations and business may suffer.

Our business depends on network and mobile infrastructure and our ability to maintain and scale our technology. Any significant interruptions or delays in service on our apps or websites or any undetected errors or design faults, including flaws in security design, could result in limited capacity, reduced demand, processing delays and loss of customers.

A key element of our strategy is to generate a significant number of visitors to, and increase their use of, our apps and websites. Our reputation and ability to acquire, retain and serve our customers are dependent upon the reliable performance of our apps and websites and the underlying network infrastructure. As our base of customer and the amount of information shared on our apps and

websites continue to grow, we will need an increasing amount of network capacity and computing power. We have spent and expect to continue to spend substantial amounts on computing, including cloud computing and the related infrastructure, to handle the traffic on our apps and websites. The operation of these systems is complex and could result in operational failures. In the event that the traffic of our consumers exceeds the capacity of our current network infrastructure or in the event that our base of consumers or the amount of traffic on our apps and websites grows more quickly than anticipated, we may be required to incur significant additional costs to enhance the underlying network infrastructure. Interruptions or delays in these systems, whether due to system failures, computer viruses, physical or electronic break-ins, undetected errors, design faults or other unexpected events or causes, could affect the security or availability of our apps and websites and prevent our consumers from accessing our apps and websites. If sustained or repeated, these performance issues could reduce the attractiveness of our product and service offerings. In addition, the costs and complexities involved in expanding and upgrading our systems may prevent us from doing so in a timely manner and may prevent us from adequately meeting the demand placed on our systems. Any internet or mobile platform interruption or inadequacy that causes performance issues or interruptions in the availability of our apps or websites could reduce customer satisfaction and result in a reduction in the number of customers using our offerings.

We depend on the development and maintenance of the internet and mobile infrastructure. This includes maintenance of reliable internet and mobile infrastructure with the necessary speed, data capacity and security, as well as timely development of complementary offerings, for providing reliable internet and mobile access. Our business, financial condition and results of operations could be materially and adversely affected if for any reason the reliability of our internet and mobile infrastructure is compromised.

We currently rely upon third-party data storage providers, including cloud storage solution providers, such as Amazon Web Services. Nearly all of our data storage and analytics are conducted on, and the data and content we create associated with sales on our apps and websites are processed through servers hosted by these providers, particularly Amazon Web Services. We also rely on email service providers, bandwidth providers, internet service providers and mobile networks to deliver email and "push" communications to consumers and to allow consumers to access our websites. If our third-party vendors are unable or unwilling to provide the services necessary to support our business, or if our agreements with such vendors are terminated, our operations could be significantly disrupted. Some of our vendor agreements may be unilaterally terminated by the licensor for convenience, including our agreement with Amazon Web Services, and if such agreements are terminated, we may not be able to enter into similar relationships in the future on reasonable terms or at all.

Any damage to, or failure of, our systems or the systems of our third-party data centers or our other third-party providers could result in interruptions to the availability or functionality of our apps and websites. As a result, we could lose consumer data and miss opportunities to acquire and retain consumers, which could result in decreased revenue. If for any reason our arrangements with our data centers or third-party providers are terminated or interrupted, such termination or interruption could adversely affect our business, financial condition and results of operations. We exercise little control over these providers, which increases our vulnerability to problems with the services they provide. We could experience additional expense in arranging for new facilities, technology, services and support. In addition, the failure of our third-party data centers or any other third-party providers to meet our capacity requirements could result in interruption in the availability or functionality of our apps and websites.

The satisfactory performance, reliability and availability of our apps, websites, transaction processing systems and technology infrastructure are critical to our reputation and our ability to acquire and retain customers, as well as to maintain adequate customer service levels. If the interface on our app is not considered user friendly by our customers or our app does not function correctly our customers may become frustrated and not order our products. Our revenue depends in part on the number of customers that visit and use our apps and websites in fulfilling their health and wellness needs. Unavailability of our apps or websites could materially and adversely affect consumer perception of our brand.

The occurrence of a natural disaster, power loss, telecommunications failure, data loss, computer virus, an act of terrorism, cyberattack, vandalism or sabotage, act of war or any similar event, or a decision to close our third-party data centers on which we normally operate or the facilities of any other third-party provider without adequate notice or other unanticipated problems at these facilities could result in lengthy interruptions in the availability of our apps and websites. Cloud computing, in particular, is dependent upon having access to an internet connection in order to retrieve data. If a natural disaster, blackout or other unforeseen event were to occur that disrupted the ability to obtain an internet connection, we may experience a slowdown or delay in our operations. While we have disaster recovery arrangements in place, our preparations may not be adequate to account for disasters or similar events that may occur in the future and may not effectively permit us to continue operating in the event of any problems with respect to our systems or those of our third-party data centers or any other third-party facilities. Our disaster recovery and data redundancy plans may be inadequate, and our business interruption insurance may not be sufficient to compensate us for the losses that could occur. If any such event were to occur to our business, our operations could be impaired and our business, financial condition and results of operations may be materially and adversely affected.

We are subject to payment processing risk.

Our customers pay for our products and services using a variety of different payment methods, including credit and debit cards, gift cards and online wallets. We rely on internal systems as well as those of third parties to process payment. Acceptance and processing of these payment methods are subject to certain rules and regulations and require payment of interchange and other fees. To the extent there are disruptions in our payment processing systems, increases in payment processing fees, material changes in the payment ecosystem, such as large re-issuances of payment cards, delays in receiving payments from payment processors, or changes to rules or regulations concerning payment processing, our revenue, operating expenses and results of operation could be adversely impacted. Compliance with the Payment Card Industry Data Security Standard and implementing related procedures, technology and information security measures requires significant resources and ongoing attention, and any security incident involving cardholder data could subject us to significant penalties and liability. We leverage our third-party payment processors to bill customers on our behalf. If these third parties become unwilling or unable to continue processing payments on our behalf, we will have to find alternative methods of collecting payments, which could adversely impact customer acquisition and retention. In addition, from time to time, we encounter fraudulent use of payment methods, which could impact our results of operations and if not adequately controlled and managed could create negative customer perceptions of our service.

Our ability to use our net operating loss to offset future taxable income may be subject to certain limitations.

As of December 31, 2022, we had U.S. federal net operating loss carryforwards (NOLs) and state NOLs of approximately $29.1 million and $47.1 million, respectively, due to prior period losses that if not utilized the federal operation loss carryforwards incurred before January 1, 2020, will begin to expire in 2030. The federal operating losses incurred in 2018 and beyond do not expire. The state operation loss carryforwards do not expire. Realization of these NOLs depends on future income, and there is a risk that our existing NOLs could expire unused and be unavailable to offset future income tax liabilities, which could adversely affect our operating results.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended (the Code), a corporation that undergoes a defined “ownership change” is subject to limitations on its ability to utilize its NOLs carryforwards to offset future taxable income. The annual limitation is based on the Company's stock value prior to the ownership change, multiplied by the applicable federal long-term, tax-exempt interest rate.

During 2022, we completed a Section 382 study and concluded that an ownership change under Section 382 occurred as a result of an equity event in 2018, resulting in a Section 382 limitation that applies to all Health Elements, LLC NOLs prior to the 2018 equity event. We have adjusted our NOL carryforwards to address the impact of the Section 382 ownership changes. This resulted in a reduction of available federal and state NOLs of $23.2 million and $18.8 million, respectively.

Future changes in our stock ownership, the causes of which may be outside of our control, could result in ownership change under Section 382 of the Code. If we undergo a deemed ownership change in the future, our NOLs arising before such an ownership change may be subject to one or more Section 382 limitations that materially limit the use of such NOLs to offset our taxable income. Our ability to utilize NOLs of companies that we have acquired or may acquire in the future may also be subject to limitations. Further, our NOLs may be impaired under state laws. In addition, under the 2017 Tax Cuts and Jobs Act (Tax Act), as modified by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), NOLs arising in taxable years beginning after December 31, 2020 may not be carried back, and NOLs generated in taxable years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such NOLs generally will be limited in taxable years beginning after December 31, 2020 to 80% of the current year taxable income. This change may require us to pay federal income taxes in future years even if our NOLs were otherwise sufficient to offset our federal taxable income in such years. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities. For these reasons, we may not be able to realize, in whole or in part, a tax benefit from the use of our NOLs, whether or not we attain profitability.

We may engage in merger and acquisition activities, which could require significant management attention, disrupt our business, dilute stockholder value and adversely affect our operating results.

As part of our business strategy, we may periodically acquire or make investments in companies that we believe will enhance our products, services or technology in the future. We may not be able to find suitable acquisition candidates and we may not be able to complete acquisitions on favorable terms, if at all, in the future. If we complete acquisitions, we may not ultimately strengthen our competitive position or achieve our goals, and any acquisitions we complete could be viewed negatively by customers or investors. An acquisition, investment or business relationship may result in unforeseen operating difficulties and expenditures, including disrupting our ongoing operations, diverting management from their primary responsibilities, subjecting us to additional liabilities, increasing our expenses and adversely impacting our business, financial condition and operating results. In addition, we may be exposed to unknown liabilities and the anticipated benefits of any acquisition, investment or business relationship may not be realized, if, for example, we fail to successfully integrate such acquisitions, or the technologies associated with such acquisitions, into our company.

To pay for any such acquisitions, we would have to use cash, incur debt, or issue equity securities, each of which may affect our financial condition or the value of our capital stock and could result in dilution to our stockholders. If we incur more debt it would result in increased fixed obligations and could also subject us to covenants or other restrictions that would impede our ability to manage our operations.

Additionally, we may receive indications of interest from other parties interested in acquiring some or all of our business. The time required to evaluate such indications of interest could require significant attention from management, disrupt the ordinary functioning of our business, and could have an adverse effect on our business, financial condition, and operating results.

We have identified material weaknesses in our internal control over financial reporting. If our remediation measures are ineffective, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to report our financial condition or results of operations accurately or on a timely basis, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

To date, we have never conducted a review of our internal control for the purpose of providing the reports required by the Sarbanes-Oxley Act. During our review and testing, we may identify deficiencies and be unable to remediate them before we must provide the required reports. In connection with the audit of our financial statements for the year ended December 31, 2022, we identified material weaknesses in our internal control over financial reporting related to an ineffective design of certain management review controls, including insufficient controls required to validate the completeness and accuracy of underlying data, ineffective controls related to the preparation and review of the annual income tax provision and related footnote disclosures under ASC 740, ineffective controls to sufficiently identify, evaluate, and disclose related party transactions, and insufficient controls required to accurately account for complex, non-routine and significant and unusual transactions, including accounting for non-routine or unusual contracts with customers in accordance with ASC 606 and accounting for business combinations in accordance with ASC 805. Additionally, we identified material weaknesses related to the insufficient design of information technology general controls ("ITGCs") in the areas of logical security access and change management, which have not been remediated as of December 31, 2022.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis.

We continue to take certain actions to address the control deficiencies in our financial reporting and IT environment, including by hiring additional qualified accounting and financial reporting personnel, and the development and implementation of processes and controls. We have also begun to review and improve the documentation of our accounting and financial processes and internal controls, build out our financial management and reporting systems infrastructure, and further develop and formalize our accounting policies and financial reporting procedures, which includes ongoing senior management review and enhancing our audit committee oversight. While we have begun taking measures and plan to continue to take measures to design and implement an effective control environment, we cannot assure you that the measures we have taken to date and other remediation and internal control measures we implement in the future will be sufficient to remediate our current material weaknesses or prevent future material weaknesses. We may discover additional weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are unable to successfully maintain internal control over financial reporting, or identify any additional material weaknesses, the accuracy and timing of our financial reporting may be adversely affected. In addition, if we are unable to assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting, when required, investors may lose confidence in the accuracy and completeness of our financial reports, we may face restricted access to the capital markets, and our stock price may be materially adversely affected. Moreover, we could become subject to investigations by regulatory authorities, which could require additional financial and management resources.

If we fail to maintain an effective system of disclosure controls and internal control over financial reporting, we may not be able to accurately report our financial results in a timely manner or prevent fraud, which would harm our business.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations in a timely manner, or at all. In addition, any testing by us conducted in connection with Section 404(a) of SOX or any subsequent testing by our

independent registered public accounting firm in connection with Section 404(b) of SOX, may reveal deficiencies in our internal controls over financial reporting that are deemed to be significant deficiencies or material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. As discussed above, we have identified material weaknesses in the past which we are in the process of remedying. However, our efforts to remediate previous material weaknesses may not be effective or prevent any future deficiency in our internal control over financial reporting. Ineffective internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

We will be required to disclose material changes made in our internal controls over financing reporting and procedures on a quarterly basis and our management will be required to assess the effectiveness of these controls annually. Beginning with our second annual report on Form 10-K, we will be required to make a formal assessment of the effectiveness of our internal control over financial reporting, and once we cease to be an emerging growth company, we will be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, for as long as we are an "emerging growth company" under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404(b).

To achieve compliance with Section 404(a) within the prescribed period, we will be engaging in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a plan to assess and document the adequacy of our internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are designed and operating effectively and implement a continuous reporting and improvement process for internal control over financial reporting.

We could be an "emerging growth company" for up to five years. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not identify. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

If our estimates or judgments relating to our critical accounting policies are based on assumptions that change or prove to be incorrect, our results of operation could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. We base our estimates on historical experience and estimates and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets, liabilities, equity, revenue and expenses that are not readily apparent from other sources. For example, in connection with the implementation of the new revenue accounting standard, management makes judgments and assumptions based on our interpretation of the new standard. The new standard is principle-based and interpretation of those principles may vary from company to company based on their unique circumstances. It is possible that interpretation, industry practice and guidance may evolve as we apply the new standard. If our assumptions underlying our estimates and judgements relating to our critical accounting policies change or if actual circumstances differ from our assumptions, estimates or judgements, our operating results may be adversely affected and could fall below our publicly announced guidance or the expectations of securities analysts and investors, resulting in a decline in the market price of our common stock.

Risks Related to Regulation

We are subject to regulation by various federal, state and foreign agencies that require us to comply with a wide variety of regulations, including those regarding the manufacture of products, advertising and product label claims, the distribution of our products and environmental matters. Failure to comply with these regulations could subject us to fines, penalties and additional costs.

Some of our operations are subject to regulation by various United States federal agencies and similar state and international agencies, including the Department of Commerce, the FDA, the FTC, the Department of Transportation (DOT), the U.S. Environmental Protection Agency (EPA) and the U.S. Department of Agriculture (USDA). These regulations govern a wide variety of product activities, from design and development to labeling, manufacturing, handling, sales and distribution of products. If we fail to comply with any of these regulations, we may be subject to fines or penalties, have to recall products or cease their manufacture and distribution, any of which would increase our costs and reduce our sales.

For example, the FDA may regulate medical or health-related software, including machine learning functionality and predictive algorithms, if such software falls within the definition of a "medical device" under the federal Drug Food and Cosmetic Act (FDCA).

However, the FDA exercises enforcement discretion for certain low-risk software, as described in its guidance documents for Mobile Medical Applications, General Wellness: Policy for Low Risk Devices, and Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices. In addition, the 21st Century Cures Act includes exemptions for certain medical-related software, including software used for administrative support functions at a healthcare facility, software intended for maintaining or encouraging a healthy lifestyle, EHR software, software for transferring, storing, or displaying medical device data or in vitro diagnostic data, and certain clinical decision support software. The FDA has also issued guidance documents to clarify how it intends to interpret and apply the exemptions under the 21st Century Cures Act. Although we believe that our software products are currently not subject to active FDA regulation, we continue to follow the FDA's developments in this area. There is a risk that the FDA could disagree with our determination or that the FDA could develop new final guidance documents that would subject our products to active FDA oversight. If FDA determines that any of our current or future software products are regulated as medical devices, we would become subject to various requirements under the FDCA and the FDA's implementing regulations, including the potential for both premarket and post-market requirements, and we would need to bring our software offerings into compliance with such requirements. Depending on the functionality and FDA classification of our software products, we may be required to register and list our products with the FDA and seek marketing authorization from FDA through a 510(k) clearance, De Novo classification, or Premarket Approval application pathway prior to marketing our software.

We are also subject to various federal, state, local and international laws and regulations that govern the handling, transportation, manufacture, use and sale of substances that are or could be classified as toxic or hazardous substances. Some risk of environmental damage is inherent in our operations and the products we manufacture, sell or distribute. Any failure by us to comply with the applicable government regulations could also result in product recalls, market withdrawals or impositions of fines and restrictions on our ability to carry on with or expand in a portion or possibly all of our operations. If we fail to comply with any or all of these regulations, we may be subject to fines or penalties, have to recall or withdraw products or cease their manufacture and distribution, which would increase our costs and reduce our sales.

Changes in the way that the FDA and other agencies regulate the tests and other products and services we offer, or the FDA's disagreement as to the regulatory classification of our tests or other products, could result in the delay or additional expense in offering the tests or products, or otherwise impact our business.

Governmental agencies throughout the world, including in the United States, strictly regulate the pharmaceutical, dietary supplement, medical device, food and cosmetic industries. Our business involves manufacturing dietary supplements, developing health and wellness products, and offering testing performed by independent laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and accredited by the College of American Pathologists (CAP). Changes in regulation or the application of regulatory requirements that we have difficulty satisfying or that make our services less competitive, could eliminate or substantially reduce the demand for our tests, products and services or could impact our marketing practices relating to the relevant tests or products, which in turn may have an adverse impact on our business, financial condition and results of operations.

Laboratory-developed tests (LDTs) are in vitro diagnostic tests that are intended for clinical use and are designed, manufactured and used within a single laboratory. Although LDTs are classified as medical devices and the FDA has statutory authority to ensure that medical devices are safe and effective for their intended uses, the FDA has historically exercised enforcement discretion and has not enforced certain applicable FDA requirements, including premarket review, with respect to LDTs. Moreover, in August 2020, the HHS announced that the FDA will not require premarket review of LDTs absent notice-and-comment rulemaking.

Legislative and administrative proposals proposing to amend the FDA's oversight of LDTs have been introduced in recent years and we expect that new legislative and administrative proposals will continue to be introduced from time to time. It is possible that legislation could be enacted into law or regulations or guidance could be issued by the FDA which may result in new or increased regulatory requirements for us to continue to offer our tests or to develop and introduce new tests as LDTs. For example, the FDA could modify its current approach to LDTs in a way that would subject our tests that we market as LDTs to the enforcement of additional regulatory requirements. In recent years, the FDA has stated its intention to modify its enforcement discretion policy with respect to LDTs. Specifically, on July 31, 2014, the FDA notified Congress of its intent to modify, in a risk-based manner, its policy of enforcement discretion with respect to LDTs. On October 3, 2014, the FDA issued two draft guidance documents entitled "Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)," or the Framework Guidance, and "FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)," or the Reporting Guidance. The FDA halted finalization of the guidance in November 2016 to allow for further public discussion on an appropriate oversight approach to LDTs and to give congressional authorizing committees the opportunity to develop a legislative solution, and the FDA issued a discussion paper on possible approaches to LDT regulation in January 2017.

In addition, the FDA and Congress have considered a number of proposals to end the FDA's enforcement discretion policy for LDTs and subject LDTs to additional regulatory requirements. For example, Congress has recently been working on legislation to create an LDT and in vitro diagnostic regulatory framework for all in vitro clinical tests (IVCTs), that would be separate and distinct

from the existing medical device regulatory framework. In March 2020, members of the U.S. House of Representatives formally introduced the Verifying Accurate Leading-edge IVCT Development Act of 2020 (the VALID Act) in the House and an identical version of the bill was introduced in the U.S. Senate. On June 24, 2021, a revised version of the VALID Act was introduced by members of the U.S. House of Representatives and the Senate. The VALID Act would create a new category of medical products separate from IVCTs and subject all such products to FDA oversight. As proposed, the bill grandfathers many existing tests from the proposed premarket approval, quality systems, and labeling requirements, but would require such tests to comply with other regulatory requirements (for example, registration and notification, adverse event reporting). The bill also provides for IVCTs introduced before the effective date, drafted to be approximately four years after the enactment date, to be transitional and remain on the market subject to certain conditions. It is unclear whether the VALID Act or any other legislative proposals will be passed by Congress or signed into law by the President. Depending on the approach adopted under any legislation, certain LDTs, likely those of higher risk, could become subject to some form of premarket review, potentially with a transition period for compliance and a grandfathering provision.

Even if the FDA does not modify its policy of enforcement discretion, whether due to changes in FDA policy or legislative action, the FDA may disagree that our tests are properly classified as LDTs within the scope of its policy of enforcement discretion and may impose significant regulatory requirements, including the requirement for premarket review and clearance or approval. We may also be required to conduct clinical studies to support our currently marketed products or planned product launches.

If this were to happen, we or our suppliers may be required to obtain premarket clearance or approval of the tests we offer, or our marketing practices relating to the relevant tests may be impacted. The process of obtaining regulatory clearances or approvals to market a medical device can be costly and time consuming, and our suppliers may not be able to obtain these clearances or approvals on a timely basis, if at all. If we or our suppliers are required to conduct clinical trials, delays in the commencement or completion of clinical testing could significantly increase our test development costs and delay commercialization of any currently marketed tests that we may be required to cease selling or the commercialization of any future tests that we may develop. Many of the factors that may cause or lead to a delay in the commencement or completion of clinical trials may also ultimately lead to delay or denial of regulatory clearance or approval. The commencement of clinical trials may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites and the eligibility criteria for the clinical trial.

Even if regulatory clearance or approval of a product is required and granted, such clearance or approval may be subject to limitations on the intended uses for which the product may be offered and reduce our potential to successfully commercialize and generate revenue from the test results. If the FDA determines that our promotional materials, labeling, training or other marketing or educational activities constitute promotion of an uncleared or unapproved use, it could request that we cease or modify our training or promotional materials or subject us to regulatory enforcement action.

We and our suppliers are also subject to other federal, state, and foreign regulations concerning the manufacture and sale of the tests we offer. Failure to comply with U.S. federal, state and foreign governmental regulations could lead to the issuance of warning letters or untitled letters, the imposition of injunctions, suspensions or loss of regulatory clearance or approvals, product recalls, termination of distribution, product seizures or civil penalties. In the most extreme cases, criminal sanctions or closure of our suppliers' manufacturing facilities are possible. The occurrence of any of these events may have an adverse impact on our business, financial condition and results of operations.

After clearance or approval of any of our products, we are subject to continuing regulation by the FDA, and if we fail to comply with FDA regulations, our business could suffer.

Even after clearance or approval of a product, we are subject to continuing regulation by the FDA, including the requirements that our facility be registered and our devices listed with the agency. We are subject to Medical Device Reporting regulations, which require us to report to the FDA if our products may have caused or contributed to a death or serious injury or malfunction in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur. We must report corrections and removals to the FDA where the correction or removal was initiated to reduce a risk to health posed by the device or to remedy a violation of the Federal Food, Drug, and Cosmetic Act caused by the device that may present a risk to health and maintain records of other corrections or removals. The FDA closely regulates promotion and advertising, and our promotional and advertising activities could come under scrutiny. If the FDA objects to our promotional and advertising activities or finds that we failed to submit reports under the Medical Device Reporting regulations, for example, the FDA may allege our activities resulted in violations.

The FDA and state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any of the following sanctions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- repair, replacement, refunds, recall or seizure of our products;

- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance or premarket approval of new products or new intended uses;
- withdrawing 510(k) clearance or premarket approvals that have already been granted; and
- criminal prosecution.

If any of these events were to occur, they could harm our business.

If we modify our 510(k)-cleared products without FDA clearance, the FDA could retroactively determine that the modifications were improper and require us to stop marketing and recall the modified products.

Any modifications to an FDA-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or a premarket approval. We may be required to submit extensive pre-clinical and clinical data depending on the nature of the changes. We may not be able to obtain additional 510(k) clearances or premarket approvals for modifications to, or additional indications for, our existing products in a timely fashion, or at all. Delays in obtaining future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our revenue and operating results. If the FDA disagrees with any of our prior determinations that a change to our 510(k)-cleared device did not require new clearances or approvals, we may be required to recall and to stop marketing the modified devices, which could harm our operating results and require us to redesign, among other things, our products.

We and our suppliers are subject to numerous laws and regulations that apply to the manufacture, sale and marketing of nutritional supplements, and compliance with these laws and regulations, as they currently exist or as modified in the future, may increase our costs, limit or eliminate our ability to sell certain products, subject us or our suppliers to the risk of enforcement action, or otherwise adversely affect our business, results of operations and financial condition.

As a manufacturer of nutritional supplements, we are subject to numerous health and safety laws and regulations. Our suppliers are also subject to such laws and regulations. These laws and regulations apply to many aspects of our business, including the manufacturing, packaging, labeling, distribution, advertising, sale, quality and safety of products we sell, as well as the health and safety of our team members and the protection of the environment. We are subject to regulation by various government agencies, including the FDA, the USDA, the FTC, the Occupational Safety and Health Administration, the Consumer Product Safety Commission and the U.S. Environmental Protection Agency, as well as various state and local agencies. For example, our products are subject to numerous and extensive laws and regulations governing the type of claims we can make regarding our products, the product constituents that can be used to manufacture our products, and whether our product constituents or the products themselves require pre-market review or pre-market notification. Outside the United States, our activities and products are also subject to numerous similar statutes and regulations. Many of these laws and regulations involve a high level of subjectivity, are inherently fact-based and subject to interpretation, and vary significantly from market to market.

Dietary supplements are regulated under the Dietary Supplement Health and Education Act of 1994 (DSHEA), a statute which is administered by the FDA which amended the FDCA. DSHEA expressly permits supplements to bear statements describing how a product affects the structure, function or general well-being of the body. However, no statement may expressly or implicitly represent that a supplement will diagnose, cure, mitigate, treat or prevent a disease. DSHEA has not been materially amended since it was enacted in 1994 but the newly constituted U.S. Congress or executive branch could decide to revisit whether changes are necessary to modernize this legislation.

Our dietary supplement products are required to be manufactured in compliance with current Good Manufacturing Practices (cGMP) requirements. As a result, the facilities used by us or any of our current or future suppliers must be compliant with cGMPs. Our manufacturing facilities are subject to ongoing periodic unannounced inspections by the FDA and corresponding state and international authorities for compliance with cGMPs and similar regulatory requirements. If we or our manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA and any applicable foreign regulatory authority, our products may be deemed noncompliant, and we could face sanctions being imposed on us, including fines, injunctions, civil penalties, delays, operating restrictions, interruptions in supply, recalls, withdrawals, issuance of safety alerts and criminal prosecutions, any of which could have a material adverse impact on our business, financial condition, results of operations and prospects. Finally, we also could experience manufacturing delays if our contractors give greater priority to the manufacture and supply of other products over our products or otherwise do not satisfactorily perform according to the terms of their agreements with us.

The FDA has broad authority to enforce the provisions of the FDCA applicable to the safety, labeling, manufacturing and promotion dietary supplements, including powers to issue a public warning letter to a company, publicize information about illegal products, institute an administrative detention, request or order a recall of illegal products from the market and request the Department

of Justice to initiate a seizure action, an injunction action or a criminal prosecution in the U.S. courts. Pursuant to the Food Safety Modernization Act (FSMA), the FDA also has the power to refuse the import of dietary supplement from a foreign supplier that is not appropriately verified as in compliance with all FDA laws and regulations. Moreover, the FDA has the authority to administratively suspend the registration of any facility producing dietary supplements, deemed to present a reasonable probability of causing serious adverse health consequences.

In connection with the marketing and advertisement of products we sell, we could be the target of claims relating to false or deceptive advertising, including under the auspices of the FTC and the consumer protection statutes of some states. Furthermore, in recent years, the FDA has been aggressive in enforcing its regulations with respect to nutrient content claims, unauthorized "health claims," which are defined as claims that characterize the relationship between a food or food ingredient and a disease or health condition, and other claims that impermissibly suggest therapeutic benefits for certain products including dietary supplements. These events could interrupt the marketing and sales of our products, severely damage our brand reputation and public image, increase the cost of our products, result in product recalls, market withdrawals or litigation and impede our ability to deliver our products, any of which could result in a material adverse effect on our business, financial condition and results of operations.

As is common in our industry, we rely on our suppliers to ensure that the products they manufacture and sell to us comply with all applicable regulatory and legislative requirements. In general, we seek certifications of compliance, representations and warranties, indemnification and insurance from our suppliers. However, even with adequate insurance and indemnification, any claims of non-compliance could significantly damage our reputation and consumer confidence in our products.

We cannot predict the nature of future laws, regulations, interpretations or applications, or determine what effect either additional government regulations or administrative orders, when and if promulgated, or disparate federal, state and local regulatory schemes would have on our business in the future. They could, however, increase our costs or require the reformulation of certain products to meet new standards, the recall or discontinuance of certain products not able to be reformulated, additional recordkeeping, expanded documentation of the properties of certain products, expanded or different labeling or scientific substantiation. Another example is that the FDA could require the production of efficacy data for nutritional supplements. Any or all of such requirements could have a material adverse effect on our business, financial condition and results of operation.

Our use, disclosure, and other processing of personal information, including health information, is subject to the Health Insurance Portability and Accountability Act (HIPAA), and other federal, state, and foreign data privacy and security laws and regulations, and our failure to comply with those laws and regulations or to appropriately secure the information we hold could result in significant liability or reputational harm and, in turn, a material adverse effect on our client base, customer base and revenue.

In the course of offering personalized health and wellness recommendations, we collect a substantial amount of personalized health information. Numerous state and federal laws and regulations govern the collection, dissemination, use, privacy, confidentiality, security, availability, integrity and other processing of protected health information (PHI), and other types of personal information. For example, HIPAA establishes a set of national privacy and security standards for the protection PHI by health plans, healthcare clearinghouses and certain healthcare providers, referred to as covered entities, and the business associates with whom such covered entities contract for services, as well as their covered subcontractors. When we act in the capacity of a business associate under HIPAA, we execute business associate agreements with our clients.

HIPAA requires covered entities and business associates, such as us, to develop and maintain policies and procedures with respect to PHI that is used or disclosed, including the adoption of administrative, physical and technical safeguards to protect such information.

Violations of HIPAA may result in significant civil and criminal penalties. HIPAA also authorizes state attorneys general to file suit on behalf of their residents. Courts may award damages, costs and attorneys' fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to sue us in civil court for violations of HIPAA, its standards have been used as the basis for duty of care in state civil suits such as those for negligence or recklessness in the misuse or breach of duties related to PHI.

In addition, HIPAA mandates that the Secretary of HHS conduct periodic compliance audits of HIPAA covered entities and business associates for compliance with the HIPAA privacy and security rules.

HIPAA further requires that patients be notified of any unauthorized acquisition, access, use or disclosure of their unsecured PHI that compromises the privacy or security of such information, with certain exceptions related to unintentional or inadvertent use or disclosure by employees or authorized individuals. HIPAA requires such notifications to be made "without unreasonable delay and in no case later than 60 calendar days after discovery of the breach." If a breach affects 500 patients or more, it must be reported to

HHS without unreasonable delay, and HHS will post the name of the breaching entity on its public web site. Breaches affecting 500 patients or more in the same state or jurisdiction must also be reported to the local media. If a breach involves fewer than 500 people, the covered entity must record it in a log and notify HHS at least annually.

In addition to HIPAA, numerous other federal, state, and foreign laws and regulations protect the confidentiality, privacy, availability, integrity and security of health-related and other personal information. These laws and regulations in many cases are more restrictive than, and may not be preempted by, HIPAA and its implementing rules. These laws and regulations are often uncertain, contradictory, and subject to changed or differing interpretations, and we expect new laws, rules and regulations regarding privacy, data protection, and to be proposed and enacted in the future. Further, the U.S. and many state attorneys general are interpreting existing federal and state consumer protection laws to impose evolving standards for the online collection, use, dissemination and security of health-related and other personal information. Courts may also adopt the standards for fair information practices promulgated by the FTC, which concern consumer notice, choice, security and access. Consumer protection laws require us to publish statements that describe how we handle personal information and choices individuals may have about the way we handle their personal information. If such information that we publish is considered untrue, we may be subject to government claims of unfair or deceptive trade practices, which could lead to significant liabilities and consequences. Furthermore, according to the FTC, violating consumers' privacy rights or failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the FTC Act.

California also has enacted the California Consumer Privacy Act (CCPA), which came into effect on January 1, 2020. Pursuant to the CCPA, certain businesses are required, among other things, to make certain enhanced disclosures related to California residents regarding the use or disclosure of their personal information, allow California residents to opt-out of certain uses and disclosures of their personal information without penalty, provide California residents with other choices related to personal information in our possession, and obtain opt-in consent before engaging in certain uses of personal information relating to California residents under the age of 16. The California Attorney General may seek substantial monetary penalties and injunctive relief in the event of our non-compliance with the CCPA. The CCPA also allows for private lawsuits from Californians in the event of certain data breaches. Moreover, the California Privacy Rights Act (CPRA), was recently passed in California. The CPRA significantly modifies the CCPA, creating additional data protection obligations relating to consumer data on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the CPRA provisions will go into effect on January 1, 2023, with enforcement beginning July 1, 2023. Aspects of the CCPA and CPRA remain uncertain, and we may be required to make modifications to our policies or practices in efforts to comply. Other states are considering similar legislation. A broad range of legislative measures also have been introduced at the federal level.

In Europe, the collection, use, disclosure, transfer or other processing of personal data regarding individuals, including personal health data and employee data, is subject to the GDPR, which took effect in May 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data of individuals within the European Economic Area (EEA), including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. In addition, the GDPR imposes strict rules on the transfer of personal data to countries outside the EEA, including the United States and, as a result, increases the scrutiny that such rules should apply to transfers of personal data from the EEA to the United States. The GDPR also permits data protection authorities to require destruction of improperly gathered or used personal information and/or impose substantial fines for violations of the GDPR, which can be up to the greater of four percent of global revenues or €20 million, and confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR provides that European Union member states may make their own further laws and regulations limiting the processing of personal data, including genetic, biometric, or health data.

Further, the United Kingdom exited the EU effective January 31, 2020. The United Kingdom's decision to leave the European Union has created uncertainty with regard to data protection regulation in the United Kingdom. As of January 1, 2021, we are also subject to the UK General Data Protection Regulation and UK Data Protection Act of 2018, which retains the GSPR in the United Kingdom's national law. Failure to comply with any of these obligations could expose us to penalties of up to the greater of four percent of global revenues or £17.5 million.

This complex, dynamic legal landscape regarding privacy, data protection, and information security creates significant compliance issues for us and our clients and potentially exposes us to additional expense, adverse publicity and liability. While we have implemented data privacy and security measures in an effort to comply with applicable laws and regulations relating to privacy, data protection and information security, PHI and other personal information is processed for us or transmitted to us by third parties,

who may not implement adequate security and privacy measures, and it is possible that laws, rules or regulations relating to privacy, data protection, or information security may be interpreted and applied in a manner that is inconsistent with our practices or those of third parties who perform services for us or transmit PHI and other personal information to us. Any failure or perceived failure by us or these third parties to comply with laws, regulations, rules or other obligations relating to privacy, data protection or information security, may result in governmental investigations or enforcement actions, litigation, claims and other proceedings, and could result in significant fines, penalties, and other liability. Additionally, defending against any claims, litigation, regulatory proceedings, or other proceedings can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions or proceedings that may be brought against us, our business may be impaired, and we may suffer reputational and other harm. Further, complying with these various laws, regulations, and other obligations could cause us to incur substantial costs or require us to change our business practices, systems and compliance procedures in a manner adverse to our business.

Furthermore, the costs of compliance with, and other burdens imposed by, the laws, regulations and policies that are applicable to the businesses of our clients may limit the use and adoption of, and reduce the overall demand for, our platform. Even the perception of privacy concerns, whether or not valid, may harm our reputation and inhibit use and adoption of our platform. Further, if any information that we collect from or otherwise process about our customers is used, accessed or disclosed in an unauthorized manner, or if this is reported or perceived to have occurred, customers may not want to provide such information to us, which could prevent us from providing recommendations, subject us to liability or damage our reputation and brand. Any of the foregoing consequences could have a material adverse impact on our business and our financial results.

From time to time, we may be subject to legal proceedings, regulatory disputes, and governmental inquiries that could cause us to incur significant expenses, divert our management's attention, and materially harm our business, financial condition and operating results.

From time to time, we may be subject to claims, lawsuits, government investigations and other proceedings involving products liability, competition and antitrust, intellectual property, privacy, data protection, information security, customer protection, securities, tax, labor and employment, commercial disputes and other matters that could adversely affect our business operations and financial condition. Litigation and regulatory proceedings, and particularly the intellectual property infringement matters that we are currently facing or could face, may be protracted and expensive, and the results are difficult to predict. Certain of these matters 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 products or services, make content unavailable, or require us to stop offering certain features, all of which could negatively affect our membership and revenue growth.

We are aware of third-party issued U.S. patents with claims relating to compositions of nicotinamide riboside, a component of some of our products, owned by the Trustees of Dartmouth and licensed to ChromaDex Corporation (ChromaDex). We have filed petitions for inter partes review against these patents at the Patent Trial and Appeal Board to seek to invalidate these patents. In May 2021, the Trustees of Dartmouth and ChromaDex initiated infringement proceedings against us. The complaint seeks to enjoin us from selling our nutritional supplement products that contain nicotinamide riboside, including our NiaCel suite of supplements, and further seeks monetary damages for alleged infringement. In August 2021, the trail judge in the patent infringement litigation issued an Order to Stay the litigation during the pendency of two inter partes reviews (described further in Item 3. Legal Proceedings), in which decision will likely be made in mid-2022. The results of litigation, investigations, claims, and regulatory proceedings cannot be predicted with certainty, and determining reserves for pending litigation and other legal and regulatory 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 harm our business, financial condition, and operating results.

If we fail to comply with governmental regulations, we could face substantial penalties and our business, financial condition and results of operations could be adversely affected.

Although our offerings are not currently covered by any third-party payor, including any commercial payor or government healthcare program, our business activities may nonetheless be subject to regulation and enforcement by the FDA, U.S. Department of Justice, HHS and other federal and state governmental authorities.

Our employees, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements. Federal and state laws and regulations that may affect our ability to conduct business include, without limitation:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order, or arranging for or recommending the purchase, lease or order of, any item or service, for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. 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;
- the federal civil false claims laws, including without limitation the federal False Claims Act, which can be enforced through "qui tam," or whistleblower actions, by private citizens, on behalf of the federal government, and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment of government funds, or knowingly making or using or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the healthcare fraud statutes under HIPAA, which impose criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for healthcare benefits, items or services by a healthcare benefit program, which includes both government and privately funded benefits programs. Similar to the federal Anti-Kickback Statute, 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;
- the federal Physician Payment Sunshine Act, which require certain manufacturers of drugs, devices, biologicals, and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to HHS under the Open Payments Program, information related to payments or other transfers of value made to teaching hospitals, physicians and, effective January 1, 2022, for transfers of value made during the prior year to certain other healthcare practitioners, as well as ownership and investment interests held by such physicians and their immediate family members;
- medical device regulations pursuant to the FDCA, which require, among other things, pre-market clearances, approved labelling, medical device adverse event reporting, and on-going post-market monitoring and quality assurance;
- federal consumer protection and unfair competition laws, which broadly regulate platform activities and activities that potentially harm consumers;
- state law equivalents of each of the above federal laws, such as anti-kickback, self-referral and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and self-pay patients; and
- state laws governing the corporate practice of medicine and other healthcare professions and related fee-splitting laws.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of our activities, including our arrangements with our network of health professionals who receive a payment for the products their patients purchase from us, could be subject to challenge under one or more of such laws.

We may face claims and proceedings by private parties, and claims, investigations and other proceedings by governmental authorities, relating to allegations that our business practices do not comply with current or future laws or regulations involving applicable fraud and abuse or other healthcare laws and regulations, and it is possible that courts or governmental authorities may conclude that we have not complied with applicable laws, or that we may find it necessary or appropriate to settle any such claims or other proceedings. The growth of our business and sales organization and our future expansion outside of the United States 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 federal, state or foreign laws described above or other laws and regulations that apply to us, we may be subject to claims and proceedings by private parties, investigations and other proceedings by governmental authorities, as well as 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 or regulations, 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. We may be required to undertake additional policies or measures in order to comply with these or other applicable laws. Any of the foregoing could seriously harm our business and our financial results.

We are dependent on our relationships with healthcare professionals to provide healthcare services, and our business would be adversely affected if those relationships were disrupted.

Our contractual relationships with our network of healthcare professionals which provide for consulting and other services may implicate certain state laws in the United States that generally prohibit non-physician entities from practicing medicine, exercising control over physicians or engaging in certain practices such as fee-splitting with physicians. Although we believe that we have structured our arrangements to ensure that the healthcare professionals maintain exclusive authority regarding the delivery of medical care and the ordering of our tests when deemed clinically appropriate, there can be no assurance that these laws will be interpreted in a manner consistent with our practices or that other laws or regulations will not be enacted in the future that could have a material and adverse effect on our business, financial condition and results of operations. Regulatory authorities, state medical boards of medicine, state attorneys general and other parties, including our affiliated healthcare professionals, may assert that we are engaged in the prohibited corporate practice of medicine, or that our arrangements with our network of healthcare professionals constitute unlawful fee-splitting. If a state's prohibition on the corporate practice of medicine or fee-splitting law is interpreted in a manner that is inconsistent with our practices, we would be required to restructure or terminate our relationship with our healthcare professionals to bring our activities into compliance with such laws. A determination of non-compliance, or the termination of or failure to successfully restructure these relationships could result in disciplinary action, penalties, damages, fines, and a loss of revenue, any of which could have a material and adverse effect on our business, financial condition and results of operations. State corporate practice of medicine doctrines and fee-splitting prohibitions also often impose penalties on healthcare professionals for aiding the corporate practice of medicine, which could discourage physicians and other healthcare professionals from participating in our network of providers.

Failure to comply with anti-corruption and anti-money laundering laws, including the FCPA and similar laws associated with our activities outside of the United States, could subject us to penalties and other adverse consequences.

We operate a global business and may have direct or indirect interactions with officials and employees of government agencies or state-owned or affiliated entities. We are subject to the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, the U.K. Bribery Act, the Canadian Corruption of Finance Public Officials Act and possibly other anti-corruption and anti-money laundering laws in countries in which we conduct activities. The FCPA prohibits providing, offering, promising, or authorizing, directly or indirectly, anything of value to government officials, political parties, or political candidates for the purposes of obtaining or retaining business or securing any improper business advantage. The provisions of the U.K. Bribery Act extend beyond bribery of government officials and create offenses in relation to commercial bribery including private sector recipients. The provisions of the U.K. Bribery Act also create offenses for accepting bribes in addition to bribing another person. In addition, U.S. public companies are required to maintain records that accurately and fairly represent their transactions and have an adequate system of internal accounting controls. In many foreign countries, including countries in which we may conduct business, it may be a local custom that businesses engage in practices that are prohibited by the FCPA, U.K. Bribery Act, or other applicable laws and regulations. We face significant risks if we or any of our directors, officers, employees, contractors, agents or other partners or representatives fail to comply with these laws and governmental authorities in the United States, U.K. and elsewhere could seek to impose substantial civil and/or criminal fines and penalties which could have a material adverse effect on our business, reputation, operating results, prospects and financial condition.

We have begun to implement an anti-corruption compliance program and policies, procedures and training designed to foster compliance with these laws, including the FCPA, the U.K. Bribery Act, the Canadian Corruption of Finance Public Officials Act, and others. However, our directors, officers, employees, contractors, agents, and other partners to which we outsource certain of our business operations, may take actions in violation of our policies or applicable law. Any such violation could have an adverse effect on our reputation, business, operating results, prospects and financial conditions.

Any violation of the FCPA, U.K. Bribery Act, the Canadian Corruption of Finance Public Officials Act other applicable anti-corruption laws, or anti-money laundering laws could result in whistleblower complaints, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions and, in the case of the FCPA, suspension or debarment from U.S. government contracts, any of which could have a materially adverse effect on our reputation, business, operating results, prospects and financial condition. In addition, responding to any enforcement action or internal investigation related to alleged misconduct may result in a significant diversion of management's attention and resources and significant defense costs and other professional fees.

The applicability of sales, use and other tax laws or regulations on our business is uncertain. Adverse tax laws or regulations could be enacted or existing laws could be applied to us or our clients, which could subject us to additional tax liability and related interest and penalties, increase the costs of our solution and adversely impact our business.

The application of tax laws to e-commerce services is evolving. New income, sales, use, value-added or other tax laws, statutes, rules, regulations, or ordinances could be enacted at any time, possibly with retroactive effect, and could be applied solely or disproportionately to services provided over the internet or could otherwise materially affect our financial position and results of operations.

In addition, state, local and foreign tax jurisdictions have differing rules and regulations governing sales, use, value-added and other taxes, and these rules and regulations can be complex and are subject to varying interpretations that may change over time. Existing tax laws, statutes, rules, regulations, or ordinances could be interpreted, changed, modified, or applied adversely to us, possibly with retroactive effect. One or more states may seek to impose incremental or new sales, use, value added or other tax collection obligations on us, including for past sales by us or our resellers and other partners. A successful assertion by a state, country or other jurisdiction that we should have been or should be collecting additional sales, use, value added or other taxes on our solutions could, among other things, result in substantial tax liabilities for past sales, create significant administrative burdens for us, discourage users from utilizing our solutions or otherwise harm our business, results of operations and financial condition. Our resellers are responsible for collecting and paying the taxes on sales of our products to end-users. We are responsible for collecting and paying taxes on product sales made directly to end users. If it is determined that we have not collected and remitted the appropriate amount of taxes to governmental authorities we could be subject to potential sales tax liabilities including interest and penalties, which could have an adverse impact on our results of operations and our cash balance.

Risks Related to our Intellectual Property

Litigation or other proceedings or third-party claims of intellectual property infringement, misappropriation or other violations may require us to spend significant time and money to defend ourselves, and could in the future require us to pay substantial damages or prevent us from selling our products or services or impact our stock price, any of which could have a material adverse effect.

Our commercial success will depend in part on our avoiding infringement of patents and infringement, misappropriation or other violations of other proprietary rights of third parties, including, for example, the intellectual property rights, such as trademarks, trade dress and name and likeness, of competitors, marketing partners and other third parties. The personalized health and wellness industries are in a crowded patent space, and there are numerous U.S. and foreign issued patents and pending patent applications owned by third parties that exist in the fields in which we operate. It may not be clear to us whether our products or methods of manufacturing, or other processes that we use may infringe the patents of third parties. Identification of third-party patent rights that may be relevant to our products and operations can be difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We also may not have the resources to perform extensive analysis of potentially relevant third-party patents, especially given the wide range of our product offerings. Furthermore, there is extensive and frequent intellectual property litigation in the personalized health and wellness products industry. Our activities may be subject to claims that we infringe or otherwise violate patents owned or controlled by third parties. We cannot assure you that our operations do not, or will not in the future, infringe existing or future patents.

For example, we are aware of third-party issued U.S. patents with claims relating to compositions of nicotinamide riboside, a component of some of our products, owned by the Trustees of Dartmouth and licensed to ChromaDex. We have filed petitions for inter partes review against these patents at the Patent Trial and Appeal Board to seek to invalidate the patents, but the outcome of such proceedings is uncertain. In May 2021, the Trustees of Dartmouth and ChromaDex initiated infringement proceedings against us. The complaint seeks to enjoin us from selling our nutritional supplement products that contain nicotinamide riboside, including our NiaCel suite of supplements, and further seeks monetary damages for alleged infringement. If we are unsuccessful in our challenge of the validity of the patent related to compositions of nicotinamide riboside, we could be required to pay damages and ongoing royalty payments or alternatively we may need to delay the sale of certain nutritional supplement products in the U.S. until 2026, when such patents will expire.

There may also be patent applications owned by third parties that, if issued as patents, could be asserted against us. Patent applications in the United States and elsewhere are typically published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain U.S. patent applications that will not be filed outside the United States can remain confidential until patents issue. Therefore, patent applications covering our products and services could have been filed by third parties without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our products and services, and their use. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history and can involve other factors such as expert opinion. Our interpretation of the relevance or the scope of claims in a patent or a pending application may be incorrect, which may negatively impact our ability to market our products and services. Further, we may incorrectly determine that our products or services are not covered by a third-party patent or may incorrectly predict whether a third-party's pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our products or services. Third-party intellectual property right holders may also actively bring infringement or other intellectual property-related claims against us, even if we have received patent protection for our products and services.

With respect to non-patent intellectual property rights of third parties, such as trademarks, names and likeness, we are at risk of claims by third parties of infringing or misappropriating such intellectual property rights. For example, we tout our relationships with many third parties, including social influencers, marketing partners, customers, athletes, sports teams, sports leagues, research institutions, universities, consumer products companies, pharmaceutical companies and collaborators to market and promote our products and services, including on our website and in our marketing literature. We do not have formal engagement or agreement with many of these third parties that we characterize as our partners or collaborators, nor do we have agreements with them regarding to the terms or conditions under which we may use their trademarks, name and likeness to market and promote our products and services. These third parties may claim that we infringed their trademarks, or that we misappropriated their name and likeness and mischaracterized our relationships with them. For third parties with whom we have current agreements concerning our rights to use their name and likeness for marketing and promotional purposes, there are restrictions on how we may characterize our relationships with them and other terms and conditions under which we may disclose our relationships with them, such as, for example, their right to pre-approve instances of our use of their names in our promotional and marketing materials. These third parties may claim that we are in violation of our agreements with them and may seek damages or terminate their relationship with us. We could be found liable for significant monetary damages, including potential treble damages, disgorgement of profits, and attorneys' fees, if we are found to have willfully infringed a trademark or other intellectual property rights of third parties.

Regardless of the merit of third parties claims against us for infringement, misappropriation or violations of their intellectual property rights, such third parties may seek and obtain injunctive or other equitable relief, which could effectively block our ability to sell our products or services or perform our tests. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay our development or sales or other activities that are the subject of such suit. Defense of these claims, even if such claims are resolved in our favor, could cause us to incur substantial expenses and be a substantial diversion of our employee resources even if we are ultimately successful. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the market price of our common stock. Any adverse ruling or perception of an adverse ruling in defending ourselves could have a material adverse impact on our cash position and stock price. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios.

As we continue to commercialize our products in their current or an updated form, launch new products and services and enter new markets, other competitors might claim that our products or services infringe, misappropriate or violate their intellectual property rights as part of business strategies designed to impede our successful commercialization and entry into new markets. If such a suit were brought, regardless of merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability or priority. Even if we are successful in defending against such suit, we could incur substantial costs and diversion of the attention of our management and technical personnel in defending ourselves against such claims. A court of competent jurisdiction could hold that third-party patents asserted against us are valid, enforceable, and infringed, which could materially and adversely affect our ability to commercialize any products or services we may develop and any other technologies covered by the asserted third-party patents and any adverse ruling or perception of an adverse ruling in defending ourselves could have a material adverse impact on our cash position and stock price. If we are found to infringe, misappropriate or otherwise violate a third-party's intellectual property rights, and we are unsuccessful in demonstrating that such rights are invalid or unenforceable, we may be required to pay substantial damages, including treble damages and attorneys' fees for willful infringement; obtain one or more licenses from third parties in order to continue developing and marketing our products and services, which may not be available on commercially reasonable terms, if at all, or may be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us; pay substantial royalties and other fees; and redesign any infringing tests or other activities, which may be impossible or require substantial time and monetary expenditure, or be prohibited from commercializing certain tests, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

As is common in the personalized health and wellness products industries, in addition to our employees, we engage the services of consultants, outside scientific collaborators, third-party manufacturers, advisors, potential partners, and other third parties to assist us in the development of our products. We have entered into and may enter in the future into non-disclosure and confidentiality agreements to protect the proprietary positions of these third parties. Many of these third-party individuals, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services or other services to, other nutritional supplements companies including our competitors or potential competitors. We could in the future be subject to claims that we or our employees or third parties that we hire to provide consulting or other services have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of former employers or competitors. Although we try to ensure that our employees and contractors do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may become subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement, that we wrongfully hired an employee from a competitor, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor.

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

While we may litigate to defend ourselves against these claims, even if we are successful, litigation could result in substantial costs and could be a distraction to management. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to our products, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. Parties making claims against us may be able to sustain the costs of complex litigation more effectively than we can because they have substantially greater resources. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, any of which would have an adverse effect on our business, results of operations, financial condition and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

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

Our ability to compete effectively will depend, in part, on our ability to maintain the proprietary nature of our products, manufacturing processes and services. We rely on manufacturing and other know-how, trade secrets, license agreements and contractual provisions to establish our intellectual property rights and protect our products, manufacturing processes and services. If our efforts to protect our intellectual property rights are not sufficient or effective, or if our licenses are terminated and any of our intellectual property rights are challenged, this could result in those rights being narrowed in scope, terminated or declared invalid or unenforceable and sales of our products or services may suffer as a result and our ability to generate revenue could be severely impacted.

We rely upon unpatented trade secret protection, unpatented or unpatentable know-how and continuing technological innovation to develop and maintain our competitive position. Trade secrets, including unpatented know-know, and other proprietary information, can be difficult to trace, protect and enforce. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our vendors, employees, consultants and others who may have access to proprietary information. We may not be able to prevent the unauthorized disclosure or use of information which we consider to be confidential, our technical know-how or other trade secrets by the parties to these agreements, however, despite the existence generally of confidentiality agreements and other contractual restrictions. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the vendors, employees, consultants and others who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. If one of our employees publicly discloses information that we believe to be confidential or a trade secret, we may be unable to protect it in the future. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or outside scientific collaborators, suppliers, third-party manufacturers, consultants, advisors, and vendors that we engage to perform research or manufacturing activities, or misappropriation by third parties, such as through a cybersecurity breach, of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive positions in our market. Even where remedies are available, enforcing a claim that a party illegally disclosed or misappropriated our trade secrets, like patent litigation, is expensive and time consuming, and the outcome is unpredictable.

We also try to protect the confidential nature of our trade secrets and other proprietary information by using reasonable physical and technological security measures. Such security measures may not provide adequate protection for our proprietary information. Our security measures may not prevent an employee, outside scientific collaborator, contract research organization, third-party manufacturer, consultant, advisor, potential partner, and other third-party from misappropriating our trade secrets and providing them to a competitor.

We may need to share our proprietary information, including trade secrets, with our current and future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced, and our competitive position would be harmed. In addition, the criteria for protection of trade secrets can vary among different jurisdictions and courts outside the United States are sometimes less willing to protect trade secrets. Trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. Trade secrets will over time be disseminated within the industry through independent development, the publication of journal articles, and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third-party, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. Though our agreements with third parties typically restrict the ability of our employees, outside scientific collaborators, suppliers, third-party manufacturers, consultants, advisors, potential partners, and other third parties, to publish data potentially relating to our trade secrets, our agreements may contain certain limited publication rights that may allow disclosure of our trade secrets.

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.

We rely on trademarks and tradenames to build brand recognition and to promote and market our products. Our current or future trademarks or trade names may be challenged, opposed, infringed, circumvented or declared generic or descriptive, determined to be not entitled to registration, or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we would be given an opportunity to respond to those rejections, we may be unable

to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, 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. Although 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 tradenames 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, and service marks may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our financial condition or results of operations.

Trademark litigation can be expensive and the outcome can be highly uncertain. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

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

The laws of some foreign countries do not protect intellectual property rights in the same manner and to the same extent as laws in the United States. Consequently, competitors may use our technologies in jurisdictions where we have no meaningful intellectual property protection to develop their own products. These products may compete with our products in these jurisdictions. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, trademarks, and other intellectual property protection, particularly those relating to nutritional supplement products, which could make it difficult for us to enforce our proprietary rights generally. Proceedings to enforce our trade secret rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business or could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

In the future, we may need to obtain licenses of third-party technology that may not be available to us or are available only on commercially unreasonable terms, and which may cause us to operate our business in a more costly or otherwise adverse manner that was not anticipated.

From time to time, we may be required to license technologies or trademarks relating to our promotional and collaborative programs from third parties to further develop or commercialize our products. Should we be required to obtain licenses for any third-party technology or trademarks, including any patents required to manufacture, use or sell our products, such licenses may not be available to us on commercially reasonable terms, or at all. The inability to obtain any third-party license required to develop or commercialize any of our products could cause us to abandon any related efforts, which could seriously harm our business and operations.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties and we may conclude that even if a third-party is infringing our intellectual property, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders. Our competitors or other third parties may be able to sustain the costs of complex patent litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our internal research programs, in-license needed technology or other products, or enter into development partnerships that would help us bring our product to market. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

We may not be able to partner with others for technological capabilities and new products and services.

Our ability to remain competitive may depend, in part, on our ability to seek partners that can offer technological improvements and improve existing products and services offered to our customers. We are committed to attempting to keep pace with changes in the nutritional supplement and health and wellness industries, and to stay abreast of technology changes and to look for partners that will develop new products and services for our customer base. We cannot assure prospective investors that we will be successful in finding partners or be able to continue to incorporate new developments in technology, to improve existing products and services, or to develop successful new products and services. We also cannot be certain that newly developed products and services will perform satisfactorily or be widely accepted in the marketplace or that the costs involved in these efforts will not be substantial.

Our use of "open source" software could subject our proprietary software to general release, adversely affect our ability to sell our products, and subject us to possible litigation.

A portion of our proprietary software that we use to perform services as part of our product offering incorporates so-called "open source" software and we may incorporate open source software into other products or technologies in the future. Such open source software is generally licensed by its authors or other third parties under open source licenses. Some open source licenses contain requirements that we disclose source code for modifications we make to the open source software and that we license such modifications to third parties at no cost. In some circumstances, distribution of our software in connection with open source software could require that we disclose and license some or all of our proprietary code in that software as well as distribute our products that use particular open source software at no cost to the user. We monitor our use of open source software in an effort to avoid uses in a manner that would require us to disclose or grant licenses under our proprietary source code, however, there can be no assurance that such efforts will be successful. Open source license terms are often ambiguous and such use could inadvertently occur. There is little legal precedent governing the interpretation of many of the terms of certain of these licenses, and the potential impact of these terms on our business may result in unanticipated obligations regarding our products and technologies. Companies that incorporate open source software into their products have, in the past, faced claims seeking enforcement of open source license provisions and claims asserting ownership of open source software incorporated into their product. If an author or other third-party that distributes such open source software was to allege that we had not complied with the conditions of an open source license, we could incur significant legal costs defending ourselves against such allegations. In the event such claims were successful, we could be subject to significant damages or be enjoined from the distribution of our products. In addition, if we combine our proprietary software with open source software in certain ways, under some open source licenses we could be required to release the source code of our proprietary software, which could substantially help our competitors develop products that are similar to or better than ours and otherwise have a material adverse effect on our business.

Risks Related to Our Common Stock

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

The market price of our common stock has been and is likely to remain volatile and could be subject to fluctuations in response to various factors, some of which are beyond our control. These fluctuations could cause you to lose all or part of your investment in our common stock since you might be unable to sell your shares at or above the price you paid. Factors that could cause fluctuations in the market price of our common stock include the following:

- price and volume fluctuations in the overall stock market from time to time;
- volatility in the market prices and trading volumes of health and wellness stocks;
- changes in operating performance and stock market valuations of other health and wellness companies generally, or those in our industry in particular;
- sales of shares of our common stock by us or our stockholders, as well as the anticipation of lock-up releases;
- failure of securities analysts to maintain coverage of us, changes in financial estimates by securities analysts who follow our company, or our failure to meet these estimates or the expectations of investors;
- the financial projections we may provide to the public, any changes in those projections, or our failure to meet those projections;
- announcements by us or our competitors of new products or services;
- the public's reaction to our press releases, other public announcements, and filings with the SEC;
- rumors and market speculation involving us or other companies in our industry;
- short selling of our common stock or related derivative securities;
- actual or anticipated changes in our results of operations or fluctuations in our results of operations;
- actual or anticipated developments in our business, our competitors' businesses or the competitive landscape generally;

- announced or completed acquisitions of businesses, offerings or technologies by us or our competitors;
- developments or disputes concerning our intellectual property or other proprietary rights;
- litigation involving us, our industry, or both, or investigations by regulators into our operations or those of our competitors;
- actual or perceived incidents relating to privacy, data protection or information security;
- new laws or regulations, or new interpretations of existing laws or regulations applicable to our business;
- changes in accounting standards, policies, guidelines, interpretations or principles;
- any significant change in our management;
- the COVID-19 pandemic, natural disasters, international conflicts or major catastrophic events (such as the war between Russia and Ukraine); and
- general economic conditions, including inflation, and slow or negative growth of our markets.

In addition, in the past, following periods of volatility in the overall market and the market price of a particular company's securities, securities action litigation has often been instituted against these companies. This litigation, if instituted against us, would result in substantial costs and a diversion of our management's attention and resources.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about us, our business, or our market, or if they change their recommendations regarding our common stock adversely, the market price and trading volume of our common stock could decline.

The trading market for our common stock depends, in part, on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. The analyst estimates are based upon their own opinions and are often different from our estimates or expectations. If any of the analysts who cover us change their recommendation regarding our common stock adversely, provide more favorable relative recommendations about our competitors, or publish inaccurate or unfavorable research about our business, the price of our securities would likely decline. If few securities analysts commence coverage of us, or if one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets and demand for our securities could decrease, which could cause the price and trading volume of our common stock to decline.

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.

As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (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. We may need to hire more personnel in the future or engage outside consultants, which will increase our operating expenses, to assist us in complying with these requirements.

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.

We also expect that being a public company and these new rules and regulations will make it more expensive for us to continue to maintain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

As a result of disclosure of information in filings required of a public company, our business and financial condition will become more visible, which may result in 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.

Our executive officers, directors, and holders of 5% or more of our common stock collectively beneficially own approximately 74% of the outstanding shares of our common stock and have substantial control over us, which limits your ability to influence the outcome of important transactions, including a change in control.

As of December 31, 2022, our executive officers, directors and our stockholders who own 5% or more of our outstanding common stock and their affiliates, in the aggregate, beneficially own approximately 74% of the outstanding shares of our common stock. As a result, these stockholders, if acting together, are able to influence or control matters requiring approval by our stockholders, including the election of directors and the approval of mergers, acquisitions or other extraordinary transactions. They may also have interests that differ from yours and may vote in a way with which you disagree and which may be adverse to your interests. This concentration of ownership may have the effect of delaying, preventing or deterring a change in control of our company, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company and might ultimately affect the market price of our common stock.

The issuance of additional stock in connection with financings, acquisitions, investments, our equity incentive plans, or otherwise will dilute all other stockholders.

Our amended and restated certificate of incorporation authorizes us to issue up to 200,000,000 shares of common stock and up to 10,000,000 shares of preferred stock with such rights and preferences as may be determined by our board of directors. Subject to compliance with applicable rules and regulations, we may issue shares of common stock or securities convertible into shares of our common stock from time to time in connection with a financing, acquisition, investment, our equity incentive plans, or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and cause the market price of our common stock to decline.

Sales, directly or indirectly, of a substantial amount of our common stock in the public markets by our existing security holders may cause the price of our common stock to decline.

Sales of a substantial number of shares of our common stock into the public market, particularly sales by our directors, executive officers, and principal stockholders, or the perception that these sales might occur, could cause the market price of our common stock to decline and could impair our ability to raise capital through the sale of additional equity securities. Many of our existing security holders have substantial unrecognized gains on the value of the equity they hold, and may take, or attempt to take, steps to sell, directly or indirectly, their shares or otherwise secure, or limit the risk to, the value of their unrecognized gains on those shares.

On March 22, 2022, all of the shares of common stock sold in our initial public offering will become freely tradable without restrictions or further registration under the Securities Act except that any shares held by our affiliates, as defined in Rule 144 under the Securities Act, would only be able to be sold in compliance with Rule 144.

In addition, as of December 31, 2022, we had stock options outstanding that, if fully exercised, would result in the issuance of 9,699,656 shares of common stock. All of the shares of common stock issuable upon the exercise of stock options, and the shares reserved for future issuance under our equity incentive plans, are registered for public resale under the Securities Act of 1933, as amended (the Securities Act). Accordingly, these shares are able to be freely sold in the public market upon issuance subject to existing lock-up or market standoff agreements and applicable vesting requirements.

The holders of 31,461,500 shares of our common stock have rights, subject to some conditions, to require us to file registration statements for the public resale of the common stock issuable upon conversion of such shares or to include such shares in registration statements that we may file for us or other stockholders.

We may also issue our shares of common stock or securities convertible into shares of our common stock from time to time in connection with a financing, acquisition, investment, or otherwise. Any further issuance could result in substantial dilution to our existing stockholders and cause the market price of our common stock to decline.

Our amended and restated bylaws designate a state or federal court located within the State of Delaware as the exclusive forum for substantially all disputes between us and our stockholders, and also provide that the federal district courts will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act of 1933, as amended, each of which could limit our stockholders' ability to choose the judicial forum for disputes with us or our directors, officers, stockholders, or employees.

Our amended and restated certificate of incorporation specifies that, unless we consent in writing to the selection of an alternative forum, the sole and exclusive forum for (a) any derivative action or proceeding brought on our behalf, (b) any action asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, stockholders, officers, or other employees to us or our stockholders, (c) any action or proceeding asserting a claim arising pursuant to, or seeking to enforce any right, obligation or remedy under, any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation, or our amended and restated bylaws, (d) any action or proceeding as to which the Delaware General Corporation Law confers jurisdiction on the Court of Chancery of the State of Delaware, or (e) any action or proceeding asserting a claim that is governed by the internal affairs doctrine shall be the Court of Chancery of the State of Delaware, or, if the Court of Chancery does not have jurisdiction, another state court in Delaware or, if no state court in Delaware has jurisdiction, the federal district court for the District of Delaware, and any appellate court therefrom, in all cases subject to the court having jurisdiction over the claims at issue and the indispensable parties; provided that the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act.

Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated bylaws also provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act.

Any person or entity purchasing or otherwise acquiring or holding or owning, or continuing to hold or own, any interest in any of our securities shall be deemed to have notice of and consented to the foregoing bylaw provisions. Although we believe these exclusive forum provisions benefit us by providing increased consistency in the application of Delaware law and federal securities laws in the types of lawsuits to which each applies, the exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum of its choosing for disputes with us or any of our directors, officers, stockholders, or other employees, which may discourage lawsuits with respect to such claims against us and our current and former directors, officers, stockholders, or other employees. Our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder as a result of our exclusive forum provisions. Further, in the event a court finds either exclusive forum provision contained in our amended and restated bylaws to be unenforceable or inapplicable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our results of operations.

Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock.

Our status as a Delaware corporation and the anti-takeover provisions of the Delaware General Corporation Law may discourage, delay or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change of control would be beneficial to our existing stockholders. In addition, our restated certificate of incorporation and restated bylaws contain provisions that may make the acquisition of our company more difficult, including the following:

- our board of directors is classified into three classes of directors with staggered three-year terms and directors will only be able to be removed from office for cause by the affirmative vote of holders of at least two-thirds of the voting power of our then outstanding capital stock;
- certain amendments to our amended and restated certificate of incorporation require the approval of stockholders holding two-thirds of the voting power of our then outstanding capital stock;
- any stockholder-proposed amendment to our amended and restated bylaws require the approval of stockholders holding two-thirds of the voting power of our then outstanding capital stock;
- our stockholders may only be able to take action at a meeting of stockholders and may not be able to take action by written consent for any matter;
- our stockholders are able to act by written consent only if the action is first recommended or approved by the board of directors;
- vacancies on our board of directors may be filled only by our board of directors and not by stockholders;

- only the chair of the board of directors, chief executive officer or a majority of the board of directors are authorized to call a special meeting of stockholders;
- certain litigation against us can only be brought in Delaware;
- our restated certificate of incorporation authorizes undesignated preferred stock, the terms of which may be established and shares of which may be issued, without the approval of the holders of our capital stock; and
- advance notice procedures apply for stockholders to nominate candidates for election as directors or to bring matters before an annual meeting of stockholders.

These anti-takeover defenses could discourage, delay or prevent a transaction involving a change in control of our company. These provisions could also discourage proxy contests and make it more difficult for stockholders to elect directors of their choosing and to cause us to take other corporate actions they desire, any of which, under certain circumstances, could limit the opportunity for our stockholders to receive a premium for their shares of our capital stock and could also affect the price that some investors are willing to pay for our common stock.

We do not intend to pay dividends for the foreseeable future.

We have never declared or paid any cash dividends on our common stock and do not intend to pay any cash dividends in the foreseeable future. Additionally, our ability to pay dividends on our common stock is limited by the restrictions under the terms of our credit agreement. We anticipate that for the foreseeable future we will retain all of our future earnings for use in the development of our business and for general corporate purposes. Any determination to pay dividends in the future will be at the discretion of our board of directors. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments.

We are an "emerging growth company" and a "smaller reporting company" and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. For so long as we remain an emerging growth company, we are permitted by SEC rules and plan to rely on exemptions from certain disclosure requirements that are applicable to other SEC registered public companies that are not emerging growth companies. These exemptions include not being required to comply with the auditor attestation requirements of Section 404 of the SOX, not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, reduced disclosure obligations regarding executive compensation and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, the information we provide stockholders will be different than the information that is available with respect to other public companies. In this Annual Report, we have not included all of the executive compensation-related information that would be required if we were not an emerging growth company. To the extent that we continue to qualify as a "smaller reporting company," as such term is defined in Rule 12b-2 under the Securities Exchange Act of 1934, after we cease to qualify as an emerging growth company, we will continue to be permitted to make certain reduced disclosures in our periodic reports and other documents that we file with the SEC. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to continue to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in this Annual Report and our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

General Risks

Our business is subject to the risk of hurricanes, earthquakes, fire, power outages, floods, and other catastrophic events, and to interruption by manmade problems such as terrorism.

Our business is vulnerable to damage or interruption from hurricanes, earthquakes, fires, floods, power losses, telecommunications failures, terrorist attacks, acts of war, human errors, break-ins, and similar events. The third-party systems and operations and manufacturers we rely on are subject to similar risks. For example, a significant natural disaster, such as a hurricane affecting our South Carolina facilities, an earthquake affecting our California facilities, or a fire, or flood, could have an adverse effect on our business, financial condition and operating results, and our insurance coverage may be insufficient to compensate us for losses that may occur. Acts of terrorism, which may be targeted at metropolitan areas that have higher population density than rural areas, such as New York City where our corporate headquarters is located, could also cause disruptions in our business or the economy as a whole. We may not have sufficient protection or recovery plans in some circumstances, such as natural disasters affecting locations that store significant inventory of our products, that house our servers, or from which we generate content. As we rely heavily on our computer and communications systems, and the internet to conduct our business and provide high-quality customer service, these disruptions could negatively impact our ability to run our business and either directly or indirectly disrupt suppliers' and manufacturers' businesses, which could have an adverse effect on our business, financial condition, and operating results. In addition, the COVID-19 pandemic and widespread shelter-in-place and other governmental restrictions have caused most of our employees to work remotely. Given these widespread remote work arrangements, if a natural disaster, power outage, connectivity issue, or other event occurs that impacts our employees' ability to work remotely, it may be difficult or, in certain cases, impossible, for us to continue our business and provide high-quality customer service for a substantial period of time.

Cybersecurity risks could adversely affect our business and disrupt our operations.

We rely, or will rely, on information technology systems to keep financial records and other sensitive business, information, including personal information about our employees, customers and other third parties, facilitate our research and development initiatives, manage our manufacturing operations, maintain quality control, communicate with customers, fulfill customer orders, maintain corporate records, communicate with staff and external parties and operate other critical functions. While we take measures to safeguard and protect this information, including using methods such as multi-layer firewalls, intrusion detection systems, content filtering, endpoint security, centralized logging and alerting, email security mechanisms, and access control mechanisms, threats to network and data security are increasingly diverse and sophisticated. We also continue to pursue independent third-party assessments and validations of our security and compliance capabilities, including through obtaining industry-standard certification like SOC 2. Despite our efforts and processes to prevent security breaches and incidents, our products and services, as well as our servers, computer systems, and those of third parties that we use in our operations are vulnerable to cybersecurity risks, including cyberattacks such as viruses and worms, phishing attacks and other forms of social engineering, denial-of-service attacks, ransomware attacks, physical or electronic break-ins, third-party or employee theft or misuse, and other negligent actions, errors or malfeasance by employees or other third parties, and similar disruptions from unauthorized tampering with our servers and computer systems or those of third parties that we use in our operations, which could lead to interruptions, delays, loss or corruption of critical data, unauthorized access to or acquisition of health-related and other personal information and loss of customer confidence. In addition, we may be the target of email scams and other social engineering attacks that attempt to acquire personal information or company assets or access to our systems. Despite our efforts to create security barriers to such threats, we may not be able to entirely mitigate these risks. Our third-party service providers face similar risks. Any cyberattack that attempts to obtain our or our customers' data or assets, disrupt our service, or otherwise access our systems, or those of third parties we use, or any other security breach or incident, could adversely affect our business, and financial condition and operating results, be expensive to remedy, and damage our reputation. We and our third-party service providers may face difficulties or delays in identifying or otherwise responding to any attacks or actual or potential security breaches or security incidents. We may incur significant costs and operational consequences of investigating, remediating, eliminating and putting in place additional tools and devices designed to prevent actual or perceived security breaches and other security incidents, including in response to any actual or perceived incident we may suffer, and substantial costs to comply with any notification or other legal obligations resulting from any security breaches or other security incidents. In addition, any such breaches or incidents, or the perception that they have occurred, may result in negative publicity, and adversely affect our brand and market perception of our platform and our company, impacting demand for our products and services, and could have an adverse effect on our business, financial condition and operating results.

Although we maintain insurance coverage that may cover certain liabilities in connection with security breaches and other security incidents, we cannot be certain our insurance coverage will be adequate for liabilities actually incurred, that insurance will continue to be available to us on commercially reasonable terms, if 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, the occurrence of changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, or denials of coverage, could have a material adverse effect on our business, including our financial condition, results of operations and reputation.

We rely heavily on third parties for most of our computing, storage, processing, and similar services. Any disruption of or interference with our use of these third-party services could have an adverse effect on our business, financial condition, and operating results.

We have outsourced our cloud infrastructure to third-party providers, and we currently use these providers to host and stream our customer-facing services and content. We are therefore vulnerable to service interruptions experienced by these providers and we expect to experience interruptions, delays or outages in service availability in the future due to a variety of factors, including infrastructure changes, human, hardware or software errors, hosting disruptions and capacity constraints. Outages and capacity constraints could arise from a number of causes such as technical failures, natural disasters, fraud or security attacks. The level of service provided by these providers, or regular or prolonged interruptions in that service, could also affect the use of, and our customers' satisfaction with, our products and services and could harm our business and reputation. In addition, hosting costs will increase as our customer base grows, which could harm our business if we are unable to grow our revenue faster than the cost of using these services or the services of similar providers.

Furthermore, our providers have broad discretion to change and interpret the terms of service and other policies with respect to us, and those actions may be unfavorable to our business operations. Our providers may also take actions beyond our control that could seriously harm our business, including discontinuing or limiting our access to one or more services, increasing pricing terms, terminating or seeking to terminate our contractual relationship altogether, or altering how we are able to analyze data in a way that is unfavorable or costly to us. Although we expect that we could obtain similar services from other third parties, if our arrangements with our current providers were terminated, we could experience interruptions of our services, as well as delays and additional expenses in arranging for alternative cloud infrastructure services. Any of these factors could further reduce our revenue, subject us to liability, and cause a loss of customers, any of which could have an adverse effect on our business, financial condition, and operating results.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

We currently lease three industrial facilities in Summerville, South Carolina which house our warehouse, production and primary distribution operations. We also lease a fourth industrial facility located in Benicia, California, for regional distribution operations. We also lease and operate two administrative and support locations in New York, New York, and Madison, Wisconsin.

Our primary manufacturing and administrative facility is located in Summerville, South Carolina. The 272,000 square-foot facility is located on 25.8 acres and houses our manufacturing and production, research and development, medical affairs, engineering, quality management, laboratory testing, brand marketing, inside sales, customer service, finance, legal, human resources, warehousing and materials management, procurement and safety functions. The lease expires in October 2037. We have the right to renew for two additional terms of five years each.

We also operate a 115,500 square-foot warehouse facility in Summerville, South Carolina, within close proximity to our primary manufacturing and administrative facility. This facility provides warehousing for finished goods, and distribution and shipping capabilities to the eastern United States and international markets. This facility is under a lease which terminates in July 2026. We have the right to renew for two additional terms of three years each.

On July 28, 2021, we entered into a lease for a to-be-constructed 360,320 square-foot industrial facility in Summerville, South Carolina, directly adjacent to 620 Omni. This lease will commence upon the completion of construction of the facility, which is currently estimated to be in April 2023 and will terminate upon the thirteenth anniversary of the commencement date. We have the right to renew for one additional term of five years. Upon commencement of this lease, we plan to relocate certain warehousing and production activities from our primary facility to provide additional space for the expansion of our current manufacturing and production capacity in support of our continued growth.

We also maintain a 16,896 square-foot warehouse in Benicia, California, that services Midwest and West Coast distribution and fulfillment operations. This lease terminates in January 2025. We have the right to renew for one additional term of five years.

On March 10, 2022, the Company amended the lease agreement for its headquarters in New York, New York. The amended agreement granted an additional right-of-use ("second substitute premises") to the Company in the future following the expiration of its current lease. The second substitute premises were substantially completed on October 3, 2022. The amendment commenced on October 3, 2022, and will terminate on the five-year anniversary of the rent commencement date.

In addition to the New York office space, our information management and digital marketing staff, including our Chief Technology Officer, occupy a 2,500 square-foot facility in Madison, Wisconsin. The lease for this office expires in October 2024.

We intend to procure additional space as we add employees, grow production and expand geographically. We believe, however, that our facilities are adequate to meet our needs for the immediate future and suitable additional space will be available to accommodate any expansion of our operations as needed.

Item 3. Legal Proceedings.

The Company is aware of two third-party U.S. patents that have claims relating to compositions of nicotinamide riboside – an ingredient contained in several of the Company's nutritional supplement products – issued to the Trustees of Dartmouth College and licensed to ChromaDex Corporation (Chromadex), of Los Angeles, California. On December 1, 2020, and February 1, 2021, the Company filed separate petitions for inter partes review against U.S. Patent No. 8,383,086 and U.S. Patent No. 8,197,807, respectively, at the U.S. Patent Trial and Appeal Board to seek to invalidate these two patents. On June 10, 2021, the Patent Trial and Appeal Board issued a decision granting institution of inter partes review against U.S. Patent No. 8,383,086. On May 31, 2022, the Patent Trial and Appeal Board issued a decision in which it invalidated the challenged claim in U.S. Patent No. 8,838,086. On August 2, 2022, the patent owner filed a "Patent Owner Notice of Appeal" with the U.S. Court of Appeals for the Federal Circuit. On December 29, 2022, the patent owner's appeal was dismissed. On August 12, 2021, the U.S. Patent Trial and Appeal Board issued a decision granting institution of inter partes review against U.S. Patent No. 8,197,807. On August 10, 2022, the Patent Trial and Appeal Board issued a decision in which it did not invalidate the challenged claims in U.S. Patent No. 8,197,807. The Company is appealing that decision. On May 12, 2021, the Trustees of Dartmouth College and ChromaDex filed a complaint against the Company in the U.S. District Court for the Southern District of New York, alleging the Company's infringement of U.S. Patent Nos. 8,383,086 and 8,197,807. The complaint seeks to enjoin the Company from selling its nutritional supplement products that contain nicotinamide riboside and further seeks monetary damages for alleged infringement of the patents. On August 20, 2021, the trial judge in the patent infringement litigation issued an Order to Stay the litigation during the pendency of the two inter partes review. The Order to Stay remains in effect.

For further information regarding Legal Proceedings please see "Risk Factors—Risks Relating to our Intellectual Property—Litigation or other proceedings or third-party claims of intellectual property infringement, misappropriation or other violations may require us to spend significant time and money, and could in the future prevent us from selling our products or services or impact our stock price, any of which could have a material adverse effect."

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

Shares of our common stock, traded under the symbol "THRN," have been publicly traded since September 23, 2021, when our common stock was listed and began trading on the Nasdaq Global Select Market (Nasdaq). Accordingly, no market for our stock existed prior to September 23, 2021.

Holders of Record

As of December 31, 2022, there were 64 registered holders of record of our common stock. Because many of our shares of common stock are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

Dividend Policy

We have not paid cash dividends on our common stock and do not anticipate paying dividends in the foreseeable future. Our board of directors currently intends to retain any future earnings for reinvestment in our growing business. Any future determination to pay dividends will also be at the discretion of our board of directors and will be dependent upon our results of operations and cash flows, our financial position and capital requirements, general business conditions, legal, tax, regulatory and any contractual restrictions on the payment of dividends, and any other factors our board of directors deems relevant.

Recent Sales of Unregistered Securities

The following list sets forth information regarding all unregistered securities sold by us since January 1, 2020. No underwriters were involved in the sales and the certificates representing the securities sold and issued contain legends restricting transfer of the securities without registration under the Securities Act or an applicable exemption from registration.

(1) On January 6, 2021, we issued 6,179,270 shares of class B common stock to the stockholders of Onegevity LLC in exchange for their shares in Onegevity LLC as part of our merger with Onegevity. The aggregate value of the exchanged shares was approximately $69.0 million.

(2) On January 6, 2021, we issued 1,959,335 stock options to certain employees and executives of Onegevity LLC in exchange for their outstanding and unvested equity option awards in Onegevity LLC, as part of our merger with Onegevity. Both the original equity option awards and the options awards received in exchange, contained accelerated vesting provisions, whereby upon the completion of an IPO by the Company or a qualified change-in-control, all unvested stock option awards would become fully vested. Upon the Company's IPO on September 22, 2021, all 1,959,335 stock options fully vested. There have been no additional stock option awards granted or issued during 2021.

(3) On January 6, 2021, we issued 472,590 restricted stock units (RSUs) to certain employees and executives of Onegevity LLC in exchange for their outstanding and unvested profits interest units in Onegevity LLC, as part of our merger with Onegevity. Both the original profits interest units and the RSUs received in exchange, contained accelerated vesting provisions, whereby upon the completion of an IPO by the Company or a qualified change-in-control, all unvested stock option awards would become fully vested. Upon the Company's IPO on September 22, 2021, all restrictions on the 472,590 RSUs lapsed.

(4) On July 29, 2021, we issued 875,760 RSUs to certain officers of our company. The aggregate fair market of these RSUs was determined by the board of directors to be approximately $12.2 million.

(5) On December 1, 2021, we issued 2,531,000 RSUs to certain directors, officers and employees of our company. The aggregate fair market of these RSUs was determined by the board of directors to be approximately $21.3 million.

(6) On April 4, 2022, we issued 2,143,000 RSUs to certain directors, officers and employees of our company. The aggregate fair market of these RSUs was determined by the board of directors to be approximately $14.9 million.

(7) On April 26, 2022, we issued 12,500 RSUs to a certain employee of our company. The aggregate fair market value of these RSUs was determined by the board of directors to be approximately $81 thousand.

(8) On June 3, 2022, we issued 61,748 RSUs to certain directors of our company. The aggregate fair market of these RSUs was determined by the board of directors to be approximately $360 thousand.

The offers, sales and issuances of the securities described in Item (1) were exempt from registration under the Securities Act under Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder as transactions by an issuer not involving a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was an accredited person and had adequate access, through employment, business or other relationships, to information about the registrant.

The offers, sales and issuances of the securities described in Item (2) and (3) were exempt from registration under the Securities Act under either (1) Rule 701 in that the transactions were under compensatory benefit plans and contracts relating to compensation as provided under Rule 701 or (2) Section 4(a)(2) of the Securities Act as transactions by an issuer not involving any public offering. The recipients of such securities were the registrant's employees, consultants or directors and received the securities under our 2010 Equity Incentive Plan. The recipients of securities in each of these transactions represented their intention to acquire the securities for investment only and not with view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions.

Use of Proceeds from Public Offering of Common Stock

On September 27, 2021, we closed our initial public offering (IPO) of 7,000,000 shares of common stock. The offer and sale of all of the shares in the initial public offering were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-257987), which was declared effective by the SEC on September 22, 2021. BofA Securities, Cowen, Evercore ISI and RBC Capital Markets acted as the underwriters. The public offering price of the shares sold in the offering was $10.00 per share. The total gross proceeds from the offering were $70.0 million.

After deducting underwriting discounts and commissions of approximately $4.9 million and offering expenses paid or payable by us of approximately $5.1 million, the net proceeds from the offering were approximately $60.0 million.

There has been no material change in the planned use of proceeds from our IPO as described in our final IPO prospectus filed with the SEC on September 23, 2021 pursuant to rule 424(b) of the Securities Act. We invested the funds received in short-term and long-term, interest-bearing investment-grade securities and government securities.

Issuer Purchases of Equity Securities

None.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our audited consolidated financial statements and related notes included elsewhere in this Annual Report. This discussion contains forward-looking statements that involve risks and uncertainties, including those described in the section titled "Special Note Regarding Forward-Looking Statements." Our actual results and the timing of selected events could differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those set forth under the section titled "Risk Factors."

Overview

We are a science-driven wellness company pioneering innovative solutions and personalized approaches to health and well-being. We are building a new health category to deliver better health outcomes through a proactive, empowered approach. Our unique, vertically integrated brands, Thorne and Onegevity, provide actionable insights and personalized data, products and services that help individuals take a proactive approach to improve and maintain their health over their lifetime. By combining our proprietary multi-omics database, artificial intelligence (AI) and digital health content with our science-backed nutritional supplements, we deliver a total system for wellness. We believe our integrated solution will redefine the expectations for good health, peak performance and healthy aging.

Founded in 1984, Thorne Research was a small company dedicated to being a "thorn" in the side of the traditional supplement industry by making the purest and highest quality nutritional supplements to sell to health professionals. With a vision for an unparalleled health ecosystem fueled by innovation and technology, our current Chief Executive Officer, Paul Jacobson, and his management team, acquired Thorne Research in 2010 and co-founded Onegevity. We completed our acquisition of Onegevity and combined these two complementary companies in early 2021. During the past ten years, we have evolved to become a transformative consumer brand, trusted by more than 5 million customers, 47,000 healthcare professionals, thousands of professional athletes, more than 100 professional sports teams and multiple U.S. Olympic teams.

Key milestones in our growth history include:

- 2011: Strategic ingredient and botanical agreement with Indena, a company dedicated to the identification, development and production of high-quality active principles derived from plants, for use in the pharmaceutical and health-food industries;
- 2014: Clinical Study Agreement with Mayo Clinic to design and conduct clinical trials of our dietary supplements;
- 2017: Launch of NSF Certified for Sport product line;
- 2018: Onegevity founded; we expanded capacity by moving to a new, state-of-the-art 272,000 square foot facility in South Carolina;
- 2019-2020: Sponsorships of the U.S. Army World Class Athlete Program, UFC, USA Rugby, and Penske Racing;
- 2020-2021: Thorne HealthTech, Inc. facilitated the merger of Thorne and Onegevity;
- 2021: Completed the acquisition of the majority of the outstanding shares of Drawbridge Health, In. (Drawbridge), a healthcare technology company;
- On September 27, 2021, we closed our initial public offering (IPO) of 7,000,000 shares of common stock. The public offering price of the shares sold in the offering was $10.00 per share. The total gross proceeds from the offering were $70.0 million. After deducting underwriting discounts and commissions of approximately $4.9 million and offering expenses paid or payable by us of approximately $5.1 million, the net proceeds from the offering were approximately $60.0 million;
- 2022: Completed the acquisition of Nutrativa LLC (Nutrativa) and its high-speed printing technology, adding quick-dissolving, environmentally friendly supplement discs to our product offerings;
- 2022: Completed large-scale surveillance study confirming the reliability of the OneDraw™ blood collection device in remote blood sample collection at home;

- 2022: Relaunched our Gut Health Test with first-to-market, user-friendly microbiome wipe technology that revolutionizes the testing experience;

- 2023: Completed the acquisition of PreCon Health, Inc., strengthening our brain health portfolio.

Our revenue is generated primarily from the sale of our supplements and health tests. We have experienced significant sales growth of our supplements and health tests through the acquisition of new customers and strong customer retention.

For the years ended December 31, 2021 and 2022:

- we generated net sales of $184.3 million and $228.7 million, respectively, representing 33.1% and 24.1% year-over-year growth, respectively;

- we generated gross profit of $96.4 million and $114.9 million, respectively, representing 52.3% and 50.2% of net sales, respectively;

- we generated net income of $6.8 million in 2021, and net income of $14.9 million in 2022; and

- our Adjusted EBITDA was $20.6 million and $24.5 million, respectively.

Our management's discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States (GAAP). In this Annual Report, we have used certain non-GAAP financial measures, including Adjusted EBITDA, Adjusted EBITDA Margin and free cash flow. These measures are derived on the basis of methodologies other than in accordance with GAAP. Non-GAAP financial measures used by us may be calculated differently from, and therefore may not be comparable to, similarly titled measures used by other companies. We have provided a reconciliation of each non-GAAP financial measure to the most directly comparable GAAP financial measure. These non-GAAP financial measures should be considered along with, but not as alternatives to, the operating performance measures as prescribed by GAAP.

Key Financial and Operating Data

Our financial profile is characterized by high growth, recurring revenue, improving gross margins, efficient customer acquisition, and free cash flow.

We measure our business using both financial and operational data and use the following metrics to assess the near-term and long-term performance of our brands and business. These metrics serve as guidance for identifying trends, formulating financial projections, making strategic decisions, assessing operational efficiencies, and monitoring our business.

Net Sales

We define net sales as sales of our goods and services and related shipping fees less discounts and returns following the accounting guidelines in accordance with Financial Accounting Standards Board (FASB), Topic 606, "Revenue from Contracts with Customers," (ASC 606). Our net sales consist of sales of our nutritional supplements, health tests and sales associated with our services leveraging our AI and multi-omics databases, such as product development services. We recognize revenues when control of the promised goods or services is transferred to our customers in an amount that reflects the consideration we expect to be entitled in exchange for those goods or services. We consider several factors in determining when control transfers to the customer upon shipment, or upon delivery for certain customers. These factors include when legal title transfers to the customer, if we have a present right to payment and whether the customer has assumed the risks and rewards of ownership at the time of shipment. Shipping and handling costs are considered a fulfillment activity and are expensed as incurred. We view net sales as a key indicator of demand for our products and services.

Gross Profit

We define gross profit as net sales less cost of sales. Cost of sales consists of depreciation and amortization, product and packaging costs, including manufacturing costs, inventory freight, testing costs of all raw materials and finished goods, inventory shrinkage costs and inventory valuation adjustments, offset by reductions for promotions and percentage or volume rebates offered by our vendors.

Adjusted EBITDA and Adjusted EBITDA Margin

We calculate Adjusted EBITDA as net income adjusted to exclude: interest income (expense), net; other income (expense), net; provision for income taxes; depreciation and amortization expense; stock-based compensation expense; change in fair value of warrant liability; write-off of acquired Drawbridge in-process research and development; loss on the Drawbridge Transaction; guarantee fees; income/loss from equity interest in unconsolidated affiliates; and acquisition costs. Adjusted EBITDA Margin is calculated by dividing Adjusted EBITDA by total net sales.

We use Adjusted EBITDA and Adjusted EBITDA Margin as measures of operating performance and the operating leverage in our business. We believe that these non-GAAP financial measures are useful to investors for period-to-period comparisons of our business and in understanding and evaluating our operating results for the following reasons:

- Adjusted EBITDA and Adjusted EBITDA Margin are widely used by investors and securities analysts to measure a company's operating performance without regard to items such as stock-based compensation expense, depreciation and amortization expense, interest expense, net, other (income) expense, net, loss from non-controlling interest and provision for income taxes, each of which can vary substantially from company to company depending upon their financing, capital structures and the method by which assets are acquired;

- our management uses Adjusted EBITDA and Adjusted EBITDA Margin in conjunction with financial measures prepared in accordance with GAAP for planning purposes, including the preparation of our annual operating budget, as a measure of our core operating results and the effectiveness of our business strategy, and in evaluating our financial performance; and

- Adjusted EBITDA and Adjusted EBITDA Margin provide consistency and comparability with our past financial performance, facilitate period-to-period comparisons of our core operating results, and also facilitate comparisons with other peer companies, many of which use similar non-GAAP financial measures to supplement their GAAP results.

Our use of Adjusted EBITDA and Adjusted EBITDA Margin have limitations as analytical tools, and you should not consider these measures in isolation or as substitutes for analysis of our financial results as reported under GAAP. Some of these limitations are, or may in the future be, as follows:

- although depreciation and amortization expense are non-cash charges, the assets being depreciated and amortized may have to be replaced in the future, and Adjusted EBITDA and Adjusted EBITDA Margin do not reflect cash capital expenditure requirements for such replacements or for new capital expenditure requirements;

- Adjusted EBITDA and Adjusted EBITDA Margin exclude stock-based compensation expense, which is a recurring expense for our business and an important part of our compensation strategy;

- Adjusted EBITDA and Adjusted EBITDA Margin do not reflect: (1) changes in, or cash requirements for, our working capital needs; (2) interest expense, or the cash requirements necessary to service interest or principal payments on our debt, which reduces cash available to us; (3) tax payments that may represent a reduction in cash available to us; or (4) the use of net operating loss (NOL) carryforwards are non-cash items that can have an impact on GAAP performance, but may not reflect the continuing operating results of our business; and

- the expenses and other items that we exclude in our calculation of Adjusted EBITDA and Adjusted EBITDA Margin may differ from the expenses and other items, if any, that other companies may exclude from Adjusted EBITDA when they report their operating results and we may, in the future, exclude other significant, unusual or non-recurring expenses or other items from these financial measures.

Because of these limitations, Adjusted EBITDA and Adjusted EBITDA Margin should be considered along with other operating and financial performance measures presented in accordance with GAAP.

The following table presents a reconciliation of Adjusted EBITDA to net income, the most directly comparable financial measure prepared in accordance with GAAP, for each of the periods indicated:

	Year Ended December 31,	
	2021	2022
EBITDA Calculation and Reconciliation		
Net income	$ 6,844,798	$ 14,932,657
Depreciation and amortization	4,453,057	5,823,357
Interest expense, net	449,908	26,328
Income tax expense (benefit)	411,919	(7,309,658)
EBITDA	$ 12,159,682	$ 13,472,684
EBITDA margin	6.6%	5.9%
Adjustments		
Stock-based compensation	4,554,024	11,335,299
Change in fair value of warrant liability	(1,872,364)	(999,223)
Write-off of acquired Drawbridge in-process research and development	1,563,015	—
Loss on Drawbridge Transaction	165,998	—
Guarantee fees	336,915	—
Loss from equity interest in unconsolidated affiliates	3,664,058	173,976
Acquisition Costs	—	519,236
Adjusted EBITDA	$ 20,571,328	$ 24,501,972
Adjusted EBITDA margin	11.2%	10.7%

Free Cash Flow

We define free cash flow as net cash provided by operating activities less capital expenditures, which consist of purchases of property and equipment as well as purchase of licensing agreements. Accordingly, we believe that free cash flow provides useful information to investors and others in understanding and evaluating our operating results in the same manner as our management and board of directors. Free cash flow may be affected in the near-to medium-term by the timing of capital investments, such as purchases of machinery, information technology and other equipment, the launch of new fulfillment centers, customer service centers and new products, fluctuations in our growth and the effect of such fluctuations on working capital and changes in our cash conversion cycle due to increases or decreases of customer and vendor payment terms as well as inventory turnover. We expect free cash flow to increase over the long term as investments made in prior years drive increased profitability. If we experience an unforeseen increase in demand, we may need to make additional capital investments in manufacturing facility expansion.

The following table presents a reconciliation of free cash flow to net cash provided by operating activities, the most directly comparable financial measure prepared in accordance with GAAP, for each of the periods indicated:

	Year Ended December 31,	
	2021	2022
Free Cash flow Calculation		
Net cash provided by operating activities	$ 9,084,286	$ 5,221,904
Purchase of property and equipment	(4,311,015)	(17,112,171)
Purchase of licensing agreements	(750,457)	(750,000)
Free cash flow	$ 4,022,814	$ (12,640,267)

Number of Subscriptions

We define subscriptions as orders resulting from direct-to-consumer (DTC) customers opting in to automatic refills or orders that are recurring on Thorne.com and on Amazon.com via our authorized reseller. Our subscription programs on both platforms offer automatic ordering, payment and delivery of our products to a customer's doorstep.

Subscription Sales as a Percentage of Net DTC Sales

We define subscription sales as sales generated from retail subscription orders on Thorne.com and on Amazon.com via our authorized reseller within a given period. Subscription sales are taken as a percentage of net sales from all DTC orders in that same period. We view subscription sales as a percentage of net DTC sales as a key indicator of our recurring sales and customer retention.

Annual LTV to CAC

We define annual life-time value (LTV) to customer acquisition costs (CAC) as LTV from a specific calendar year divided by the CAC of that same year. Annual LTV is defined as the average gross contribution per purchasing DTC customer within a particular calendar year divided by one less the customer retention rate (Churn Rate) during the same period. Average gross contribution is defined as the cumulative revenue from our DTC customers during a calendar year less the cost of goods divided by the number of purchasing DTC customers in the same period. To arrive at the annual LTV for a particular calendar year, we divide the average gross contribution by that year's Churn Rate. Annual CAC is defined as the total advertising and marketing expenses, inclusive of cooperative advertising costs treated as a reduction of net sales, less headcount and associated benefit expenses as well as costs attributed to value-in-kind, product samples, and sponsorships for professional and B2B customers, divided by the number of DTC customers who placed their first order during that same calendar year. We view the annual LTV to CAC ratio as a key indicator for marketing efficiency.

Orders per Customer per Year

We define orders per customers per year as the total number of sales orders placed by our DTC customers in a given year divided by the total number of DTC customers who purchased within that same period. We view orders per customer per year as a key indicator of our customers' purchasing patterns, including their initial and repeat purchase behavior, and as an indication of the desirability of our products to our customers. We expect orders per customer per year to remain steady or increase modestly over the long term as we continue to grow and acquire new customers and as our customers continue to demand our high-quality products.

Factors Affecting Our Performance

Ability to Increase Brand Awareness and Attract New Customers

Our long-term growth will depend on our continued ability to attract new customers. Our historical growth was largely driven by organic customer acquisition. We are still in the early stages of our growth and believe we can significantly expand our customer base as we increase brand awareness. Growing brand awareness through efficient, impactful communications and through building brand equity and loyalty is central to our marketing and growth strategy. We believe optimizing the message of our brand as one that defies expectations of good health differentiates us and is key to our ability to attract customers and retain them within our ecosystem. As our brand awareness grows, we intend to strengthen our reach across demographics and markets.

Growth in Our Subscriptions

We offer our customers the ability to opt in to recurring automatic refills on both our website and on Amazon.com via our authorized reseller. On both platforms, a customer can cancel or modify a subscription at any time at no cost to the customer. On our website, we allow customers to subscribe monthly, every 45 days, every two months, every three months, or every four months. For all these frequencies, we offer a 10% discount on retail refill orders when a customer is subscribed to 1 to 2 products, and a 20% discount when subscribed to 3 or more products, with an average discount of approximately 17%. On Amazon.com, the discount ranges from 5% to 10% to 15% depending on the product and the number of products to which a customer is subscribed, with an average discount of approximately 6%.

We view our growing subscription business on Thorne.com and on Amazon.com via our authorized reseller as a key driver of future sales growth. Our subscriptions grew from 257,070 as of December 31, 2021, to 375,185 as of December 31, 2022, representing 45.9% year-over-year growth. We expect subscription sales to continue to grow as we continue to invest in brand awareness, innovate new products and solutions, and market the convenience and savings of our nutritional supplements and tests.

Efficiency of Spending on Advertising and Marketing

We are disciplined in measuring and managing CAC and LTV of our customers. We are consistently looking for new ways to acquire customers more efficiently, grow revenue per customer, and retain our customers for longer periods of time. In 2022, we implemented a holistic, full funnel strategy that balanced long term brand objectives with performance marketing goals using a mix of paid, owned, and earned media. We take a data-driven approach to managing our marketing campaigns constantly optimizing and adjusting to improve performance.

At the end of March 2022, we launched our "Redefining Healthy Aging" brand campaign, which ran for 12-weeks and included deploying campaign assets across connected TV, YouTube, influencers, out of home, Amazon, search, and social platforms. The primary objectives of the campaign was to increase brand awareness and drive new customer acquisition. The campaign flight garnered over 1 billion impressions, drove over 12 million pageviews across our digital properties, and resulted in efficient cost per thousand impressions (CPMs) and cost per action (CPAs) across channels.

Despite reducing Marketing spend by $9M against plan in the second half of 2022, DTC sales grew 44.3% year-over-year, driven by an increase in unpaid customer acquisition, effective paid media performance, new product launches, and significant growth in subscribers. Unpaid acquisition tactics included implementing technical optimizations and keywords to increase our SERP rankings for SEO, an increase in long form content we put out through our blog and podcast, activating our ambassadors through product seeding and program promotion, and expanding email marketing automation tactics. Sixteen new products launched, which included thirteen new nutritional supplements and three new health tests; Daily Greens Plus, Metabolic Health and the Gut Health Test with the patent-pending microbiome wipe drove new customer acquisition and garnered media attention. Active subscriptions grew year-over-year 45.9% to 375,185 active subscriptions, while subscription sales grew 74% year-over-year as a result of increased website visibility, promotion through paid ads, and email marketing.

We experience high retention, repeat purchases and low CAC, as seen by our 2021 and 2022 LTV to CAC ratios of 4.5x and 4.6x, respectively.

Ability to Engage and Retain Our Existing Customers

Our success is impacted not only by efficient and profitable customer acquisition, but also by our ability to retain customers and encourage repeat purchases. In 2022, 42.7% of our DTC sales were generated from new, first-time purchasers versus 57.3% from existing customers on Thorne.com. We deepen our relationships with our customers and drive retention by engaging them with digital health content and educational resources. Out of our total 2022 DTC sales, we estimate 35% were generated from recurring subscriptions to end consumers on Thorne.com and on Amazon.com via our authorized reseller. We expect the growth in net sales each year to continue as we generate and grow sales from existing customers and from newly acquired customers.

Health Professionals

Our network of 47,000 health professionals helps serve two key purposes. First, it allows us to distinguish our brand by offering both credibility and validation to patients at times when the industry has struggled with trust. Secondly, health professionals carry, promote and distribute our products to consumers. Based on a 2018 survey conducted with 1,188 consumers, primary care physicians were identified as the most common entry point for supplement category consumers with nearly 60% of patients looking to their primary care providers when considering which supplements to buy. Therefore, retention and expansion of our professional network is important to our strategy.

Ability to Invest

We expect to continue to make investments across our business to drive growth and therefore we expect expenses to increase. We plan to continue to invest in sales and marketing to drive demand for our products and services. We expect to continue to invest in research and development to enhance our platform, develop new nutritional supplements, expand our testing portfolio, grow our multi-omics database and AI capabilities and improve our brand ecosystem's infrastructure.

Ability to Grow in New Geographies

Entering new geographic markets requires us to invest in distribution and marketing, infrastructure and personnel. Our international growth will depend on our ability to sell in international markets. In 2022, we shipped to 29 countries. We believe capital investment coupled with our regulatory expertise will lead to promising results. However, international sales are dependent upon local regulations and custom practices, which both change continuously.

Components of our Operating Results

Net Sales

Our net sales consist of sales of our nutritional supplements, health tests and sales associated with our services leveraging our AI and multi-omics databases, such as product development services. We recognize net sales when control over the product has transferred to customers in accordance with our revenue recognition policy.

Cost of Sales

Cost of sales consists of depreciation and amortization, product and packaging costs, including manufacturing costs, inventory freight, testing costs of all raw materials and finished goods, inventory shrinkage costs and inventory valuation adjustments, offset by reductions for promotions and percentage or volume rebates offered by our vendors, which may depend on reaching minimum purchase thresholds. We expect cost of sales to increase on an absolute dollar basis and improve as a percentage of net sales over the long term.

Operating Expenses

Operating expenses consist of:

- sales and marketing;
- research and development;
- payroll and related expenses for employees involved in general corporate functions, including accounting, finance, tax, legal and human resources;
- costs associated with use by these functions, such as depreciation expense and rent relating to facilities and equipment;
- professional fees and other general corporate costs;
- stock-based compensation; and
- fulfillment costs.

Marketing expenses consist of performance marketing media spend, asset creation, and other brand creation, as well as sales and marketing personnel-related expenses. We intend to continue to invest in our sales and marketing capabilities in the future and expect this increase in absolute dollars in future periods as we release new products and expand internationally. Sales and marketing expense as a percentage of net sales may fluctuate from period to period based on net sales and the timing of our investments in our sales and marketing functions as these investments may vary in scope and scale over future periods.

Our research and development expenses support our efforts to add new features to our existing solutions and to ensure the reliability and scalability of our product development and testing. Research and development expenses consist of personnel expenses, including salaries, bonuses, stock-based compensation expense and benefits for employees and contractors for our engineering, product, and design teams and allocated overhead costs. We have expensed our research and development costs as they were incurred, except those costs that have been capitalized as software development costs.

We plan to hire employees for our science and engineering team to support our research and development efforts. We expect that research and development expenses will increase on an absolute dollar basis in the foreseeable future as we continue to increase investments in our technology platform. However, our research and development expenses may fluctuate as a percentage of revenue from period to period due to the timing and amount of these expenses.

Fulfillment costs represent costs incurred in operating, manufacturing, staffing order fulfillment and customer service teams, including costs attributable to buying, receiving, inspecting and warehousing inventories, picking, packaging and preparing customer orders for shipment, payment processing and related transaction costs and responding to inquiries from customers. Included within fulfillment costs are merchant processing fees charged by third parties that provide merchant processing services for credit cards.

We expect to incur additional expenses as a result of operating as a public company, including expenses to comply with the rules and regulations applicable to companies listed on the Nasdaq, expenses related to compliance and reporting obligations pursuant to the rules and regulations of the SEC, as well as higher expenses for general and director and officer insurance, investor relations and professional services. We also anticipate that fulfillment costs will fluctuate as a percentage of net sales over the long term. Overall, as we continue to grow as a company, we expect that our selling, general and administrative costs will increase on an absolute dollar basis but decrease as a percentage of net sales over the long term.

Interest expense, net

Interest expense, net consists primarily of interest earned on cash we hold, and interest incurred on borrowings.

Income Tax Provision

Our income tax provision consists of an estimate of federal and state income taxes based on enacted federal and state tax rates, as adjusted for allowable credits, deductions and uncertain tax positions. Our income tax provision consists of cash taxes paid during the year in review.

Results of Operations

The following table summarizes our results of operations for each of the periods indicated:

	Years Ended December 31,	
	2021	2022
Net sales	$ 184,301,485	$ 228,731,362
Cost of sales	87,892,579	113,797,288
Gross profit	96,408,906	114,934,074
Gross margin	52.3%	50.2%
Operating expenses:		
Research and development	5,935,514	7,423,884
Marketing	22,768,555	26,442,805
Selling, general and administrative	56,389,672	75,586,115
Write-off of acquired Drawbridge in-process research and development	1,563,015	—
Income from operations	9,752,150	5,481,270
Other income:		
Interest expense, net	(449,908)	(26,328)
Guarantee fees	(336,915)	—
Change in fair value of warrant liability	1,872,364	999,223
Loss on Drawbridge Transaction	(165,998)	—
Other income, net	249,082	1,342,810
Total other income, net	1,168,625	2,315,705
Income before income taxes and loss from equity interest in unconsolidated affiliates	10,920,775	7,796,975
Income tax expense (provision)	411,919	(7,309,658)
Net income before loss from equity interest in unconsolidated affiliates	10,508,856	15,106,633
Loss from equity interest in unconsolidated affiliates	(3,664,058)	(173,976)
Net income	6,844,798	14,932,657
Net loss—non-controlling interest	(408,625)	(741,383)
Net income attributable to Thorne HealthTech, Inc	7,253,423	15,674,040
Undistributed earnings attributable to Series E convertible preferred stockholders	(3,507,892)	—
Net income attributable to common stock—basic	$ 3,745,531	$ 15,674,040
Net income attributable to common stockholders—diluted	$ 3,349,308	$ 15,674,040
Earnings per share:		
Basic	$ 0.14	$ 0.30
Diluted	$ 0.10	$ 0.30
Weighted average common shares outstanding:		
Basic	27,478,411	52,757,834
Diluted	32,328,565	52,757,834

Net sales

Net sales consist of sales of our products and services, net of discounts and customer returns. We enter into transactions and makes payments to certain of our customers related to advertising, some of which involve cooperative relationships with customers. When no distinct good or service is received in exchange for consideration, or if the fair value of the benefit cannot be reasonably estimated, the Company records its share of the costs for these transactions paid to customers as a reduction of the transaction price within net sales. The Company recorded $9.5 million and $4.2 million of cooperative advertising costs as a reduction of net sales for the years ended December 31, 2022 and 2021, respectively.

Net sales for the year ended December 31, 2022, increased by $44.4 million, or 24.1%, to $228.7 million, compared to $184.3 million in the year ended December 31, 2021. This growth was largely driven by growth in our DTC customers. The increase in net sales was primarily attributable to organic growth from progress executing our core growth strategies, resulting in DTC channel sales growth of 44.3% and Professional/B2B channel sales growth of 11.8%, respectively.

The DTC channel continued to be a significant growth catalyst through efficient new customer acquisition, including an increasing base of active subscriptions, strong customer satisfaction metrics and stable retention. We believe our steady pace of innovation with the launch of new premium offerings and customer engagement tools has increased our value proposition to customers. Similarly, Professional/B2B channel sales benefited from heightened brand awareness and ongoing delivery of science-backed solutions that increase personalization and improve user experiences. As heightened awareness of the benefits of a healthy lifestyle and the consumerization of healthcare on a global scale have significantly increased the size of our end markets, we believe successful execution of our core strategies will continue to drive significant increases in net sales above industry growth rates.

Cost of Sales and Gross Profit

The following table summarizes our cost of sales and gross profit for the periods indicated:

	Years Ended December 31,			
	2021	2022	Change	Percent Change
Net Sales	$ 184,301,485	$ 228,731,362	$ 44,429,877	24.1%
Cost of sales	87,892,579	113,797,288	25,904,709	29.5%
Percent of net sales	47.7%	49.8%	210 bps	4.4%
Gross profit	$ 96,408,906	$ 114,934,074	$ 18,525,168	19.2%
Percent of net sales	52.3%	50.2%	-210 bps	(4.0)%

We currently believe that the benefit of our anticipated net sales growth, product pricing strategies, sales mix shift towards the DTC channel and new product innovations will be partially offset by sustained higher costs in the near term. However, we also currently believe that gross profit as a percentage of net sales will increase over time primarily from (i) incremental improvements in macroeconomic conditions and (ii) as we begin realizing the benefits of greater scale and operational efficiencies expected to be achieved following completion of the construction of our new world-class production facility, which is currently in progress.

Cost of sales for the year ended December 31, 2022, increased by $25.9 million, or 29.5%, to $113.8 million, compared to $87.9 million in the year ended December 31, 2021. This increase in cost of sales was primarily due to a 24.1% increase in net sales and associated product costs. The increase in cost of sales was more than the increase in net sales primarily from higher raw material costs due to the recent unfavorable global macroeconomic conditions, including supply chain disruptions and inflationary pressures. While we currently believe that certain actions we have taken during 2022 mitigate against some of the cost increases, such as entering into new long-term supply arrangements, we currently believe these costs will remain elevated in the near term relative to their historical levels.

Gross profit for the year ended December 31, 2022, increased by $18.5 million, or 19.2%, to $114.9 million, compared to $96.4 million in the year ended December 31, 2021. The increase in gross profit was attributable to the increase in net sales, partially offset by the increase in cost of sales, in each case as described above.

Operating Expenses

The following table summarizes our operating expenses for periods indicated:

	Years Ended December 31,			
	2021	2022	Change	Percent Change
Net sales	$ 184,301,485	$ 228,731,362	$ 44,429,877	24.1%
Operating expenses:				
Stock-based compensation	4,554,024	10,913,207	$ 6,359,183	139.6%
Percent of net sales	2.5%	4.8%	230 bps	92.0%
Depreciation and amortization	2,441,405	3,016,573	$ 575,168	23.6%
Percent of net sales	1.3%	1.3%	0 bps	—
Non-cash lease expense	1,590,062	883,105	$ (706,957)	(44.5)%
Percent of net sales	0.9%	0.4%	-50 bps	(55.6)%
Change in receivables reserve	(249,468)	266,667	$ 516,135	(206.9)%
Percent of net sales	-0.1%	0.1%	20 bps	(200.0)%
Other marketing	22,768,555	25,367,447	$ 2,598,892	11.4%
Percent of net sales	12.4%	11.1%	-130 bps	(10.5)%
Other research and development	5,486,126	6,065,297	$ 579,171	10.6%
Percent of net sales	3.0%	2.7%	-30 bps	(10.0)%
Other selling, general and administrative expenses	48,503,037	62,940,508	$ 14,437,471	29.8%
Percent of net sales	26.3%	27.5%	120 bps	4.6%
Write-off of acquired Drawbridge in-process research and development	1,563,015	-	$ (1,563,015)	(100.0)%
Percent of net sales	0.8%	0.0%	-80 bps	(100.0)%
Total Operating expenses	$ 86,656,756	$ 109,452,804	$ 22,796,048	26.3%
Percent of net sales	47.0%	47.9%	90 bps	1.9%

Total operating expenses for the year ended December 31, 2022 increased by $22.8 million, or 26.3%, to $109.5 million, compared to $86.7 million in the year ended December 31, 2021. This increase was primarily due to an increase in marketing, selling, and stock based compensation expense during the year ended December 31, 2022, offset by the write-off of acquired Drawbridge in-process research and development of $1.6 million during the prior year ended December 31, 2021.

Other selling, general and administrative expenses for the year ended December 31, 2022, increased $14.4 million, or 29.8%, to $62.9 million, compared to $48.5 million in the year ended December 31, 2021. The increase was primarily due to increased selling costs pertaining to commissions, shipping, and credit card processing of approximately $13.2 million correlated with the increase in net sales, along with an increase in payroll related costs of approximately $3.2 million, offset by prior year costs of approximately $2.0 million associated with the initial public offering.

Other marketing expenses for the year ended December 31, 2022, increased by $2.6 million, or 11.4% to $25.4 million, compared to $22.8 million for the year ended December 31, 2021. The increase was primary due to our investment in paid media, which consists of the advertising and media costs associated with our efforts to acquire new customers, promote our brand and build awareness of our products and services among consumers that purchase on Thorne.com. These paid media costs include advertising across social media, search, online video, out-of-home media, podcasts, and various other outlets. Other marketing expenses aimed at driving awareness and acquisition of consumers include costs associated with personnel, content production, public relations, influencers, and consulting fees. Marketing expenses also include sponsorships and value-in-kind selling expenses aimed at driving awareness and sales in the professional channel particularly for sports performance organizations and health professionals.

Other research and development expense for the year ended December 31, 2022, increased by $0.6 million, or 10.6%, to $6.1 million, compared to $5.5 million in the year ended December 31, 2021. The increase was primarily due to achieving the objective to increase research spending as a percent of sales to drive new product development and clinical trial investments. Within the $0.6 million increase in research and development costs there were significant output increases both in new products and key product related studies. In 2021, we developed 8 new products, versus 12 new products in 2022, constituting a 50% increase in products developed year-over-year. Within the product related trial pipeline, we saw an addition of 3 key studies capitalizing on strategic research partnerships, such as Mayo, to further reduce research associated costs. This highlights the continued efforts to optimize research and development productivity efficiencies in increasing both our physical portfolio and knowledge-based assets.

Interest Expense, Net

The following table summarizes our interest expense, net for the periods indicated:

	Years Ended December 31,			
	2021	2022	Change	Percent Change
Interest expense, net	$ 449,908	$ 26,328	$ (423,580)	(94.1)%
Percent of net sales	0.2%	0.0%	-20 bps	(100.0)%

Interest expense, net for the year ended December 31, 2022 decreased by $0.4 million, or 94.1%, to $0.03 million, compared to interest expense of $0.4 million for the year ended December 31, 2021. This decrease was primarily due to the repayment of outstanding long-term debt in October 2021.

Liquidity and Capital Resources

Historically and through December 31, 2022, we have financed our operations and business development efforts primarily from product sales, public sales of equity securities, and the proceeds of secured borrowings.

Based on current conditions, we believe we have sufficient financial resources to fund our activities and execute our business plans. However, the cost of obtaining financing for our projects needs may increase significantly or such financing may be difficult to obtain.

As of December 31, 2022, we had access to: (i) $36.0 million in cash and cash equivalents; and (ii) $40.1 million of available borrowing capacity under our Revolver, with an option to obtain an additional $15.0 million, subject to agreement by the lender.

As of December 31, 2022, $13.2 million in the aggregate was outstanding under credit arrangements with several banks. For a description of our credit arrangements, refer to Note 13 in the Notes to Consolidated Financial Statements.

Our estimated capital needs for 2023 include approximately $39.6 million for capital expenditures on new projects under development or construction including leasehold improvements and lease footprint expansion. In addition, we expect $0.5 million for long-term debt repayment during 2023.

Our capital expenditures primarily relate to leasehold improvements and footprint expansion for our manufacturing and distribution facility located in Summerville, South Carolina. We have budgeted $46.8 million in capital expenditures for new warehouse construction and leasehold improvements and expansion for our existing facility, of which we had invested $14.9 million as of December 31, 2022. We expect to invest approximately $31.6 million in 2023 and the remaining approximately $0.3 million thereafter.

In addition, we estimate approximately $8.0 million in additional capital expenditures in 2023 to be allocated as follows: (i) approximately $6.0 million for new machinery; and (ii) approximately $2.0 million for machinery replacement and spare parts, laboratory equipment, and other furniture, fixtures, and office equipment.

We expect to finance these requirements with (i) the sources of liquidity described above; (ii) positive cash flows from our operations; and (iii) future project financings and re-financings. Management believes that, based on the current stage of implementation of our business plan, the sources of liquidity and capital resources described above will address our anticipated liquidity, capital expenditures, and other investment requirements.

Sources and Uses of Our Cash and Cash Equivalents

Operating Activities

Cash provided by operating activities consisted of net income, adjusted for non-cash items, including depreciation and amortization, stock-based compensation, change in fair value of warrant liability and certain other non-cash items, as well as the effect of changes in working capital and other activities.

Net cash provided by operating activities was $5.2 million for the year ended December 31, 2022, primarily consisting of net income of $14.9 million, plus depreciation and amortization expense of $5.8 million, $11.3 million of stock-based compensation expense, the loss from equity interest in unconsolidated affiliates of $(0.1) million, non-cash lease expense of $3.7 million, the change in fair value of warrant liability of $1.0 million, as well as a $20.9 million decrease in cash due to changes in working capital amounts, primarily related to an increase in inventories of $16.8 million to support continued sales growth, an increase in accounts receivable of $8.8 million due to the timing of product orders and related payments received from contracts with customers, offset by an increase in accounts payable of $4.4 million due to the timing of purchase orders placed and related payments due to vendors.

Net cash provided by operating activities was $9.1 million for 2021, primarily consisting of net income of $6.8 million, plus depreciation and amortization expense of $4.5 million, $4.6 million of stock-based compensation expense, non-cash expenses of $1.6 million associated with the Drawbridge Transaction, the loss from equity interest in unconsolidated affiliates of $3.7 million, non-cash lease expense of $6.0 million, the change in fair value of warrant liability of $1.9 million, as well as a $16.2 million decrease in cash due to changes in working capital amounts, primarily related to an increase in inventories of $12.9 million to support continued sales growth.

Investing Activities

Our primary investing activities consisted of purchases of property and equipment, mainly to increase our manufacturing and fulfillment capabilities to support our growth, as well as leasehold improvements. Use of cash for investing activities also includes payments to support agreements with non-consolidated subsidiaries and the purchase and use of certain license and research agreements.

Net cash used in investing activities was $33.6 million for the year ended December 31, 2022, primarily consisting of capital spending of $17.1 million to support our continued growth, investing in the acquisition of Nutrativa of $14.9 million, the investment in an unconsolidated subsidiary of $1.0 million, proceeds from the disposal of property, plant and equipment of $0.1 million, and the entry into certain licensing and research agreements with Mayo Clinic of $0.8 million.

Net cash used in investing activities was $7.2 million for 2021, primarily consisting of capital spending of $4.3 million to support our continued growth, investing in the acquisition of Drawbridge of $1.4 million, investment in an equity-method investee of $0.7 million, and the entry into certain licensing and research agreements with Mayo Clinic of $0.8 million.

Financing Activities

Net cash provided by financing activities was $13.4 million for the year ended December 31, 2022, primarily consisting of proceeds from the term loan of $12.0 million, investment from minority partner in joint venture of $2.6 million, proceeds from supplier financing agreements of $1.2 million, proceeds from the exercise of stock options of $0.4 million, offset by the repurchase of common stock of $1.0 million, repayments on finance leases of $0.9 million, repayments on notes payable and notes payable - equipment financing of $0.3 million and $0.5 million, respectively, and debt issuance costs of $0.1 million.

Net cash provided by financing activities was $38.8 million for 2021, primarily consisting of gross proceeds from our IPO of $70.0 million, reduced by the payment of related offering costs of $10.0 million, as well as the repayment of $20.0 million against our outstanding revolving line of credit, and payments for finance leases of $1.2 million.

Contractual Obligations and Commitments

We have contractual obligations in the form of noncancelable leases and equipment loans. Future minimum payments due in the next 12 months under our leases and outstanding equipment loans are $5.7 million and $0.5 million, respectively. With the completion of our IPO in September 2021, we raised $60.0 million of net proceeds. As of December 31, 2022, we had unrestricted cash of $36.0 million and accounts receivable of $14.4 million as of December 31, 2022.

Considering recent market conditions, we have reevaluated our operating cash flows and cash requirements and continue to believe that current cash and future cash flows from operating activities will be sufficient to meet our anticipated cash needs, including working capital needs, capital expenditures, and contractual obligations for at least 12 months from the issuance date of the consolidated financial statements included herein.

Our future capital requirements will depend on many factors, including our revenue growth rate, our working capital needs primarily for inventory build, our global footprint, the expansion of our marketing activities, the timing and extent of spending to support product development efforts, the introduction of new and enhanced products and the continued market consumption of our products. We may seek additional equity or debt financing in the future in order to acquire or invest in complementary businesses, products and/or new supportive infrastructures. In the event that we require additional financing, we may not be able to raise such financing on terms acceptable to us or at all. If we are unable to raise additional capital or general cash flows necessary to expand our operations and invest in continued product innovation, we may not be able to compete successfully, which would harm our business, operations, and financial condition.

Off Balance Sheet Arrangements

We currently do not have, and did not have during the periods presented, any off-balance sheet arrangements.

Critical Accounting Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States (GAAP). The preparation of our consolidated financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events, and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in the notes to our consolidated financial statements, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition

Under ASC 606, we account for revenue using the following steps:

- identify the contract, or contracts, with a customer;
- identify the performance obligations in the contract;
- determine the transaction price
- allocate the transaction price to the identified performance obligations; and
- recognize revenue when, or as, we satisfy the performance obligations.

We recognize revenues when control of the promised goods or services is transferred to its customers in an amount that reflects the consideration we expect to be entitled in exchange for those goods or services. We consider several factors in determining that control transfers to the customer upon shipment. These factors include that legal title transfers to the customer, we have a present right to payment, and the customer has assumed the risks and rewards of ownership at the time of shipment. Shipping and handling costs are considered a fulfillment activity and are expensed as incurred. Our standard business practice is to collect upfront payment for its products for direct-to-consumer sales and to recognize a receivable for sales to distributors when the performance obligation is satisfied.

Certain distributors resell our products in online marketplaces, however no inventories are held on consignment; revenue is recognized when control of the goods is transferred to these distributors, whom are ultimately our customers, which is typically at the time of shipment. The terms of payment over the recognized receivables from distributors are less than one year and therefore these sales do not have any significant financing components. We use standard business practices and standard price lists in determining the transaction price. Any discounts stated or implied are allocated entirely to the sole performance obligation. We primarily sell to customers throughout the United States but also sell to international markets. Regardless of customer location, all customer payments are required to be made in U.S. dollars. Given the inherent nature of selling to international markets, there is a risk of higher volatility pertaining to collecting payment on account; however, we review each customer account for collectability and provides for probable uncollectible amounts through a charge to earnings and a credit to a valuation allowance based on its assessment. This process of assessing for collectability is performed for all on account customers, both international and domestic.

We have elected to exclude sales tax for non-exempt customers from the transaction price and is therefore excluded from revenue. For certain sales, we incur incremental costs of obtaining the contract through the form of sales commissions. The sales commissions incurred are directly correlated to the sales generated and are therefore expensed as incurred as the amortization period of the asset that otherwise would have been recognized is one year or less.

The Company sells direct to consumers online through a Company owned and operated website. Revenue from online sales is recognized at time of shipment of the product. In addition, the Company sells testing services and test kits. Testing services and testing kits are recorded as revenue when the testing results are provided to the customer. Shipping and handling costs are considered a fulfillment activity and are expensed as incurred. Further, the Company sells its products to a distributor for sales direct to consumers on Amazon.com. Revenue from sales to the distributor is recognized at the time of shipment of the product to the distributor.

The Company offers its customers the ability to opt in to recurring automatic refills. Revenue is recognized under the subscription program when product is shipped to the consumer. No funds are collected at the time a consumer signs up for a subscription and the customer can cancel or modify a subscription at any time at no cost to the customer. On the Company website, customers are allowed to subscribe at a frequency of monthly, every 45 days, every 2 months, every 3 months, or every 4 months. For all frequencies, a 10% discount is offered on retail refill orders when a customer is subscribed to 1 to 2 products and a 20% discount when subscribed to 3 or more products, the discount ranges from 5% to 10% to 15% depending on the number of products to which a customer is subscribed. The Company records revenues, net of estimated discounts.

If a customer is not satisfied for any reason with a product purchased, the customer can return it to the place of purchase to receive a refund, a credit, or a replacement product. The return or refund request must be submitted within 60 days of the date of purchase. The Company estimates returns and accrues for potential returns based on historical data.

There are no material differences in our revenue recognition policy between one-time purchases and subscription purchases of our products.

Stock-Based Compensation

We account for stock-based compensation by measuring and recognizing compensation expense for all share-based awards made to employees and non-employees based on estimated grant-date fair values. We use the straight-line method to allocate compensation cost to reporting periods over the requisite service period, which is generally the vesting period. We recognize actual forfeitures by reducing the stock-based compensation in the same period as the forfeitures occur. We estimate the fair value of share-based awards to employees and non-employees using the Black-Scholes option-pricing valuation model. The Black-Scholes model requires the input of subjective assumptions, including fair value of common stock, expected term, expected volatility, risk-free interest rate, and expected dividend yield, which are described in greater detail below.

Estimating the fair value of equity-settled awards as of the grant date using the Black-Scholes option pricing model is affected by assumptions regarding a number of complex variables. Changes in the assumptions can materially affect the fair value and ultimately how much stock-based compensation is recognized. These inputs are subjective and generally require significant analysis and judgment to develop. These inputs are as follows:

- Fair value of common stock - Prior to our IPO, there was no public market for our common stock. As such, the estimated fair value of our common stock and underlying stock options has been determined at each grant date by our board of directors, with input from management, based on the information known to us on the grant date and upon a review of any recent events and their potential impact on the estimated per share fair value of our common stock. As part of these fair value determinations, our board of directors obtained and considered valuation reports prepared by a third-party valuation firm in accordance with the guidance outlined in the American Institute of Certified Public Accountants Technical Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. For valuations after the completion of our initial public offering, the fair value of each share of underlying common stock is based on the closing price of our common stock as reported on the date of grant.

- Expected term - The expected term for options granted to employees and directors represents the average period that our options granted are expected to be outstanding and is determined using the simplified method (based on the mid-point between the weighted-average vesting date and the end of the contractual term). We have very limited historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior for our stock option grants. The expected term for options granted to non-employees is the contractual term.

- Expected volatility - As we had no publicly available stock price information prior to our IPO and limited publicly available stock price information subsequent to our IPO, the expected volatility was estimated based on the historical average volatility for comparable publicly traded life sciences technology companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on their similar size, life cycle stage, or area of specialty. We will continue to apply this process until enough historical information regarding the volatility of our own stock price becomes available.

- Risk-free interest rate - The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of the options.

- Expected dividend yield - We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero.

We will continue to use judgment in evaluating the expected volatility, expected terms, and interest rates utilized for our stock-based compensation calculations on a prospective basis. Assumptions we used in applying the Black-Scholes option-pricing model to determine the estimated fair value of our stock options granted involve inherent uncertainties and the application of significant judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our equity-based compensation could be materially different.

Warrant Liability

We determine the accounting classification of a warrant, as either liability or equity, by first assessing whether the warrant meets liability classification in accordance with ASC 480, Distinguishing Liabilities from Equity (ASC 480), and then in accordance with ASC 815-40, Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock (ASC 815-40). If the warrant does not meet liability classification under ASC 480, we assess the requirements under ASC 815-40, including whether the warrant is indexed to our common stock and whether the warrant meets the other requirements to be classified as equity under ASC 815-40. After all relevant assessments are made, we conclude whether the warrant should be classified as liability or equity.

We have warrants that are classified as a liability on our consolidated balance sheet. The warrants classified as a liability are measured at fair value using the Black-Scholes pricing model which takes into account, as of the valuation date, factors including the current exercise price, the contractual life of the warrant, the current fair value of the underlying stock, its expected volatility, and the risk-free interest rate for the term of the warrant. The warrant liability is revalued at each reporting period and changes in fair value are recognized in the consolidated statements of operations. The selection of the appropriate valuation model and the inputs and assumptions that are required to determine the valuation requires significant judgment and requires management to make estimates and assumptions that affect the reported amount of the related liability and reported amounts of the change in fair value. Actual results could differ from those estimates, and changes in these estimates are recorded when known. As the warrant liability is required to be measured at fair value at each reporting date, it is reasonably possible that these estimates and assumptions could change in the near term.

Common Stock Valuations

The fair value of our equity instruments has historically been determined based on information available at the time of granting. Given the absence of a public trading market for our equity, and in accordance with the American Institute of Certified Public Accountants Practice Aid, Valuation of Privately Held Company Equity Securities Issued as Compensation, our management has exercised reasonable judgment and considered numerous objective and subjective factors to determine the best estimate of the fair value of our equity instruments at each grant date.

These factors included:

- our operating and financial performance;
- current business conditions and projections;
- the lack of marketability of our shares;
- using third-party experts to support the valuation of the shares; and
- the market performance of comparable publicly-traded companies.

In valuing our equity instruments, we determined the equity value of our business using a weighted blend of the income and market approaches. The income approach estimates the fair value of a company based on the present value of such company's future estimated cash flows and the residual value of such company beyond the forecast period. These future values are discounted to their present values to reflect the risks inherent in such company achieving these estimated cash flows.

Significant inputs of the income approach, in addition to our estimated future cash flows themselves, include the long-term growth rate assumed in the residual value, discount rate and normalized long-term operating margin. The terminal value was calculated to estimate our value beyond the forecast period by applying valuation metrics to the final year of our forecasted net sales and discounting that value to the present value using the same weighted average cost of capital applied to the forecasted periods.

Application of these approaches involves the use of estimates, judgment and assumptions that are highly complex and subjective, such as those regarding our expected future revenue, expenses and future cash flows, discount rates, market multiples, the selection of comparable companies and the probability of possible future events. Changes in any or all of these estimates and assumptions or the relationships between those assumptions impact our valuations as of each valuation date and may have a material impact on the valuation of our common stock.

Income Taxes

Income taxes are accounted for using an asset and liability approach that requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the consolidated financial statements. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date. A valuation allowance is provided when it is more likely than not that some portion or all of the net deferred tax assets will not be realized. We recognize the tax benefit from uncertain tax positions if it is more likely than not the tax positions will be sustained on examination by the tax authorities, based on the technical merits of the position. The tax benefit is measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. We recognize interest and penalties related to income tax matters in income tax expense. Health Elements, LLC made a previous election to be taxed as a Subchapter C corporation. As such, a provision for income taxes has been made for our investment in this entity and is included in the accompanying consolidated financial statements.

As of December 31, 2022, we had U.S. federal net operating loss carryforwards (NOLs) and state NOLs of approximately $29.1 million and $47.1 million, respectively, due to prior period losses. If not utilized the federal operating loss carryforwards incurred before January 1, 2020, will begin to expire in 2030. The federal operating losses incurred in 2018 and beyond do not expire. The state operating loss carryforwards do not expire. Realization of these NOLs depends on future income, and there is a risk that our existing NOLs could expire unused and be unavailable to offset future income tax liabilities, which could adversely affect our operating results.

In general, under Section 382 of the Internal Revenue Code of 1986, as amended (the Code), a corporation that undergoes a defined “ownership change” is subject to limitations on its ability to utilize its NOLs carryforwards to offset future taxable income. The annual limitation is based on the Company's stock value prior to the ownership change, multiplied by the applicable federal long-term, tax-exempt interest rate.

During 2022, we completed a Section 382 study and concluded that an ownership change under Section 382 occurred as a result of an equity event in 2018, resulting in a Section 382 limitation that applies to all Health Elements, LLC NOLs prior to the 2018 equity event. We have adjusted our NOL carryforwards to address the impact of the Section 382 ownership changes. This resulted in a reduction of available federal and state NOLs of $23.2 million and $18.8 million, respectively.

Future changes in our stock ownership, the causes of which may be outside of our control, could result in ownership change under Section 382 of the Code. If we undergo a deemed ownership change in the future, our NOLs arising before such an ownership change may be subject to one or more Section 382 limitations that materially limit the use of such NOLs to offset our taxable income. Our ability to utilize NOLs of companies that we have acquired or may acquire in the future may also be subject to limitations. Further, our NOLs may be impaired under state laws. In addition, under the 2017 Tax Cuts and Jobs Act (Tax Act), as modified by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), NOLs arising in taxable years beginning after December 31, 2020 may not be carried back, and NOLs generated in taxable years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such NOLs generally will be limited in taxable years beginning after December 31, 2020 to 80% of the current year taxable income. This change may require us to pay federal income taxes in future years even if our NOLs were otherwise sufficient to offset our federal taxable income in such years. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities. For these reasons, we may not be able to realize, in whole or in part, a tax benefit from the use of our NOLs, whether or not we attain profitability.

Recent Accounting Pronouncements

See Note 2 to our consolidated financial statements 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 yet, of their potential impact on our financial condition of results of operations.

Emerging Growth Company Status

We are an emerging growth company, as defined in the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. Other exemptions and reduced reporting requirements under the JOBS Act for emerging growth companies include presentation of only two years audited financial statements in a registration statement for an initial public offering, an exemption from the requirement to provide an auditor's report on internal controls over financial reporting pursuant to the Sarbanes-Oxley Act, an exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation, and less extensive disclosure about our executive compensation arrangements. We have elected to use the extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that (i) we are no longer an emerging growth company or (ii) we affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our consolidated financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

We will remain an emerging growth company under the JOBS Act until the earliest of (i) the last day of our first fiscal year in which we have total annual gross revenue of $1.07 billion or more, (ii) the date on which we have issued more than $1.0 billion of non-convertible debt instruments during the previous three fiscal years or (iii) the date on which we are deemed a "large accelerated filer" under the rules of the SEC with at least $700.0 million of outstanding equity securities held by non-affiliates, or (iv) the last day of the fiscal year following the fifth anniversary of completion of our initial public offering.

Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with GAAP. As a result of becoming a public company, we will be required, pursuant to Section 404 of the Sarbanes-Oxley Act, as amended, to furnish a report by our management on, among other things, the effectiveness of our internal control over financial reporting for the first fiscal year beginning after our IPO. This assessment will need to include disclosures of any material weaknesses identified by our management in our internal control over financial reporting.

In connection with the audits of our financial statements, we identified the material weaknesses described as follows:

- We did not properly design or maintain effective controls over the financial reporting process to enable timely reporting of complete and accurate financial information. Specifically, we did not design and implement review controls with a sufficient precision to prevent or detect a material misstatement and to validate the completeness and accuracy of underlying data used in certain review controls, did not consistently perform independent reviews of journal entries or consistently retain adequate supporting documentation of the preparation and review of financial information supporting financial statement balances and the related footnote disclosures.
- We did not design and maintain sufficient information technology general controls ("ITGCs") in the areas of logical security access and change management in certain financially relevant systems, including adequate segregation of duties, and reinforcing independent journal entry review. Due to the pervasive impact of the ineffective ITGCs, certain control activities including manual controls that rely on data produced by and maintained within these IT system applications such as the management review control deficiencies described above, were also considered ineffective, potentially impacting all financial statement accounts.
- We did not properly design or maintain effective formal processes and controls related to the accounting for and disclosure of complex, non-routine, and significant and unusual transactions, including accounting for non-routine or unusual contracts with customers in accordance with ASC 606 and accounting for business combinations in accordance with ASC 805.
- We did not design and maintain effective controls related to the preparation and review of the annual income tax provision and related footnote disclosures in accordance with ASC 740.
- We did not design and maintain effective formal processes and controls to ensure the completeness and accuracy of our disclosures regarding related party transactions

Under standards established by the Public Company Accounting Oversight Board, a material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected and corrected on a timely basis.

We are working to remediate the material weaknesses and are taking steps to strengthen our internal control over financial reporting through the hiring of additional finance and accounting personnel. With the additional personnel, we intend to take appropriate and reasonable steps to remediate these material weaknesses through the implementation of appropriate segregation of duties, formalization of accounting policies and controls and retention of appropriate expertise for complex accounting transactions. However, we cannot assure you that these measures will significantly improve or remediate the material weaknesses described above. As of December 31, 2022, the material weaknesses have not been remediated.

The actions that we are taking are subject to ongoing executive management review and will also be subject to audit committee oversight. If we are unable to successfully remediate the material weakness, or if in the future, we identify further material weaknesses in our internal control over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Market Risk Disclosure

Our cash is held on deposit in demand accounts at large financial institutions in amounts in excess of the Federal Deposit Insurance Corporation ("FDIC") insurance coverage limit of $250,000 per depositor, per FDIC-insured bank, per ownership category. We have reviewed the consolidated financial statements of these institutions and believe they have sufficient assets and liquidity to conduct their operations in the ordinary course of business with little or no credit risk to us. We do not hold market risk-sensitive trading instruments, nor do we use financial instruments for trading purposes. All sales, operating items and balance sheet data are denominated in U.S. dollars; therefore, we have no significant foreign currency exchange rate risk.

We use many different commodities such as Vitamin C and Vitamin D. Commodities are subject to price volatility caused by commodity market fluctuations, supply and demand and currency fluctuations. Commodity price increases will result in increases in raw material costs and operating costs.

In the ordinary course of our business, we enter into commitments to purchase raw materials over a period of time, generally six months or less at contracted prices. As of December 31, 2022, these future commitments were not at prices in excess of current market, or in quantities in excess of normal requirements. We do not utilize derivative contracts either to hedge existing risks or for speculative purposes.

Interest Rate Risk

We invest excess cash in variable income investments consisting of cash equivalents. The magnitude of the interest income generated by these cash equivalents is affected by market interest rates. We do not use marketable securities or derivative financial instruments in our investment portfolio.

The Company is exposed to market risk related to changes in interest rates, primarily from its borrowing activities. The Company's outstanding balance under its credit agreement as of the year ended December 31, 2022 is subject to a variable rate of interest, which fluctuates with changes in the lender's reference rate (SOFR). An increase or decrease in interest rates by 25 bps would increase monthly interest expense by approximately $2,500 based on the Company's outstanding balance as of December 31, 2022. The Company may use derivative financial instruments for trading purposes to protect trading performance from exchange rate fluctuations on material contracts, though there are no such instruments in place during any periods presented in this Annual Report.

Currency Risk

For the years ended December 31, 2022, and 2021, we did not sell any product or services for payment in currency other than U.S. dollars.

Item 8. Financial Statements and Supplementary Data.

THORNE HEALTHTECH, INC.
Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors
Thorne HealthTech, Inc.
New York, New York

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Thorne HealthTech, Inc. (the "Company") as of December 31, 2022 and 2021, the related consolidated statements of operations, comprehensive income, convertible preferred stock and stockholders' equity (deficit), and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2022 and 2021, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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/ BDO USA, LLP

We have served as the Company's auditor since 2019.

Raleigh, North Carolina
March 31, 2023

THORNE HEALTHTECH, INC.
Consolidated Balance Sheets

	December 31, 2022	December 31, 2021
Assets		
Current Assets		
Cash	$ 36,024,847	$ 51,100,915
Current portion of restricted cash	4,900,000	—
Accounts receivable, net	14,367,785	5,285,321
Related party receivables	68,731	366,590
Inventories, net	58,643,928	41,012,124
Prepaid expenses and other current assets	2,615,593	3,494,473
Total current assets	116,620,884	101,259,423
Restricted cash, net of current portion	—	4,900,000
Property and equipment, net	49,176,844	27,030,400
Operating lease right-of-use asset, net	17,546,240	17,836,756
Finance lease right-of-use asset	3,143,592	883,076
Intangible assets, net	11,830,249	6,592,316
Goodwill	20,041,040	14,440,683
Investments	1,400,000	400,000
Equity-method investments	942,501	963,685
Other related party receivables	153,556	—
Deferred tax assets	7,782,187	—
Other assets	1,166,928	993,538
Total assets	$ 229,804,021	$ 175,299,877

THORNE HEALTHTECH, INC.
Consolidated Balance Sheets

	December 31, 2022	December 31, 2021
Liabilities, Convertible Preferred Stock and Stockholders' Equity		
Current Liabilities		
Accounts payable	$ 26,997,203	$ 16,889,756
Accrued payroll	3,508,583	2,526,917
Other accrued liabilities	3,563,843	1,144,573
Related party payables	988,778	1,634,775
Current portion of operating lease liability	1,504,433	2,633,236
Current portion of finance lease liability	1,660,404	413,487
Current portion of notes payable	814,576	—
Current portion of long-term debt	523,510	494,173
Total current liabilities	39,561,330	25,736,917
Long-term Liabilities		
Operating lease liability, net of current portion	28,430,474	27,605,739
Finance lease liability, net of current portion	1,455,011	482,544
Long-term debt, net of current portion	12,646,049	1,083,634
Warrant liability	1,059,343	2,058,566
Total liabilities	83,152,207	56,967,400
Commitments and Contingencies (Note 21)		
Series E convertible preferred stock; par value $0.01, 0 shares authorized as of December 31, 2022 and December 31, 2021; 0 shares issued and outstanding as of December 31, 2022 and December 31, 2021	—	—
Stockholders' Equity		
Common stock; par value $0.01, 200,000,000 shares authorized as of December 31, 2022 and December 31, 2021, respectively; 53,487,517 and 52,554,214 issued and outstanding as of December 31, 2022 and December 31, 2021, respectively	534,875	525,542
Common stock, Class B; no par value, 0 shares authorized as of December 31, 2022 and December 31, 2021; 0 shares issued and outstanding as of December 31, 2022 and December 31, 2021	—	—
Treasury stock	(9,678)	—
Additional paid-in capital	260,978,339	250,163,984
Accumulated deficit	(116,483,976)	(132,158,016)
Accumulated other comprehensive loss	(29,136)	—
Total stockholders' equity —Thorne HealthTech, Inc.	144,990,424	118,531,510
Non-controlling interest	1,661,390	(199,033)
Total stockholders' equity	146,651,814	118,332,477
Total liabilities, convertible preferred stock and stockholders' equity	$ 229,804,021	$ 175,299,877

See accompanying notes to consolidated financial statements.

THORNE HEALTHTECH, INC.
Consolidated Statements of Operations

	Years Ended December 31,	
	2022	2021
Net sales	$ 228,731,362	$ 184,301,485
Cost of sales	113,797,288	87,892,579
Gross profit	114,934,074	96,408,906
Operating expenses:		
Research and development	7,423,884	5,935,514
Marketing	26,442,805	22,768,555
Selling, general and administrative	75,586,115	56,389,672
Write-off of acquired Drawbridge in-process research and development	—	1,563,015
Income from operations	5,481,270	9,752,150
Other income:		
Interest expense, net	(26,328)	(449,908)
Guarantee fees	—	(336,915)
Change in fair value of warrant liability	999,223	1,872,364
Loss on Drawbridge Transaction	—	(165,998)
Other income, net	1,342,810	249,082
Total other income, net	2,315,705	1,168,625
Income before income taxes and loss from equity interests in unconsolidated affiliates	7,796,975	10,920,775
Income tax (provision) expense	(7,309,658)	411,919
Net income before loss from equity interests in unconsolidated affiliates	15,106,633	10,508,856
Loss from equity interests in unconsolidated affiliates	(173,976)	(3,664,058)
Net income	14,932,657	6,844,798
Net loss—non-controlling interest	(741,383)	(408,625)
Net income attributable to Thorne HealthTech, Inc.	15,674,040	7,253,423
Undistributed earnings attributable to Series E convertible preferred stockholders	—	3,507,892
Net income attributable to common stockholders—basic	$ 15,674,040	$ 3,745,531
Net income attributable to common stockholders—diluted	$ 15,674,040	$ 3,349,308
Earnings per share:		
Basic	$ 0.30	$ 0.14
Diluted	$ 0.30	$ 0.10
Weighted average common shares outstanding:		
Basic	52,757,834	27,478,411
Diluted	52,757,834	32,328,565

See accompanying notes to consolidated financial statements.

THORNE HEALTHTECH, INC.
Consolidated Statements of Comprehensive Income

	Years Ended December 31,	
	2022	2021
Net Income	$ 14,932,657	$ 6,844,798
Other comprehensive loss:		
Foreign currency translation adjustment, net of tax	(29,136)	—
Total other comprehensive loss	(29,136)	—
Comprehensive income	14,903,521	6,844,798
Comprehensive loss attributable to non-controlling interests	(741,383)	(408,625)
Comprehensive income attributable to Thorne HealthTech, Inc.	$ 15,644,904	$ 7,253,423

See accompanying notes to consolidated financial statements.

THORNE HEALTHTECH, INC.
Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)

	Equity Attributable to Thorne Stockholders								
	Common Stock		Treasury Stock						
	Shares	Amount	Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Non-controlling Interest	Total Stockholders' Equity
Year ended December 31, 2022:									
Balance at December 31, 2021	52,554,214	$ 525,542	—	$ —	$ 250,163,984	$ (132,158,016)	$ —	$ (199,033)	$ 118,332,477
Issuance of ownership interest in consolidated subsidiary	—	—	—	—	—	—	—	2,601,806	2,601,806
Exercise of stock options	304,303	3,043	—	—	443,496	—	—	—	446,539
Vesting of Restricted Stock Units	629,000	6,290	—	—	(6,290)	—	—	—	—
Shares repurchased for tax withholdings on vesting of Restricted Stock Units	—	—	197,832	(9,678)	(958,150)	—	—	—	(967,828)
Stock-based compensation	—	—	—	—	11,335,299	—		—	11,335,299
Current translation adjustment	—	—	—	—	—	—	(29,136)	—	(29,136)
Net income	—	—	—	—	—	15,674,040	—	(741,383)	14,932,657
Balance at December 31, 2022	53,487,517	$ 534,875	197,832	$ (9,678)	$ 260,978,339	$ (116,483,976)	$ (29,136)	$ 1,661,390	$ 146,651,814

	Convertible Preferred Stock		Common Stock		Class B Common Stock					
	Shares	Amount	Shares	Amount	Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Non-controlling Interest	Total Stockholders' Equity (Deficit)
Year ended December 31, 2021:										
Balance at January 1, 2021	27,011,500	$ 133,484,531	12,323,830	$ 123,238	—	$ —	$ 52,451,862	$ (132,964,365)	$ (6,447,074)	$ (86,836,339)
Common stock issued in exchange for remaining interest in consolidated affiliate	—	—	—	—	6,179,270	—	—	(6,447,074)	6,447,074	—
Non-controlling interest in acquired subsidiary	—	—	—	—	—	—	—	—	209,592	209,592
Conversion of all shares of Class B common stock to common stock	—	—	6,179,270	61,793	(6,179,270)	—	(61,793)	—	—	—
Conversion of Series E convertible preferred stock to common stock	(27,011,500)	(133,484,531)	27,011,500	270,115	—	—	133,214,416	—	—	133,484,531
Issuance of common stock in September 2021 IPO at $10.00 per share, net of issuance costs of $9,999,748	—	—	7,000,000	70,000	—	—	59,930,252	—	—	60,000,252
Exercise of stock options	—	—	39,614	396	—	—	75,223	—	—	75,619
Stock-based compensation	—	—	—	—	—	—	4,554,024	—	—	4,554,024
Net income	—	—	—	—	—	—	—	7,253,423	(408,625)	6,844,798
Balance at December 31, 2021	—	$ —	52,554,214	$ 525,542	—	$ —	$ 250,163,984	$ (132,158,016)	$ (199,033)	$ 118,332,477

See accompanying notes to consolidated financial statements.

THORNE HEALTHTECH, INC.
Consolidated Statements of Cash Flows

	Years Ended December 31,	
	2022	2021
Cash Flows from Operating Activities		
Net income	$ 14,932,657	$ 6,844,798
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	5,823,357	4,453,057
Change in fair value of warrant liability	(999,223)	(1,872,364)
Non-cash lease expense	3,687,380	5,963,123
Stock-based compensation	11,335,299	4,554,024
Deferred income tax benefit	(7,782,187)	—
Amortization of debt issuance cost and debt discount	6,280	—
Provision for doubtful accounts	(266,719)	(10,767)
Inventory write-downs	(725,074)	(56,781)
Loss on sale of equipment	5,527	—
(Gain) loss from equity interests in unconsolidated affiliate	(131,607)	3,664,058
Loss on Drawbridge Transaction	—	165,998
Write-off of acquired Drawbridge in-process research and development	—	1,563,015
Other non-cash	24,886	—
Change in operating assets and liabilities		
Accounts receivable	(8,801,275)	(2,886,874)
Related party receivables	(383,682)	(231,191)
Related party payables	(645,997)	825,695
Inventories	(16,753,665)	(12,879,268)
Prepaid expenses and other current assets	843,758	(2,417,918)
Accounts payable	4,432,440	7,217,084
Accrued payroll	981,666	(65,226)
Other accrued liabilities	2,249,931	(952,043)
Operating lease liability	(2,611,848)	(4,794,134)
Net cash provided by operating activities	5,221,904	9,084,286
Cash Flows from Investing Activities		
Purchase of property and equipment, net	(17,112,171)	(4,311,015)
Proceeds from disposal of property and equipment, net	99,000	—
Acquisition of Nutrativa, net of cash acquired	(14,861,996)	—
Acquisition of Drawbridge Health assets, net of cash acquired	—	(1,412,279)
Purchase of investment in unconsolidated subsidiaries	(1,000,000)	—
Purchase of investment in equity method investments	—	(704,637)
Purchase of license agreements	(750,000)	(750,457)
Net cash used in investing activities	(33,625,167)	(7,178,388)

THORNE HEALTHTECH, INC.
Consolidated Statements of Cash Flows

	Years Ended December 31,	
	2022	2021
Cash Flows from Financing Activities		
Proceeds from term loan	$ 12,000,000	$ —
Proceeds from notes payable	1,163,680	—
Proceeds from issuance of common stock in IPO	—	70,000,000
Payment of notes payable - equipment financing	(498,215)	—
Payments on notes payable	(349,104)	—
Payments on finance leases	(934,975)	(1,242,948)
Payments of revolving line of credit	—	(20,000,000)
Debt issuance costs	(105,572)	—
Investment from minority partner in joint venture	2,601,806	—
Proceeds from exercise of stock options	446,539	75,619
Shares repurchased for tax withholdings on vesting of Restricted Stock Units	(967,828)	—
Common stock issuance costs	—	(9,999,748)
Net cash provided by financing activities	13,356,331	38,832,923
Effect of exchange rate changes on cash and restricted cash	(29,136)	—
Net (decrease) increase in cash and restricted cash	(15,076,068)	40,738,821
Cash and restricted cash, beginning of year	56,000,915	15,262,094
Cash and restricted cash, end of year	$ 40,924,847	$ 56,000,915
Supplemental Disclosure of Cash Flows Information:		
Cash paid during the period:		
Interest	$ 77,209	$ 383,569
Income taxes, net of refunds	263,650	380,200
Noncash Investing and Financing Activities:		
Additions to property and equipment, net included in accounts payable and other accrued expenses	$ 5,493,094	$ —
Equipment acquired through finance lease obligations	3,352,693	540,433
Right-of-use assets obtained in exchange for lease liabilities	2,307,468	2,913,002
Equipment acquired through debt obligations	—	1,274,601
Conversion of Series E convertible preferred stock to common stock	—	133,484,531

See accompanying notes to consolidated financial statements.

1. Organization and Nature of Operations

Thorne HealthTech, Inc. was originally incorporated under the name of Thorne Holding Corp. (the Company) and was incorporated under the laws of the state of Delaware on June 17, 2010, to acquire 100% of the stock of Thorne Research, Inc. (Thorne Research). On November 13, 2020, the Company changed its name to Thorne HealthTech, Inc.

The Company is a science-driven wellness company, pioneering innovative solutions and personalized approaches to health and wellness. The Company is building a new health category to deliver better health outcomes through a proactive, empowered approach. Its unique, vertically integrated brands, Thorne and Onegevity, provide actionable insights and personalized data, products and services that help individuals take a proactive approach to improve and maintain their health over their lifetime. By combining its proprietary multi-omics database, artificial intelligence (AI) and digital health content with its science-backed nutritional supplements, the Company delivers a total system for health and wellness.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with United States generally accepted accounting principles (U.S. GAAP). The consolidated financial statements include the operations of the Company and all of its wholly-owned subsidiaries, as well as majority-owned subsidiaries over which the Company exercises control and, when applicable, entities for which the Company has a controlling financial interest or variable interest for which the Company is the primary beneficiary. All significant intercompany accounts and transactions have been eliminated in consolidation.

On September 10, 2021, the Company approved and effected a 445-for-1 forward stock split of the Company's Class A common stock, Class B common stock, and Series E convertible preferred stock. The par value and other terms of the common stock and preferred stock were not affected by the stock split. All related share and per share amounts have been retroactively adjusted in these consolidated financial statements for all periods presented to reflect the 445-for-1 forward stock split. Furthermore, other related information, including shares of common stock underlying the Company's warrants, stock options and restricted stock units and their respective exercise prices have been retroactively adjusted in these consolidated financial statements for all periods presented to reflect the 445-for-1 forward stock split.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, and expenses, as well as related disclosure of contingent assets and liabilities. The Company bases its estimates on its historical experience and on assumptions that the Company believes are reasonable; however, actual results could significantly differ from those estimates.

On an ongoing basis, we evaluate our estimates, including those related to the allowance for credit losses, useful lives of property, equipment and software, incremental borrowing rates for lease liability measurement, fair values of intangible assets and reporting units, useful lives of intangible assets, share-based compensation, warrant liability, contingencies, and income taxes, among others.

Reclassifications

Certain balances have been reclassified from prior years to conform to the current year presentation. Such reclassifications are not material and had no effect on the Company's results of operations or financial position in any of the periods presented.

Correction of an Immaterial Error

During the fourth quarter of 2022, we reclassified certain amounts in the consolidated statements of operations as a result of certain immaterial classification errors related to prior interim periods reflecting a decrease of $3.4 million to net sales, a decrease of $4.2 million to marketing expenses, and a net increase of $0.8 million to selling, general and administrative expenses for the year-to-date period ended September 30, 2022. There was no impact of the immaterial classification errors on net income. To conform with current year presentation, certain amounts have been reclassified within the consolidated statements of operations for the year ended December 31, 2021, the impact of which resulted in a decrease of $0.9 million to net sales, a decrease of $2.4 million to marketing expenses, and a net increase of $1.5 million to selling, general and administrative expenses. Based on our quantitative and qualitative analyses, we do not consider the out of period impact to be material to our financial position or results of operations for any prior periods or for the years ended December 31, 2022 and December 31, 2021.

Cash

Cash includes all cash balances. At times, cash balances may exceed the amount insured by the Federal Deposit Insurance Corporation. The Company deems this credit risk to be not significant as cash is held at well-capitalized financial institutions in the U.S. The Company has not experienced any losses resulting from these excess deposits.

Restricted Cash

The Company's restricted cash consists of cash that the Company is contractually obligated to maintain in accordance with the terms of its Standby Letter of Credit with Sumitomo Mitsui Banking Corporation (SMBC). See Notes 3 and 13 for additional information related to the SMBC Standby Letter of Credit.

Accounts Receivable

Accounts receivable consist of balances due from customers and are recorded at net realizable value. Past due balances that are delinquent beyond the acceptable terms of credit for each customer are reviewed individually for collectability. The allowance for doubtful accounts was $248 thousand and $10 thousand as of December 31, 2022 and 2021, respectively.

Concentrations of Risk

Credit Risk - Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash and accounts receivable. Although the Company places its cash with high quality institutions, these balances often exceed federally insured limits. Concentrations of credit risk primarily relate to unsecured trade receivables. Major customers who accounted for more than 10% of the Company's total receivables were as follows:

	As of December 31,	
	2022	2021
iHerb, Inc.	29.6%	41.3%
Pattern, Inc.	23.7%	*
Emerson Ecologics, LLC	*	33.3%

* Represents less than 10%

Sales - Major customers who accounted for more than 10% of the Company's total net sales were as follows:

	Years Ended December 31,	
	2022	2021
Pattern, Inc.	32.6%	24.8%

Inventories

Raw materials consist primarily of powders, soft gels, and packaging components such as bottles, lids, and labels. Work-in-process consists of premixed powders and encapsulated powders actively in the manufacturing process, but not yet bottled. Inventories are stated at the lower of cost, as determined on the first-in, first-out method, or net realizable value. Finished goods and work-in-process include the inventory costs of raw materials, direct labor and normal manufacturing overhead. The Company uses an inventory reserve to adjust our inventory costs down to a net realizable value and to reserve for estimated obsolescence of both raw materials and finished goods. At the point of loss recognition, a new, lower-cost basis for that inventory is established, and any subsequent improvements in facts and circumstances do not result in the restoration or increase in that newly established cost basis. Any purchase discounts received are included in the cost of inventories.

Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets include annual insurance premiums and annual equipment and software maintenance expense, paid on a non-calendar year basis such that portions of the advance payments relate to future periods.

Property and Equipment

Property and equipment are stated at historical cost, less accumulated depreciation and amortization. Depreciation and amortization are computed using the straight-line method over the estimated useful lives of the assets. Amortization of leasehold improvements is computed using the straight-line method over the shorter of the remaining lease term (including renewals that are reasonably certain to occur) or the estimated useful lives of the improvements. The estimated useful lives of property and equipment are as follows:

Machinery and equipment	3 to 15 years
Furniture and fixtures	3 to 7 years
Office equipment	3 to 7 years
Leasehold improvements	3 to 20 years
Vehicles	7 years
Lab equipment	5 to 10 years
Software	7 years

Leases

The Company has operating and finance lease agreements for its production, shipping and customer service centers and corporate offices. At inception, the Company determines whether an agreement represents a lease and, at commencement, the Company evaluates each lease agreement to determine whether the lease constitutes an operating or financing lease. Some of our lease agreements have renewal options, tenant improvement allowances, rent holidays and rent escalation clauses.

The Company accounts for its leases as operating or finance leases under Accounting Standards Codification (ASC) Topic 842. The Company has elected not to separate lease components from non-lease components for all fixed payments.

Right-of-use lease assets represent the Company’s right to use the underlying asset for the lease term, and the operating lease obligation represents its commitment to make the lease payments arising from the lease. The Company has elected not to recognize on the consolidated balance sheet leases with terms of one-year or less. Lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company utilizes the appropriate incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. Certain adjustments to the right-of-use asset may be required for items such as initial direct costs paid or incentives received. The lease term may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Operating lease expense is recognized on a straight-line basis over the lease term, subject to any changes in the lease or expectations regarding the terms.

Other Assets

Other assets are primarily deposits required by contractual obligations for real estate leases.

Impairment of Long-lived Assets

Management reviews long-lived assets and certain identifiable intangible assets with finite lives for impairment in accordance with ASC 360, "Property, Plant, and Equipment." Goodwill and intangible assets not subject to amortization are reviewed annually for impairment in accordance with ASC 350, "*Intangibles — Goodwill and Other*," or more often if there are indications of possible impairment.

The analysis to determine whether or not an asset is impaired requires significant judgment that is dependent on internal forecasts, including estimated future cash flows, estimates of long-term growth rates for the business, the expected life over which cash flows will be realized and assumed discount rates. Changes in these estimates and assumptions could materially affect the determination of fair value and any impairment charge. While the fair value of these assets exceeds their carrying value based on management's current estimates and assumptions, materially different estimates and assumptions in the future in response to changing economic conditions, changes in the business, increased competition or loss of market share, product innovation or obsolescence, product claims that result in a significant loss of sales or profitability over the product life or for other reasons could result in the recognition of impairment losses.

For assets to be held and used, including acquired intangible assets and long-lived assets subject to amortization, the Company initiates a review whenever events or changes in circumstances indicate that the carrying amount of these assets may not be recoverable. Recoverability of an asset is measured by comparison of its carrying amount, to the future undiscounted cash flows that the asset is expected to generate. Any impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds its fair value. Significant management judgment is required in this process.

During the years ended December 31, 2022 and 2021, no impairment losses were identified.

Goodwill

Goodwill, which represents the excess of the purchase price paid over the fair value of the identifiable net assets acquired, is carried at cost. Goodwill is not amortized; rather, it is subject to a periodic assessment for impairment by applying a fair value-based test. The Company is organized in one reporting unit and evaluates the goodwill for the Company as a whole. The Company evaluates goodwill for impairment on an annual basis or more frequently if events or changes in circumstances indicate that the asset may be impaired. In the third quarter of 2022, the Company voluntarily changed its annual goodwill impairment testing date from December 31st to October 1st. The change in the annual goodwill impairment testing date is a change in accounting principle, which management believes is preferable, as the new date of the assessment better aligns with the reporting timeline for public companies following the Company's recent IPO. The change in accounting principle was applied prospectively from September 30, 2022, as retrospective application was deemed impracticable. This change was immaterial to the Company's consolidated financial statements as it did not delay, accelerate or avoid any potential goodwill impairment charge.

As part of the assessment of goodwill, the Company has the option to first assess the qualitative factors to determine whether it is more likely than not that the fair value of the reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform a quantitative goodwill impairment test. If the Company determines that it is more likely than not that the fair value of a reporting unit is less than its carrying amount based on the qualitative factors, then the quantitative goodwill impairment test is performed. The quantitative goodwill impairment test requires the Company to estimate the fair value of the reporting unit and to compare the fair value of the reporting unit with its carrying amount. If the fair value exceeds the carrying amount, then no impairment is recognized. If the carrying amount recorded exceeds the fair value calculated, then an impairment charge is recognized for the difference, limited to the amount of goodwill recorded. The judgments made in determining the projected cash flows used to estimate the fair value can materially impact the Company's financial condition and results of operations. There was no impairment of goodwill for the years ended December 31, 2022 and 2021.

Intangible Assets

Intangible assets are initially recorded at fair value and amortized over the estimated period of benefit on a straight line basis and include customer relationships with estimated useful lives of 20 years, trade names with estimated useful lives ranging from 5 to 15 years, existing technology and reformulations with estimated useful lives ranging from 3 to 15 years, research formulas with estimated useful lives of 10 years and license agreements with estimated useful lives of 3 to 15 years. Amortization expense is generally recognized in selling, general and administrative expense. The carrying value of definite life intangibles is reviewed at each balance sheet date if indication of impairment exists.

Investments

The Company has investments in various other entities. The equity method of accounting is used for entities in which the Company exercises significant influence but does not have a controlling interest or a variable interest in which it is the primary beneficiary. Investments not accounted for using the equity method do not have readily determinable fair values and do not qualify for the practical expedient to measure the investment using a net asset value per share. These investments are recorded using the measurement alternative in which the Company's equity interests are recorded at cost, less impairments, adjusted for observable price changes in orderly transactions for an identical or similar investment of the same issuer. At each reporting period, the Company assesses if these investments continue to qualify for this measurement alternative. An impairment is recorded when there is evidence that the expected fair value of the investment has declined to below the recorded cost. During the years ended December 31, 2022 and 2021, no impairment losses were identified.

Equity Method Investments

The Company reports investments in unconsolidated entities, over whose operating and financial policies it has the ability to exercise significant influence but not control, under the equity method of accounting. Under this method of accounting, the Company's pro rata share of the applicable entity's earnings or losses are included in the consolidated statements of operations. Initially the investments are recorded based on assets contributed or the cash invested.

The Company evaluates its equity method investments for impairment whenever events or changes in circumstances indicate that the carrying value of the investments may exceed the fair value. If it is determined that a decline in the fair value of the investments is not temporary, and if such reduced fair value is below its carrying value, an impairment is recorded. Determining fair value involves significant judgment. Estimates consider available evidence including the present value of the expected future cash flows discounted at market rates, general economic conditions and other relevant factors. No impairments were recorded related to our equity-method investments for the years ended December 31, 2022 and 2021.

Fair Value Measurements

ASC 820*, Fair Value Measurements and Disclosures,* establishes a fair value hierarchy which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The standard describes three levels of inputs that may be used to measure fair value:

- *Level 1:* Quoted prices (unadjusted) for identical assets or liabilities in active markets that the entity has the ability to access as of the measurement date.
- *Level 2:* Significant other observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data.
- *Level 3:* Significant unobservable inputs that reflect a reporting entity's own assumptions about the assumptions that market participants would use in pricing an asset or liability.

The carrying amounts of certain financial instruments, which include cash, receivables, accounts payable, and accrued expenses approximate their fair values at December 31, 2022 and 2021 due to their short-term nature and management's belief that their carrying amounts approximate the amount for which the assets could be sold or the liabilities could be settled.

Defined Contribution Plan

The Company maintains a 401(k) defined contribution plan which covers all employees who meet minimum requirements and elect to participate. The Company is currently matching employee contributions, up to specified percentages of those contributions.

Warrant Liability

The Company determines the accounting classification of a warrant, as either liability or equity, by first assessing whether the warrant meets liability classification in accordance with ASC 480, *Distinguishing Liabilities from Equity* (ASC 480), and then in accordance with ASC 815-40, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock* (ASC 815-40). If the warrant does not meet liability classification under ASC 480, the Company assesses the requirements under ASC 815-40, including whether the warrant is indexed to its common stock and whether the warrant meets the other requirements to be classified as equity under ASC 815-40. After all relevant assessments are made, the Company concludes whether the warrant should be classified as liability or equity.

The Company has warrants that are classified as a liability on the consolidated balance sheet. The warrants classified as a liability are measured at fair value using the Black-Scholes pricing model which takes into account, as of the valuation date, factors including the current exercise price, the contractual life of the warrant, the current fair value of the underlying stock, its expected volatility, and the risk-free interest rate for the term of the warrant. The warrant liability is revalued at each reporting period and changes in fair value are recognized in the consolidated statements of operations. The selection of the appropriate valuation model and the inputs and assumptions that are required to determine the valuation requires significant judgment and requires management to make estimates and assumptions that affect the reported amount of the related liability and reported amounts of the change in fair value. Actual results could differ from those estimates, and changes in these estimates are recorded when known. As the warrant liability is required to be measured at fair value at each reporting date, it is reasonably possible that these estimates and assumptions could change in the near term. See Note 16 for additional information related to the previously issued and outstanding warrants.

Equity-Classified Warrants

The Company has common stock warrants that are classified within equity on the consolidated balance sheet. The Company has concluded that these warrants do not meet the requirements to be accounted for as liability under ASC 480 as they are for a fixed number of shares and do not contain provisions that require the Company to cash-settle the warrants. Additionally, the Company determined that these warrants are indexed to the Company's stock as they do not contain exercise contingencies or adjustments to exercise price that are not an input to a fixed-for-fixed model. The warrants also meet the other equity-classification criteria under ASC 815-40. Equity classified warrants are accounted for at fair value on the issuance date and are not remeasured every reporting period.

Revenue Recognition

The Company accounts for revenue in accordance with FASB Topic 606, "*Revenue from Contracts with Customers*," (ASC 606), using the following steps:

- identify the contract, or contracts, with a customer;
- identify the performance obligations in the contract;
- determine the transaction price;
- allocate the transaction price to the identified performance obligations; and
- recognize revenue when, or as, the Company satisfies the performance obligations.

The Company recognizes revenues at a point in time when it satisfies a performance obligation by transferring control over a product and other promised goods and services to a customer. Significant judgments made in the application of ASC 606 include determining the transaction price, and the timing of transfer of control of the performance obligation (i.e., the sale of product). The Company considers several factors in determining the point in time at which control transfers to the customer, including when legal title transfers to the customer based upon shipping terms, the Company has a present right to payment, and the customer has assumed the risks and rewards of ownership.

Professional/B2B Sales: The Company sells to wholesale customers that include health professionals, retail stores and through various online sites operated by authorized resellers. Certain customers resell Company products in online marketplaces, and such inventories are not held on consignment. Revenue is recognized when control of the goods is transferred to these customers in accordance with respective shipping terms. The terms of payment over the recognized receivables from distributors are less than one year and therefore these sales do not have any significant financing components. The Company uses standard price lists in determining the transaction price, adjusted for estimates of variable consideration. Any discounts stated or implied are allocated entirely to the sole performance obligation.

DTC Sales: The Company sells direct to consumers online through a Company owned and operated website. Revenue from online sales is recognized at time of shipment of the product. In addition, the Company sells testing services and test kits. Testing services and testing kits are recorded as revenue when the testing results are provided to the customer. Shipping and handling costs are considered a fulfillment activity and are expensed as incurred. Further, the Company sells its products to a distributor for sales direct to consumers on Amazon.com. Revenue from sales to the distributor is recognized at the time of shipment of the product to the distributor.

The Company offers its customers the ability to opt in to recurring automatic refills. Revenue is recognized under the subscription program when product is shipped to the consumer. No funds are collected at the time a consumer signs up for a subscription and the customer can cancel or modify a subscription at any time at no cost to the customer. On the Company website, customers are allowed to subscribe at a frequency of monthly, every 45 days, every 2 months, every 3 months, or every 4 months. For all frequencies, a 10% discount is offered on retail refill orders when a customer is subscribed to 1 to 2 products and a 20% discount when subscribed to 3 or more products, the discount ranges from 5% to 10% to 15% depending on the number of products to which a customer is subscribed. The Company records revenues, net of estimated discounts.

If a customer is not satisfied for any reason with a product purchased, the customer can return it to the place of purchase to receive a refund, a credit, or a replacement product. The return or refund request must be submitted within 60 days of the date of purchase. The Company estimates returns and accrues for potential returns based on historical data.

There are no material differences in our revenue recognition policy between one-time purchases and subscription purchases of our products.

The Company primarily sells to customers throughout the United States but also sells to international markets. Regardless of customer location, all customers are invoiced and payments are required to be made in U.S. dollars.

The Company has elected to exclude sales and use taxes for non-exempt customers from the transaction price and, therefore, sales and use taxes are excluded from revenue.

The aggregate amount of the transaction price allocated to unsatisfied performance obligations as of December 31, 2022 and 2021 is $1.2 and $0.3 million, respectively, which the Company expects to recognize in the subsequent year based on when the performance obligation is complete. These amounts are included in other accrued liabilities within the consolidated balance sheets.

Product Returns, Sales Incentives and Other Forms of Variable Consideration

In measuring revenue and determining the consideration the Company is entitled to as part of a contract with a customer, the Company takes into account the related elements of variable consideration. Such elements of variable consideration include product return rights, discounts, rebates, volume discounts and rebates and promotional offers and other marketing offers that may impact net sales.

For the sale of goods with a right of return, the Company only recognizes revenue for the consideration it expects to be entitled to (considering the products to be returned) and records a sales return accrual within other accrued expenses for the amount it expects to credit back to its customers. Given that most product returns cannot be resold to another customer, the Company does not recognize an asset in inventory, or a corresponding adjustment to cost of sales, for the right to recover goods from customers associated with the estimated returns.

The sales return accrual includes estimates that directly impact reported net sales. These estimates are calculated based on a history of actual returns and estimated future returns. In addition, as necessary, sales return accruals may be established for significant future known or anticipated events. The types of known or anticipated events that are considered, and will continue to be considered, include the Company's decision to continue to support new and existing products.

Returns are handled on a case-by-case basis, but generally all returns are accepted if the customer is unsatisfied with the product. The Company has accrued an estimate for returns related to a future period. Sales returns accrued for the years ended December 31, 2022 and 2021 were approximately $146 thousand and $50 thousand, respectively, and reduced net sales. This amount is included within other accrued liabilities within the consolidated balance sheets.

The Company estimates sales incentives and other variable consideration using the expected value method. The variable consideration included in the transaction price is the amount for which, in the Company's judgment, is probable that a significant future reversal of cumulative revenue under the contract will not occur. Under this method, certain forms of variable consideration are based on volumes of sales to the customer, which requires subjective estimates. These estimates are supported by historical results as well as specific facts and circumstances related to the current period. A select few customers, because of their size, are offered a discount for early payment.

The Company enters into transactions and makes payments to certain of its customers related to advertising, some of which involve cooperative relationships with customers. These activities may be arranged either with unrelated third parties or in conjunction with the customer. To the extent that the Company receives a distinct good or service in exchange for consideration and the fair value of the benefit can be reasonably estimated, the Company's share of the costs of these transactions (regardless of to whom they were paid) are reflected as marketing expenses in the accompanying consolidated statements of operations. When no distinct good or service is received in exchange for consideration, or if the fair value of the benefit cannot be reasonably estimated, the Company records its share of the costs for these transactions paid to customers as a reduction of the transaction price within net sales in the accompanying consolidated statements of operations. The Company recorded $9.5 million and $4.2 million of cooperative advertising costs as a reduction of net sales for the years ended December 31, 2022 and 2021, respectively.

For certain sales, the Company incurs incremental costs of obtaining the contract through the form of sales commissions. The sales commissions incurred are short-term (less than 12 months in duration) and directly correlated to the sales generated and are therefore expensed as incurred.

The following table presents revenue disaggregated by geography, as determined by the country products were shipped to:

	Year Ended December 31, 2022		Year Ended December 31, 2021	
	Amount	Percentage of Total	Amount	Percentage of Total
Domestic	$ 215,257,232	94.1%	$ 173,415,091	94.1%
Foreign	13,474,130	5.9%	10,886,394	5.9%
Total sales	$ 228,731,362	100.0%	$ 184,301,485	100.0%

The following table presents disaggregated revenues based upon sales channel:

	Year Ended December 31, 2022		Year Ended December 31, 2021	
	Amount	Percentage of Total	Amount	Percentage of Total
DTC sales	$ 100,495,298	43.9%	$ 69,646,773	37.8%
Professional/B2B sales	128,236,064	56.1%	114,654,712	62.2%
Total	$ 228,731,362	100.0%	$ 184,301,485	100.0%

Cost of Sales

Cost of sales includes the cost of inventory sold and includes all direct and indirect costs to bring the product to its saleable condition, including, inbound freight costs associated with inventory, inventory shrinkage costs, labor associated with manufacturing, lab testing, depreciation and amortization of assets used in the manufacturing process, costs to maintain production equipment, quality assurance costs and other costs associated with manufacturing.

Research and Development

Research and development costs, which are expensed as incurred, totaled approximately $7.4 million and $5.9 million for the years ended December 31, 2022 and 2021, respectively. Research and development costs include research payroll and payroll related costs, new product development and line extensions, clinical trials, product efficacy research, product shelf-life validation and new dietary ingredient research, among other things.

In-process Research and Development

In-process research and development (IPR&D) was recorded at its fair value using a discounted cash flow model and was assigned to acquired research and development assets that were not fully developed as of the completion of the acquisition of Drawbridge Health, Inc. (the Drawbridge Transaction; see Note 4). IPR&D acquired in an asset purchase is capitalized on the Company's consolidated balance sheets at its acquisition-date fair value if the acquired IPR&D has alternative future use. For the IPR&D acquired from the Drawbridge Transaction it was determined that the IPR&D had no alternative future use, and therefore, it was expensed immediately following the Drawbridge Transaction. Fair value measurement was classified as Level 3 under the fair value hierarchy.

Selling, General and Administrative

Selling, general and administrative expenses consist of payroll and related expenses for employees involved in general corporate functions, including accounting, finance, legal, selling and human resources; costs associated with use by these functions of facilities and equipment, such as depreciation expense and rent, share-based compensation expense, professional fees and other general corporate costs. It also includes shipping costs incurred in operating and staffing distribution operations, including costs attributable to picking, packaging and preparing customer orders for shipment, payment processing and related transaction costs, and responding to inquiries from customers.

Shipping and Handling

The costs of out-bound freight are included in selling, general and administrative expenses and marketing expenses in the Consolidated Statement of Operations. For the year ended December 31, 2022, the costs of out-bound freight were $11.2 million in total, with $11.1 included in selling, general and administrative expenses and $0.1 million in marketing expenses. For the year ended December 31, 2021, the total costs were $8.6 million, with the entire balance included in selling, general and administrative expenses.

Advertising

The cost of advertising is expensed as incurred. These costs are included within marketing expenses in the Consolidated Statements of Operations. Total advertising expense was approximately $17.1 million and $19.2 million for the years ended December 31, 2022 and December 31, 2021, respectively.

Deferred Offering Costs

The Company capitalizes within other assets certain legal, accounting and other third-party fees directly related to the Company's in-process equity financings until such financings are consummated. After consummation of the equity financing, these costs are recorded as a reduction of the proceeds received as a result of the offering. Should a planned equity financing be abandoned, terminated or significantly delayed, the deferred offering costs are immediately written off to operating expenses.

On September 22, 2021, the Company's Registration Statement on Form S-1, as amended, was declared effective and on September 23, 2021, the Company's common stock began trading on the Nasdaq Global Select Market, under the ticker symbol "THRN". On September 27, 2021, the Company closed its initial public offering (IPO) of 7 million shares of common stock. Through the completion of the offering, the Company incurred $10.0 million of offering costs, which had been capitalized prior to the completion of the offering. Upon closing of the offering, the Company reclassified these amounts to additional paid-in capital, as a reduction of the offering proceeds.

Stock-based Awards

The Company follows ASC 718 "Stock Compensation", which provides guidance in accounting for share-based awards exchanged for services rendered and requires companies to expense the estimated fair value of these awards over the requisite service period. The Company recognizes as expense, the grant-date fair value of stock options and other stock-based compensation issued to employees and non-employee directors over the requisite service periods, which are typically the vesting periods. The Company uses the Black-Scholes-Merton model to estimate the fair value of our stock-based payments. The volatility assumption used in the Black-Scholes-Merton model is based on the calculated historical volatility based on an analysis of reported data for a peer group of companies. The expected term of options granted has been determined based upon the simplified method, because the Company does not have sufficient historical information regarding its options to derive the expected term. Under this approach, the expected term is the mid-point between the weighted average of vesting period and the contractual term. The risk-free interest rate is based on U.S. Treasury rates whose term is consistent with the expected life of the stock options. The Company has not paid and does not anticipate paying cash dividends on its shares of common stock; therefore, the expected dividend yield is assumed to be zero. Restricted stock awards are valued based on the fair value of the stock on the grant date and the related compensation expense is recognized over the service period. We recognize forfeitures of stock-based compensation as they occur.

Common Stock Valuation

Due to the absence of an active market for the Company's common stock prior to the IPO, the Company has historically utilized methodologies, approaches and assumptions consistent with the American Institute of Certified Public Accountants' Audit and Accounting Practice Guide: Valuation of Privately-Held Company Equity Securities Issued as Compensation to estimate the fair value of its common stock. In determining the exercise prices for options granted, the Company has considered the fair value of the common stock as of the grant date. The fair value of the common stock has been determined based upon a variety of factors, including the prices at which the Company sold shares of its convertible preferred stock to outside investors in arms-length transactions, if any, and the superior rights, preferences and privileges of the preferred stock relative to the common stock at the time of each grant; the Company's historical and forecasted performance and operating results and the lack of an active public market for the Company's common stock. Significant changes to the key assumptions underlying the factors used could result in different fair values of common stock at each valuation date.

Income Taxes

Income taxes are accounted for using an asset and liability approach that requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in income in the period that includes the enactment date. We evaluate both the positive and negative evidence that is relevant in assessing whether we will realize the deferred tax assets. A valuation allowance is provided when it is more likely than not that some portion or all of the net deferred tax assets will not be realized. This projected realization is directly related to our future projections of the performance of our business and management's planning initiatives at any point in time. As a result, valuation allowances are subject to change as proven business trends and planning initiatives develop.

In accordance with the accounting standard for uncertainty in income taxes, liabilities for uncertain tax positions are recognized based on the two-step process prescribed by the accounting standards. The first step is to recognize the tax benefit from uncertain tax positions if it is more likely than not the tax positions will be sustained on examination by the tax authorities, based on the technical merits of the position. The second step is that the tax benefit is measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement. The Company recognizes interest and penalties related to income tax matters in income tax expense.

Health Elements, LLC made a previous election to be taxed as a Subchapter C corporation. As such, a provision for income taxes has been made for this entity and is included in the consolidated financial statements. See Note 17 for additional information related to the provision for income taxes.

In accordance with Section 382 of the Internal Revenue Code of 1986, as amended, a change in equity ownership of greater than 50% within a three-year period results in an annual limitation on the Company's ability to utilize its net operating loss carryforwards and general business credits, including the research and development credits, created during the tax periods prior to the change in ownership.

During the course of preparing the Company's consolidated financial statements as of and for the year ended December 31, 2022, the Company completed an Internal Revenue Code Section 382 analysis of its historical net operating loss and tax credit carryforward amounts. As a result, a portion of the prior year net operating loss and tax credit carryforwards were determined to be limited. See Note 17 for additional information regarding the results of the Company's Section 382 analysis and related limitations. If the Company experiences another change in equity ownership which exceeds the Section 382 threshold, the Company's net operating loss carryforwards and research and development credits may be subject to additional limitations.

Segments

The Company operates in one reportable segment: the selling of innovative solutions and personalized approaches to health and wellness. The Company's chief operating decision maker (determined to be the Chief Executive Officer) does not manage any part of the Company separately, and the allocation of resources and assessment of performance are based on the Company's consolidated operating results and where the best future opportunities arise.

Loss Contingencies

Certain conditions may exist which may result in a loss to the Company, but which will only be resolved when one or more future events occur or fail to occur. The Company's management assesses such contingent liabilities and such assessment inherently involves an exercise of judgment. In assessing loss contingencies related to legal proceedings that are pending against the Company, or unasserted claims that may result in such proceedings, the Company evaluates the perceived merits of any legal proceedings or unasserted claims as well as the perceived merits of the amount of relief sought or expected to be sought therein.

If the assessment of a contingency indicates that it is probable that a material loss has been incurred and the amount of the liability is estimable, the liability would be accrued in the Company's consolidated financial statements. If the assessment indicates that a potentially material loss contingency is not probable but is reasonably possible, or is probable but cannot be estimated, the nature of the contingent liability, together with an estimate of the range of possible loss, if determinable and material, would be disclosed.

Loss contingencies considered remote are generally not disclosed. Unasserted claims that are not considered probable of being asserted and those for which an unfavorable outcome is not reasonably possible have not been disclosed.

Recent Accounting Pronouncements - Adopted

ASU 2020-06, Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity. On January 1, 2022, the Company adopted this Accounting Standards Update (ASU) using the modified retrospective approach. This ASU simplified the accounting for convertible instruments and requires entities to use the if-converted method for all convertible instruments in calculating diluted earnings-per-share. The adoption did not have a material impact on its consolidated financial statements.

ASU 2021-04, Earnings Per Share (Topic 260), Debt-Modifications and Extinguishments (Subtopic 470-50), Compensation (Topic 718), and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options, a consensus of the Emerging Issues Task Force. On January 1, 2022, the Company adopted this ASU, which provides explicit guidance on accounting by issuers for modifications or exchanges of freestanding equity-classified written call options that remain equity classified after the modification or exchange. The adoption did not have a material impact on its consolidated financial statements.

Recent Accounting Pronouncements - Not Yet Adopted

ASU 2016-13, Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments. In June 2016, the FASB issued this ASU to amend the current accounting guidance which requires the measurement of all expected losses to be based on historical experience, current conditions and reasonable and supportable forecasts. For trade receivables, loans, and other financial instruments, the Company will be required to use a forward-looking expected loss model that reflects probable losses rather than the incurred loss model for recognizing credit losses. This ASU was amended by ASU 2019-10 to be effective for smaller reporting companies beginning after December 15, 2022. The Company is planning to adopt this ASU in Q1 FY23 and does not believe the adoption of this ASU will have a material impact on its consolidated financial statements and related disclosures.

ASU 2020-04, Reference Rate Reform (Topic 848), Facilitation of the Effects of Reference Rate Reform on Financial Reporting. In March 2020, the FASB issued guidance providing optional expedients and exceptions to account for the effects of reference rate reform to contracts, hedging relationships, and other transactions that reference LIBOR or another reference rate expected to be discontinued. The optional guidance became effective on March 12, 2020, and can be applied through the sunset date of December 31, 2022, has not impacted the Company's consolidated financial statements. In December 2022, the FASB issued ASU 2022-06, Reference Rate Reform (Topic 848), Deferral of the Sunset Date of Topic 848. The amendments in this Update defer the sunset date of Topic 848 from December 31, 2022 to December 31, 2024. The Company does not believe the adoption of this ASU will have a material impact on its consolidated financial statements and related disclosures.

ASU 2021-08, Business Combinations – Accounting for Contract Assets and Contract Liabilities from Contracts with Customers. In October 2021, the FASB issued guidance intended to improve the accounting for acquired revenue contracts with customer in a business combination by addressing diversity in practice. The guidance requires an acquirer to recognize and measure contract assets and liabilities acquired in a business combination in accordance with Topic 606 as if they had originated the contracts, as opposed to fair value on the date of acquisition. The standard will be effective for business combinations occurring after January 1, 2023. The Company does not believe the adoption of this ASU will have a material impact on its consolidated financial statements and related disclosures.

ASU 2022-04, Liabilities - Supplier Finance Programs (Subtopic 405-50), Disclosure of Supplier Finance Program Obligations. In September 2022, the FASB issued guidance requiring a buyer that uses supplier finance programs to make annual disclosures about the program's key terms, the balance sheet presentation of related amounts, the confirmed amount outstanding at the end of the period, and associated roll-forward information. The standard will be effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years, except for the requirement to disclose roll-forward information, which is effective for fiscal years beginning after December 15, 2023. The Company does not believe the adoption of this ASU will have a material impact on its consolidated financial statements and related disclosures.

No other new accounting pronouncement issued or effective during the fiscal year had, or is expected to have, a material impact on our consolidated financial statements.

3. Related Party Transactions

Transactions with Mitsui & Co. Ltd. and Kirin Holdings Company, Limited

Series E Convertible Preferred Stock Financing

On July 5, 2018, the Company issued and sold an aggregate of 27,011,500 shares of Series E convertible preferred stock to Mitsui & Co., Ltd. (Mitsui), and Kirin Holdings Company, Limited (Kirin), at a purchase price of $5.12 per share for aggregate gross proceeds of approximately $138.4 million (the Series E Financing). Immediately prior to the completion of the Company's IPO on September 22, 2021, all outstanding shares of the Series E convertible preferred stock automatically converted on a one-to-one basis into an aggregate of 27,011,500 shares of common stock. See Note 15 for additional information related to the Series E convertible preferred stock.

Kirin and Mitsui Feasibility Review Agreement

On March 19, 2019, Onegevity entered into a feasibility review agreement (Feasibility Agreement) with Kirin and Mitsui. Entities affiliated with both Mitsui and Kirin each held more than 5% of our capital stock as of and for the years ended December 31, 2022 and 2021. Pursuant to the Feasibility Agreement, Onegevity is required to conduct a feasibility study for the successful commercialization of Onegevity's Gutbio product (Gutbio Product) and in return each of Kirin and Mitsui paid the Company $0.5 million (Feasibility Payment Amount) in 2019. Under the Feasibility Agreement, Kirin and Mitsui may, acting jointly, any time prior to March 19, 2022, make the decision to commercialize the Gutbio Product. If they choose to commercialize the Gutbio Product, then Onegevity is required to enter into a definitive license agreement to license the Gutbio Product to Kirin and Mitsui for their exclusive use in Japan. If they do not choose to commercialize the Gutbio Product, the Feasibility Agreement requires Onegevity to issue equity securities of Onegevity to each of Kirin and Mitsui in equal amounts in consideration for the Feasibility Payment Amount. This agreement was subsequently amended on June 8, 2021 with the Amendment Agreement extending the date of determination by one year to March 19, 2023; see 'Kirin and Mitsui Amendment Agreement' below.

On December 21, 2022, Kirin and Mitsui elected to commercialize the Gutbio Product. Under the executed election notification, Kirin and Mitsui desire to enter into a service agreement under which the Company provides certain services to Kirin and (or) any third parties designated by Kirin and Mitsui with terms and conditions of the service agreement to be discussed with the Company in lieu of entering into a definitive license agreement. As of December 31, 2022, the Company has not entered into a service agreement with Kirin and Mitsui.

Kirin and Mitsui Amendment Agreement

On June 8, 2021, the Company entered into an Amendment Agreement with Kirin and Mitsui in order to amend the Feasibility Agreement, the Thorne Japan Agreement and the Onegevity Agreement. This Amendment Agreement removed the requirement from the Thorne Japan Agreement that the parties enter into separate agreements related to the exclusivity provisions discussed above and removed any provisions regarding the establishment of a joint venture in Japan. The Amendment Agreement further removed certain obsolete intercompany commitments between the Company and Onegevity, in light of the Company's merger with Onegevity. The Amendment Agreement also amended the Onegevity Agreement to replace Onegevity with the Company as a party to the agreement. Finally, the Amendment Agreement amended the Feasibility Agreement discussed above to obligate the Company (rather than Onegevity) to issue equity securities to each of Kirin and Mitsui in the event Kirin and Mitsui elect to not commercialize the Gutbio Product by March 19, 2023. On December 21, 2022, Kirin and Mitsui elected to commercialize the Gutbio Product, thus relieving the Company of any obligation to issue equity securities to each of Kirin and Mitsui under the Amended Agreement.

Kirin and Mitsui Letter Agreements

On July 5, 2018, the Company entered into a letter agreement with Kirin and Mitsui (the Thorne Japan Agreement) in connection with the Company's Series E convertible preferred stock financing which designates Kirin and Mitsui as the Company's exclusive strategic partners in Japan, including with respect to the commercialization in Japan of any products and services designed, developed, manufactured, marketed, provided, licensed, sold or bought by the Company from time to time. This agreement further appoints Kirin and Mitsui as the exclusive marketers and distributors of the Company's products in Japan and provides Kirin and Mitsui with the exclusive right to conduct research and development activities related to the Company's products in Japan, as well as manage any regulatory approvals required to market or distribute the Company's products in Japan. This agreement also provides Kirin and Mitsui with an exclusive right of first negotiation with respect to marketing of the Company's products in any country in Asia, including China, ASEAN member countries, Australia, New Zealand and any other countries in which Kirin and Mitsui have an interest. This agreement expires on July 5, 2028. This agreement was subsequently amended on June 8, 2021 with the Amendment Agreement; see 'Kirin and Mitsui Amendment Agreement' below.

Also on July 5, 2018, the Company and Onegevity entered into a letter agreement with Kirin and Mitsui (the Onegevity Agreement) in connection with the Company's Series E convertible stock financing which provided for certain exclusive commitments between the Company and Onegevity. Kirin and Mitsui also received a right of first negotiation with respect to any business collaboration, including with respect to Onegevity products, intellectual property, services or technology, in or with respect to Japan. The agreement also provides Kirin and Mitsui a right of first refusal over any agreement, arrangement or understanding with any third-party regarding a business collaboration in the Asia Pacific region other than Japan. This agreement does not expire. This agreement was subsequently amended on June 8, 2021 with the Amendment Agreement; see 'Kirin and Mitsui Amendment Agreement' below.

Kirin Juntendo Agreement

On October 16, 2020, Onegevity Health, LLC entered into a service agreement (Juntendo Agreement) with Juntendo University and Kirin. Pursuant to the Juntendo Agreement, we shall provide DNA analysis services for up to 600 samples and in return may receive up to $129 thousand. During the year ended December 31, 2022, we recorded $33 thousand in related revenue for analysis service provided under the agreement. During the year ended December 31, 2021, we recorded $15 thousand in related revenue for analysis service provided under the agreement. As of December 31, 2022, we had no receivables outstanding from Juntendo University and Kirin, related to the service agreement.

Kirin and Mitsui Employment Secondments

The Company is party to secondment agreements with Kirin's employee, Mr. Yasuhiro Oki, dated March 18, 2019 (Kirin Secondment Agreement), and Mitsui's employee, Mr. Shuntaro Yamamoto, dated February 28, 2019 (Mitsui Secondment Agreement), under which they provide full-time services to Thorne and Thorne reimburses Kirin and Mitsui for such services. Under the Kirin Secondment Agreement and the Mitsui Secondment Agreement, we reimburse each of Kirin and Mitsui up to $120 thousand annually for such services.

During each of the years ended December 31, 2022 and December 31, 2021, the Company recorded employment related expense of $84 thousand related to the Kirin Secondment Agreement. As of December 31, 2022 and 2021, the Company had an associated and outstanding related party payable to Kirin of $21 thousand related to the secondment reimbursement.

During each of the years ended December 31, 2022 and 2021, the Company recorded employment related expense of $120 thousand related to the Mitsui Secondment Agreement. As of December 31, 2022 and 2021, the Company had an associated and outstanding related party payable to Mitsui of $30 thousand related to the secondment reimbursement.

Kirin and Mitsui Fee Letters for $20.0 Million Revolver Guarantee

On February 14, 2020, the Company entered into additional fee letters with Mitsui (2020 Mitsui Fee Letter) and Kirin (2020 Kirin Fee Letter), whereby both Mitsui and Kirin individually agree to guarantee half of the $20.0 million of borrowings under the Uncommitted and Revolving Credit Line Agreement with SMBC, dated February 14, 2020 (2020 Credit Agreement). Under the 2020 Mitsui Fee Letter and 2020 Kirin Fee Letter, the Company is required to pay each, Mitsui and Kirin, an annual fee equal to 2.0% of their half of the $20.0 million guarantee.

On February 12, 2021, in connection with entering into the Uncommitted and Revolving Credit Line Agreement with SMBC, dated February 12, 2021 (2021 Credit Agreement), the Company entered into new fee letters with Mitsui (2021 Mitsui Fee Letter) and Kirin (2021 Kirin Fee Letter), whereby both Mitsui and Kirin individually agreed to guarantee half of the $20.0 million of borrowings. Under the 2021 Mitsui Fee Letter and 2021 Kirin Fee Letter, the Company is required to pay each Mitsui and Kirin an annual fee equal to 1.2% of their half of the $20.0 million guarantee. During the years ended December 31, 2022 and 2021, the Company recorded guarantee fee expense related to the $20.0 million guarantees of $0 and $203 thousand, respectively.

On October 4, 2021, the Company repaid the $20.0 million of outstanding borrowings under the 2021 Credit Agreement, plus interest accrued and unpaid on the loan through the date of repayment. Upon repayment of the outstanding borrowings under the 2021 Credit Agreement, the related Kirin and Mitsui guarantees were released and terminated. See Note 13 for additional information related to the 2021 Credit Agreement.

Kirin and Mitsui Fee Letters for $4.9 Million Letter of Credit Guarantee

The Company is party to certain fee letters with Mitsui and Kirin, under which Mitsui and Kirin provide certain guarantees of certain of the Company's obligations. On November 30, 2018, the Company entered into fee letters with Mitsui (2018 Mitsui Fee Letter) and Kirin (2018 Kirin Fee Letter), whereby both Mitsui and Kirin individually agree to guarantee half of the $4.9 million letter of credit under the Reimbursement Agreement with SMBC, dated October 31, 2018 (LC Reimbursement Agreement). Under the 2018 Mitsui Fee Letter and 2018 Kirin Fee Letter, the Company is required to pay each Mitsui and Kirin an annual fee equal to twelve-month LIBOR, plus 300 basis points of their half of the $4.9 million guarantee.

On December 3, 2018, the Company issued an irrevocable standby letter of credit pursuant to the LC Reimbursement Agreement in the amount of $4.9 million to serve as security under the lease for the manufacturing facility in Summerville, South Carolina. The irrevocable standby letter of credit had an original expiration date of December 3, 2019 and automatic renewals until October 31, 2037. During the years ended December 31, 2022 and 2021, the Company recorded guarantee fee expense of $0 and $134 thousand, respectively, related to the $4.9 million letter of credit guarantee.

On October 29, 2021, the Company deposited $4.9 million into a restricted interest-bearing account with SMBC to fund the standby letter of credit and release the guarantees provided by Kirin and Mitsui. As of December 31, 2022, the $4.9 million deposit is recorded as restricted cash within the consolidated balance sheets. See Note 13 for additional information related to the standby letter of credit.

Kirin Client Research Services Agreements

On November 1, 2021, the Company entered into a feasibility review agreement with Kirin to provide research services. For the year ended December 31, 2022, the Company recognized $83 thousand related to these research services. As of December 31, 2022 and December 31, 2021, the Company had no related party receivable related to these research services.

On December 21, 2022, the Company entered into a client research services agreement with Kirin to provide certain research services. As of December 31, 2022, the Company had recorded deferred revenue of $60 thousand related to this research services agreement, which has been included in other accrued liabilities within the consolidated balance sheets. As of December 31, 2022, the Company had recorded related party receivables of $60 thousand outstanding from Kirin related to this research services agreement.

Kirin HIaaS Software License Agreement

On November 21, 2022, the Company entered into a software license agreement with Kirin to develop and license software to Kirin in exchange for $25 thousand in total consideration. As of December 31, 2022, the Company has recorded deferred revenue of $13 thousand related to this agreement, which has been included in other accrued liabilities within the consolidated balance sheets. As of December 31, 2022, there was no receivable outstanding from Kirin related to this agreement.

Kirin and Kyowa Hakko Bio Co., Ltd. Research Agreements

The Company provides certain research services under several research contracts with Kirin, a significant shareholder, and Kyowa Hakko Bio Co., Ltd., a subsidiary of Kirin. During the years ended December 31, 2022 and 2021, the Company recognized $98 thousand and $24 thousand, respectively, of revenue related to these research services. As of December 31, 2022, there was no deferred revenue related to this research services agreement. As of December 31, 2021, the Company had recorded deferred revenue of $98 thousand, respectively, related to this research services agreement. As of December 31, 2022 and 2021, there was no receivable outstanding from Kirin related to the research agreements.

Other Related Party Transactions with Kirin and Kyowa Hakko Bio Co., Ltd.

The Company purchases certain raw materials from Kyowa Hakko Bio Co., Ltd., a subsidiary of Kirin. During the year ended December 31, 2022, the Company purchased $127 thousand of inventory from Kyowa Hakko Bio Co., Ltd. As of December 31, 2022, the Company had a related party payable of $40 thousand.

Other Related Party Transactions

Registration Rights Agreement

The Company is party to a registration rights agreement, as amended, with certain holders of the Company's capital stock. Under the Company’s registration rights agreement, certain holders of our capital stock, have the right to demand that we file a registration statement or request that their shares of our capital stock be covered by a registration statement that the Company is otherwise filing. As of and for the year ended December 31, 2022, the Company had incurred no costs associated with a registration or offering of shares of our common stock for Mitsui or Kirin.

Merger with Onegevity

On January 6, 2021, the Company announced a merger with Onegevity Health, LLC (Onegevity). Paul Jacobson, the Company's Chief Executive Officer, owned 5,712 (4.0%) of Onegevity’s outstanding shares. The merger transaction was approved by a majority of each of our and Onegevity’s board’s independent board members. The transaction exchanged all outstanding Onegevity equity for 14.1% of the outstanding equity of the combined Thorne and Onegevity entity. This transaction increased Paul Jacobson’s ownership in our company to 4.4% based on our common stock outstanding following the merger transaction. The transaction was completed on March 3, 2021. See Note 4 for additional information related to the Onegevity merger.

Merger with Drawbridge

On April 21, 2021, the Company entered into a Merger Agreement with Drawbridge to acquire the majority of outstanding shares of Drawbridge, a healthcare technology company. Prior to the merger, the Company owned approximately 11.2% of the outstanding shares of Drawbridge and accounted for the investment in Drawbridge as an equity method investment, as the Company determined it had significant influence over Drawbridge. The Company's portion of Drawbridge’s loss during 2021, up to the date of the merger, was $0.2 million. As of March 31, 2021 and immediately preceding the merger, the Company’s net equity investment was approximately $3.2 million. Under the Merger Agreement, the Company increased its ownership interest in Drawbridge by 76.3 percentage points, to a total ownership of 87.5%. The Merger Agreement called for the payment of approximately $1.4 million in cash and the assumption of certain liabilities of Drawbridge. See Note 4 and Note 10 for additional information related to the Drawbridge merger.

Supply Agreement with NR Therapeutics, LLC

The Company is party to an exclusive supply agreement dated June 5, 2020 with NR Therapeutics, LLC (NR Therapeutics) pursuant to which the Company purchases inventory of nicotinamide riboside (NR). Paul Jacobson, the Company's Chief Executive Officer, is a member of NR Therapeutics' board of directors, and the Company holds a 49% interest in NR Therapeutics. As of December 31, 2022, the Company had a related party payable of $1.68 million, of which $745 thousand is recorded within accounts payable in the consolidated balance sheets. As of December 31, 2021, the Company had a related party payable of $175 thousand. respectively. During the years ended December 31, 2022 and 2021, the Company purchased inventory from NR Therapeutics totaling $4.4 million and $4.1 million, respectively. See Note 9 for additional information related to the investment in NR Therapeutics.

Letter Agreement with Tecton Group, LLC

The Company is party to a letter agreement between the Company, Tecton Group, LLC (Tecton), Kirin and Mitsui (Tecton Letter Agreement) providing the Company with, amongst other things, a right of first offer to commercialize any Tecton product or service. The Tecton Letter Agreement also provides Kirin and Mitsui, with a right of first negotiation for any commercialization of Tecton products or services in Japan. The Company's Chief Executive Officer, Paul Jacobson, was previously a member of Tecton's board of directors. During the year ended December 31, 2021, the Company paid certain fees on behalf of Tecton, totaling approximately $705 thousand in exchange for additional equity interest in Tecton. During the year ended December 31, 2022, the Company did not pay any fees on behalf of Tecton. As of December 31, 2022 and December 31, 2021, there were no amounts outstanding to the Company from Tecton. See Note 9 for additional information related to the investment in Tecton.

Strategic Supplier Agreement with Nutrativa LLC

The Company is party to a strategic supplier agreement dated August 2, 2018, as amended, with Nutrativa LLC (Nutrativa). As part of the strategic supplier agreement, the Company serves as Nutrativa's contract manufacturer for Nutrativa's Effusio product. The Company also provides support services including customer service, order processing, warehousing and fulfillment, safety and surveillance, production planning, finance, legal and regulatory, human resources, and marketing. All manufacturing and development of Nutrativa products currently reside within the Company's facilities located in Summerville, South Carolina. Paul Jacobson, the Company's Chief Executive Officer, is the Chief Executive Officer of Nutrativa. As of December 31, 2021, the Company had recorded a related party receivable with Nutrativa of approximately $364 thousand. During the year ended December 31, 2021, the Company recognized revenue related to the supply agreement of $125 thousand. On February 28, 2022, the Company completed the purchase of all the outstanding membership interest of Nutrativa. See Note 4 for additional information related to the acquisition of Nutrativa.

Investment in Oova, Inc.

The Company maintains an investment in Oova, Inc. (Oova). As of December 31, 2022 and 2021, the Company had a related party receivable with Oova of approximately $5 thousand and $2 thousand, respectively. During the years ended December 31, 2022 and December 31, 2021, the Company recognized $57 thousand and $28 thousand, respectively, of revenue related to the contractual fulfillment services. See Note 9 for additional information related to the investment in Oova.

License and Purchase Agreement with ThorneVet Companion Animal Products, LLC

On October 1, 2010, the Company entered into a memorandum of understanding (MOU) with the Veterinary Institute of Integrative Medicine (VIIM). Pursuant to the MOU, the Company is obligated to repay VIIM the amount of $2.98 million for previous royalties earned by VIIM on sales of Thorne veterinary products (the Royalties). The amount of $2.98 million is due to be paid to VIIM in the form of monthly 3.0% royalty payments on gross sales of Thorne products to veterinarians.

On December 2, 2019, (the Effective Date) the Company entered into a License and Purchase agreement, together with a Distributor Agreement and a Commission Agreement (altogether, the License and Purchase Agreement) with ThorneVet Companion Animal Health Products, LLC, of which Kim Pearson, General Counsel, is the Chief Executive Officer and sole owner. Pursuant to the License and Purchase Agreement, the Company granted ThorneVet a license for certain formulations and trademarks (the IP) to continue manufacturing, marketing, and distributing the Company's veterinarian product line, which consists of fifteen (15) nutritional supplements for companion animals offered by the Company as of the Effective Date, as well as any other nutritional supplements for companion animals that utilize, in whole or in part, the licensed nutritional product formulations (altogether, the Licensed Assets). The License and Purchase Agreement is for a term of five years, expiring in December 2024, with an option to renew the License and Purchase Agreement for an additional five-year period. Further, the License and Purchase Agreement provides ThorneVet the exclusive right of first negotiation to purchase the IP for the Licensed Assets after the three years ended December 2022 at a purchase price then agreed to, provided, however, that VIIM releases the Company from all remaining financial liability for the Royalties.

As consideration for the license and right to purchase the Licensed Assets, ThorneVet assumed the liability to continue making the monthly 3.0% royalty payments to VIIM, although the Company continues to remain liable to VIIM for the remaining balance of the Royalties due, plus an additional $160 thousand of unpaid royalties, if ThorneVet were to fail to perform their obligations under the MOU. In consideration for the license granted, ThorneVet will pay to the Company a monthly royalty fee of 5.0% of net sales of the Licensed Assets sold by or on behalf of ThorneVet. As further consideration, ThorneVet will pay to the Company a commission of 20% of the net sales of the Licensed Assets to retail accounts introduced by the Company that are not established as of the Effective Date. Pursuant to the License and Purchase Agreement, ThorneVet may purchase finished goods inventory labeled as Animal Health Products (Purchased Products) as of the Effective Date for a purchase price of the fully allocated cost of such Purchased Products plus 5.0% margin.

As of the years ended December 31, 2022 and 2021, the remaining obligation due to VIIM by ThorneVet was $2.26 million and $2.29 million, respectively. During the years ended December 31, 2022 and 2021, the Company recognized $32.1 thousand and $25.3 thousand of other income for royalties and commissions earned on net sales of Licensed Assets generated by ThorneVet. During the years ended December 31, 2022 and 2021, the Company recognized $134.1 thousand and $127.8 thousand, respectively, of net sales of Purchased Products purchased by ThorneVet for resale to end customers. As of December 31, 2022 and December 31, 2021, there was $29.7 thousand and $29.1 thousand, respectively, outstanding to the Company from ThorneVet pertaining to sales of Purchased Products.

Other Related Party Transactions

As of December 31, 2022, and December 31, 2021, the Company had a related party payable of $0 and $43 thousand, respectively, to Chief Executive Officer, Paul Jacobson.

4. Mergers and Acquisitions

Onegevity Health, LLC Merger

On January 6, 2021, the Company announced a merger with Onegevity, a health intelligence company.

As of December 31, 2020 the Company’s ownership in Onegevity was approximately 50%. Since Onegevity’s inception in 2018, the Company determined that it has been the primary beneficiary of Onegevity and has accordingly consolidated the assets and liabilities of Onegevity in accordance with ASC 810, *Consolidations*.

To effect the merger, the Company issued 6,179,270 shares of Class B common stock, 472,590 which were subject to time-based restrictions, to the minority shareholders of Onegevity, plus an additional 1,959,335 stock options with various strike prices to key managers of Onegevity who had stock options in Onegevity in a tax-free exchange. No cash was involved in the transaction. The shares of Class B common stock did not have voting rights among other restrictions.

As part of the merger, the legal entity Onegevity Health, LLC was dissolved; its wholly-owned subsidiary, Health Elements, LLC, became a wholly-owned subsidiary of the Company.

The merger did not lead to a change in control and therefore the transaction was recorded in the equity section of the Company’s balance sheet.

Drawbridge Health, Inc. Merger

On April 26, 2021, the Company entered into a merger agreement (the Merger Agreement) with Drawbridge Health, Inc. (Drawbridge), to acquire the majority of the outstanding shares of Drawbridge, a healthcare technology company (the Drawbridge Transaction). Prior to the merger, the Company owned approximately 11.2% of the outstanding shares of Drawbridge and accounted for its investment in Drawbridge as an equity-method investment, because the Company determined it had significant influence over Drawbridge. The Company's net equity investment was approximately $3.2 million as of March 31, 2021. Under the Merger Agreement, the Company increased its ownership of Drawbridge by 76.3 percentage points to a total ownership of 87.5%. The Merger Agreement calls for the payment of approximately $1.4 million in cash and the assumption of certain liabilities of Drawbridge.

The Drawbridge Transaction was accounted for as an asset acquisition because the Company concluded the assets acquired and liabilities assumed did not constitute a business under ASC 805, Business Combinations (ASC 805). The Company performed a reassessment of Drawbridge as a variable interest entity under ASC 810 and concluded Drawbridge to be a variable interest entity as of the date of the transaction. Furthermore, the Company determined it was the primary beneficiary of Drawbridge as of the transaction date. Accordingly, the Drawbridge Transaction was accounted for as an asset acquisition under ASC 810, rather than under ASC 805. Under ASC 810, the Company is required to recognize a gain (loss) on the acquisition, equal to the sum of the consideration paid, the carrying value of the existing equity-method investment, and the fair value of the resulting non-controlling interest less the fair value of the net assets acquired. The Company concluded the carrying value of the Company's existing Drawbridge investment of approximately $3.2 million was impaired in the second quarter of 2021 prior to the transaction and recorded a loss from equity interest in unconsolidated affiliates of approximately $3.0 million within the consolidated statements of operations for the year ended December 31, 2021. Additionally, a loss on the Drawbridge Transaction of approximately $0.2 million was recorded during the year ended December 31, 2021 within other (income) expense in the consolidated statements of operations. The net tangible and intangible assets acquired, and liabilities assumed, in connection with the Drawbridge Transaction were recorded based on their fair values as of the acquisition date and the value associated with in-process research and development was expensed because it was determined to have no alternative future use. The in-process research and development costs of approximately $1.6 million are recorded as an operating expense on the consolidated statement of operations. Subsequent to the acquisition, the operations of Drawbridge were fully consolidated in the Company's consolidated financial statements, and a non-controlling interest of approximately $0.2 million was recorded for the 12.5% equity interest held by other investors.

The assets and liabilities acquired based on their fair value were as follows:

Cash	$	11,823
Accounts receivable		8,686
Prepaid expenses and other current assets		711,389
Inventories		10,051
Property and equipment		914,716
Operating lease right-of-use asset		410,732
Intangible asset consisting of in process research and development		1,563,015
Other assets		22,782
Accounts payable		(701,242)
Other accrued expenses		(864,483)
Current portion of operating lease obligations		(263,509)
Long term operating lease, net of current portion		(147,223)
Net assets acquired	$	1,676,737
Less: non-controlling interest		(209,592)
Net assets acquired by Thorne HealthTech, Inc.	$	1,467,145

Nutrativa LLC Acquisition

On February 28, 2022, the Company completed the purchase of all the outstanding membership interests of Nutrativa (the Nutrativa Acquisition). Nutrativa leverages proprietary two-dimensional high-speed printing technology to develop and manufacture dissolvable supplement discs. Paul Jacobson, the co-founder, CEO and director for the Company, is also the CEO of Nutrativa. A special committee of independent directors (the "Special Committee") of the Company's Board of Directors negotiated and approved the Nutrativa Acquisition in consultation with an independent advisory firm.

The consideration provided to the unit-holders was $15.4 million, comprised of $14.9 million in cash and the forgiveness of $0.5 million of amounts due to the Company at the time of the transaction (net of $18 thousand cash acquired). The Company funded the purchase with available cash on hand. The Nutrativa Acquisition will allow the Company to utilize innovative printing technology to help address consumer needs in a green, sustainable fashion, while at the same time enabling the Company to expand its portfolio of products and services into new target markets. The operations of Nutrativa have been consolidated with those of the Company beginning February 28, 2022.

We have accounted for the acquisition of Nutrativa under the acquisition method of accounting in accordance with ASC 805, Business Combinations. The acquisition price has been allocated among assets acquired and liabilities assumed at fair value based on information currently available, with the excess recorded as goodwill (non-deductible for tax purposes). The goodwill recognized is attributable primarily to expected synergies to be realized by Nutrativa in leveraging the Company's existing manufacturing, distribution, research and development and marketing capabilities to efficiently scale the Nutrativa products and business. Estimates of fair value included in the consolidated financial statements represent management's best estimates and valuations. During the measurement period in 2022, the Company updated certain fair value measurement assumptions related to the acquired developed technology intangible asset which resulted in the reclassification of $3.5 million from intangible assets, net to goodwill.

Total transaction costs incurred by the Company during the year ended December 31, 2022 were $0.5 million. These transaction costs were expensed as incurred and are included as a component of selling, general and administrative expense within the consolidated statements of operations.

The following table sets forth the final allocation of the purchase price to Nutrativa's identifiable tangible and intangible assets acquired and liabilities assumed, including measurement period adjustments:

Cash	$	17,713
Accounts receivable		14,470
Inventories		274
Property and equipment		3,256,996
Intangible asset		6,700,000
Goodwill		5,600,357
Accounts payable		(181,913)
Other accrued expenses		(202)
Net assets acquired	$	15,407,695

5. Consolidated Variable Interest Entities

The Company consolidates variable interest entities where the Company is determined to be the primary beneficiary, under ASC 810. The Company consolidates into its consolidated financial statements two legal entities (Health Elements, LLC and Onegevity Health, LLC) in which it holds a controlling interest. The Company presents non-controlling interest as a component of stockholders' equity on its consolidated balance sheet and reports net loss-non-controlling interest in the consolidated statements of operations. The Company's acquisition or disposal of ownership interests in the variable interest entities is a reconsideration event that requires a reassessment of whether the entity continues to be a variable interest entity and whether the primary beneficiary has changed. If after making these reassessments, the primary beneficiary remains the same (i.e., a controlling financial interest is maintained), and the transaction is in the scope of ASC 810, the Company accounts for the acquisition or disposal of a non-controlling interest as an equity transaction, consistent with the principles of ASC 810-10. Any difference between the price paid and the carrying amount of the non-controlling interest is not reflected in net income, but instead reflected directly in equity.

Onegevity Health, LLC. As of January 1, 2021, the Company owned 58,252 shares of Onegevity Health, LLC (Onegevity) capital stock, which equated to approximately a 50% ownership interest. After evaluating relevant factors, the Company determined that it is the primary beneficiary of Onegevity and accordingly consolidated the assets and liabilities of Onegevity in accordance with ASC 810.

During the first quarter of 2021, the Company merged with Onegevity. As part of the merger, the legal entity Onegevity Health, LLC was dissolved; its wholly-owned subsidiary, Health Elements, LLC, became a wholly-owned subsidiary of the Company. The merger did not lead to a change in control, and therefore the transaction was recorded in the equity section of the Company's consolidated balance sheets. See Note 4 for additional information related to the Onegevity merger.

Thorne HealthTech Asia PTE, Ltd. On January 10, 2022, the Company entered into an agreement with Mitsui and TM HealthTech Pte. Ltd., a wholly-owned subsidiary of Mitsui, to form a joint venture entity, Thorne HealthTech Asia PTE, Ltd. (Thorne Asia JV), to exclusively market, distribute and sell Thorne's products across Singapore, Hong Kong, Taiwan, Thailand, Indonesia, Malaysia, Australia, the Philippines, Vietnam, India and New Zealand. On January 20, 2022, Thorne and Mitsui contributed $2.7 million and $2.6 million, respectively, in cash and hold 51% and 49%, respectively, of the total issued share capital of Thorne Asia JV. After evaluating relevant factors, the Company determined that it is the primary beneficiary of Thorne Asia JV, as substantially all of the activities either involve, or are conducted on behalf of, the Company. Under ASC 810, the Company has consolidated Thorne HealthTech Asia PTE, Ltd. in its consolidated financial statements as of and for the year ended December 31, 2022.

The board of directors of Thorne Asia JV is composed of five directors, of which three were nominated by Thorne and two by Mitsui. Each director is appointed for a term of office of one year and will be eligible for re-election. Summary information for Thorne Asia JV, excluding intercompany activity with the Company, is included in the December 31, 2022 consolidated balance sheet as presented below:

	December 31, 2022
Cash and cash equivalents	$ 4,484,326
Other assets	141,712
Total assets	4,626,038
Less: Total liabilities	89,779
Net assets (liabilities)	$ 4,536,259

The results of operations for Thorne Asia JV, excluding intercompany activity with the Company, included in the year ended December 31, 2022 consolidated statements of operations is as follows:

	Year ended December 31, 2022
Net sales	$ 32,079
Net loss	(772,520)
Net loss - non-controlling interests	(378,535)
Net loss attributable to Thorne HealthTech, Inc.	$ (393,985)

6. Inventories, net

Inventories are as follows:

	December 31,	
	2022	2021
Raw materials	$ 35,305,418	$ 22,620,773
Work in process	292,212	422,196
Finished goods	23,491,961	18,413,853
Reserve for slow moving and obsolete inventory	(445,663)	(444,698)
Inventories, net	$ 58,643,928	$ 41,012,124

7. Property and Equipment, net

Property and equipment are as follows:

	December 31,	
	2022	2021
Machinery and equipment	$ 13,774,090	$ 9,937,510
Furniture and fixtures	521,032	491,173
Office equipment	848,714	1,111,141
Leasehold improvements	19,703,960	19,431,916
Vehicles	114,454	98,282
Lab equipment	2,784,563	2,930,059
Software	2,934,239	2,107,327
Total property and equipment	40,681,052	36,107,408
Less accumulated depreciation and amortization	(13,385,482)	(11,262,651)
In-process assets including deposits on new equipment	21,881,274	2,185,643
Property and equipment, net	$ 49,176,844	$ 27,030,400

In-process assets are stated at cost, which includes the cost of construction and other directly attributable costs. No provision for depreciation is made on in-process assets until the relevant assets are completed and available for intended use.

Depreciation expense of property and equipment was approximately $3.6 million for the year ended December 31, 2022, of which $2.8 million, $0.5 million, and $0.3 million were recorded within cost of sales, selling, general and administrative expenses, and research and development expenses, respectively, within the consolidated statements of operations. Depreciation expense of property and equipment was approximately $2.7 million for the year ended December 31, 2021, of which $2.0 million, $0.5 million, and $0.2 million were recorded within cost of sales, selling, general and administrative expenses, and research and development expenses, respectively, within the consolidated statements of operations.

8. Goodwill and Intangible Assets

Goodwill

The following table sets forth the change in the carrying amount of goodwill during the year ended December 31, 2022:

Balance as of December 31, 2021	$ 14,440,683
Acquisitions	5,600,357
Balance as of December 31, 2022	$ 20,041,040

In June 2010, the Company acquired all the outstanding shares of capital stock of Thorne Research, which is now a wholly owned subsidiary of the Company. The Company accounted for the transaction as a business combination in accordance with ASC 805, Business Combinations, and recorded the consideration transferred and assets acquired, and liabilities assumed at their fair values, resulting in the recording of goodwill of approximately $14.4 million.

In February 2022, the Company acquired all of the outstanding ownership interests of Nutrativa, which is now a wholly-owned subsidiary of the Company. The Company accounted for the transaction as a business combination in accordance with ASC 805, Business Combinations, and recorded the consideration transferred, assets acquired and liabilities assumed at their fair values, resulting in the recording of goodwill of $5.6 million. See Note 4 for additional information related to the acquisition of Nutrativa.

Finite-lived Intangible Assets

Finite-lived intangible assets are as follows:

	December 31, 2022		
	Gross Carrying Value	Accumulated Amortization	Net Carrying Value
Customer relationships	$ 6,500,000	$ (4,062,500)	$ 2,437,500
Trade names	7,600,000	(6,333,333)	1,266,667
Existing technology/reformulations	8,900,000	(2,252,084)	6,647,916
License agreements	3,129,002	(1,650,836)	1,478,166
	$ 26,129,002	$ (14,298,753)	$ 11,830,249

	December 31, 2021		
	Gross Carrying Value	Accumulated Amortization	Net Carrying Value
Customer relationships	$ 6,500,000	$ (3,737,500)	$ 2,762,500
Trade names	8,640,000	(6,866,667)	1,773,333
Existing technology/reformulations	3,207,923	(2,694,590)	513,333
Research and development formulas	800,000	(800,000)	—
License agreements	8,591,822	(7,048,672)	1,543,150
	$ 27,739,745	$ (21,147,429)	$ 6,592,316

The Company’s intangible assets include intangible assets acquired through the Thorne Research acquisition in 2010 and Nutrativa in 2022. See Note 4 for additional information related to the acquisition of Nutrativa. As of December 31, 2022 and December 31, 2021, the net carrying value of acquired intangible assets was $10.4 million and $5.0 million, respectively. Intangible assets also include payments under license agreements related to trademarks and content. As of December 31, 2022 and December 31, 2021, these had a net carrying value of $1.5 million.

When applicable, the balances as of December 31, 2022 have been reduced to reflect the impact of intangible assets when the gross carrying value has become fully amortized during the year ended December 31, 2022. The impact of this resulted in a reduction to carrying value and accumulated amortization of $1.0 million to trade names, $1.0 million to existing technology/reformations, $0.8 million to research and development formulas and $6.2 million to license agreements.

Amortization expense totaled $2.2 million and $1.8 million for the years ended December 31, 2022 and 2021, respectively.

Future estimated amortization expense of the Company's intangible assets as of December 31, 2022 is as follows:

Year ended December 31,	Amount
2023	$ 2,224,567
2024	1,914,151
2025	1,337,484
2026	917,067
2027	917,067
Thereafter	4,519,913
	$ 11,830,249

9. Investments

Heart-Tech Health, Inc. On January 7, 2022, the Company entered into a Strategic Partnership Agreement with Heart-Tech Health, Inc. (Heart-Tech). Heart-Tech was formed by Dr. Suzanne Steinbaum, a leading holistic cardiologist, and has developed a program for women's holistic health prevention. Together, the Company and Heart-Tech plans to open and operate a Thorne Lab location in New York, New York. Simultaneous to executing the Strategic Partnership Agreement with Heart-Tech, the Company made a $1.0 million investment in Heart-Tech through a simple agreement for future equity, or SAFE. During the year ended December 31, 2022, there was no reportable activity between the Company and Heart-Tech.

Oova. As of December 31, 2022 and 2021, the Company had an investment of $0.4 million in Oova, representing a 2.54% and 3.46% equity interest, respectively. As management has determined it does not have the ability to exercise significant influence over the operating and financial activities of the investee, and the fair value of the investment is not readily determinable, the Company's investment in Oova is accounted for at cost minus impairment, in accordance with ASC 321, Equity Securities. As there were not any observable price changes in identical or similar securities to Oova, the Company has not adjusted the value of this investment upward or downward, either on a cumulative basis or in either of the years ended December 31, 2022 or 2021. Since the Company invested in Oova, the investee has successfully brought its product to market. Although there are no restrictions on the Company's ability to sell this investment, the timing of when or if the Company would sell this asset is unknown at this time. There are no unfunded commitments related to the Company's investment. Management concluded that no impairment was necessary for the years ended December 31, 2022 or 2021.

10. Equity-method Investments

Equity-method investments are as follows:

	December 31, 2022		December 31, 2021	
	Carrying Amount	Economic Interest	Carrying Amount	Economic Interest
Drawbridge Health, Inc. (1)	$ —	87.5%	$ —	87.5%
NR Therapeutics LLC	942,501	49.0%	963,685	49.0%
Tecton Group LLC	—	11.0%	—	30.0%
Total	$ 942,501		$ 963,685	

The following summarizes the (loss) income of equity-method investees:

	Years ended December 31,	
	2022	2021
Drawbridge Health, Inc. (2)	$ —	$ (3,173,106)
NR Therapeutics LLC	(173,976)	213,685
Tecton Group LLC	—	(704,637)
Total	$ (173,976)	$ (3,664,058)

(1) On April 26, 2021, the Company entered into a merger agreement with Drawbridge Health, Inc., to acquire the majority of the remaining outstanding shares. See Note 5 for additional information related to the Drawbridge merger transaction.

(2) Represents the Company's proportionate share of net loss for the period of January 1, 2021 through April 26, 2021 (the date of merger).

Drawbridge Health, Inc. (Drawbridge) is a privately held healthcare technology company that has developed a blood draw device that is regulated as a Class II medical device and received 510(k) clearance in 2019. The Company's Chief Executive Officer was a member of the board of directors for Drawbridge until 2020. Management has determined it had the ability to exercise significant influence over Drawbridge's operating and financial activities due to its equity ownership and board representation, which began in 2019. The investment, therefore, was accounted for using the equity method, and the Company's proportionate share of the net loss of the investee was reported under the line item captioned "loss from equity interest in unconsolidated affiliates" in the consolidated statements of operations.

Tecton Group LLC (Tecton) is a privately held company focused on the development of a revolutionary nutrition technology providing improved cognitive and physical performance in addition to fueling the brain to protect against concussion and secondary damage of traumatic brain injury. After evaluating the relevant factors, the Company determined that it has significant influence with respect to Tecton, and accounted for the investment using the equity method, with the investee's proportionate share of the net loss of the investee reported under the line item captioned "loss from equity interests in unconsolidated affiliates" in the consolidated statements of operations. As of December 31, 2022, the total suspended loss in the investee was approximately $0.5 million, for which the Company has no further obligation. As of December 31, 2021, the Company's ownership interest was 30%. During the year ended December 31, 2022, Tecton issued additional equity to investors, which the Company did not participate, reducing our ownership interest to 11% as of December 31, 2022.

The Company is also party to a letter agreement between us, Tecton, Kirin and Mitsui (Tecton Letter Agreement) providing us with, amongst other things, a right of first offer to commercialize any Tecton product or service. The Tecton Letter Agreement also provides Kirin and Mitsui, with a right of first negotiation for any commercialization of Tecton products or services in Japan.

NR Therapeutics LLC (NR) is a privately held company focused on the sale and distribution of nicotinamide riboside, a natural compound present in almost all living organisms. During the year ended December 31, 2021, the Company determined that it has significant influence with respect to NR, and began accounting for the investment using the equity method, with the investee's proportionate share of the net income of the investee reported under the line item captioned "loss from equity interests in unconsolidated affiliates" in the consolidated statements of operations. Management concluded that there was no impairment for the years ended December 31, 2022 and 2021.

11. Other Accrued Liabilities

Other accrued liabilities as of December 31, 2022 and 2021 were as follows:

	December 31,	
	2022	2021
Accrued expenses (1)	$ 1,434,420	$ 98,042
Income tax payable	317,610	363,552
Interest payable	23,626	1,504
Loyalty rewards payable	141,614	32,551
Sales/use tax payable	210,737	193,144
Deferred revenue	1,156,103	311,333
Gift card liability	133,770	65,287
Returns allowance liability	145,963	49,629
Other current liabilities	—	29,531
Total	$ 3,563,843	$ 1,144,573

(1) Accrued expenses for the year ended December 31, 2022, primarily consists of marketing and other selling, general and administrative costs incurred as of the year ended December 31, 2022, for which the Company has not yet been invoiced by the vendor as of the year ended December 31, 2022.

12. Notes Payable

The Company enters into various premium finance agreements with a credit finance institution to pay the premiums on insurance policies for its directors' and officers' liability, general liability, workers' compensation, umbrella, auto and pollution coverage needs. During the year ended December 31, 2022, the aggregate amount of the premiums financed was $1.2 million, payable in equal monthly installments at a weighted average interest rate of 4.5%. These premium finance agreements are due within one year and are recorded as notes payable under current liabilities in the consolidated balance sheets. At December 31, 2022, the Company had a remaining balance of $0.8 million related to notes payable. At December 31, 2021, the Company did not have any premium finance agreements for its directors' and officers' liability, general liability, workers' compensation, umbrella, auto coverage nor pollution coverage needs.

13. Long-term Debt

Long-term debt balances consist of the following:

	December 31,	
	2022	2021
2022 Term loan	$ 12,000,000	$ —
Other		
Notes payable - equipment financing	1,169,559	1,577,807
Total long-term debt	13,169,559	1,577,807
Less: current maturities	523,510	494,173
Total long-term debt, net of current portion	$ 12,646,049	$ 1,083,634

Credit Facility

On December 21, 2022, the Company, entered into a Credit Agreement (the “2022 Credit Agreement”) that provides for (1) a $45.0 million revolving credit promissory note (“Revolver”) with a maturity date of December 21, 2027 and (2) a $12.0 million term promissory note (“2022 Term Loan”) with a maturity date of December 21, 2027. The Company refers to the Revolver and 2022 Term Loan collectively as the “Credit Facility.”

On December 21, 2022, the Company entered into a $45.0 million Revolver. The Revolver contains an option allowing the Company to increase the size of its Revolver by up to an additional $15.0 million subject to agreement by the lender. The Company may repay principal amounts on borrowings under the Revolver and reborrow them any time without penalty or premium until the maturity date of December 21, 2027. The Revolver is available for issuance of letters of credit to a specified limit of $5.0 million. Any outstanding and undrawn letters of credit shall be reserved under the Revolver and such amount shall not be available for borrowings. The letter of credit previously issued by SMBC on October 29, 2021, in the amount of $4.9 million and secured by a cash deposit of $4.9 million, will be returned to the Company in exchange for $4.9 million of the letters of credit issued under the Revolver. As of December 31, 2022, additional borrowing of $40.1 million was available under the Revolver. The Company incurred $0.2 million of debt issuance costs, which will be amortized as additional interest expense over the life of the Revolver.

Under the Revolver, the Company can elect the tranche rate (greater of 0.5% or the Secured Overnight Financing Rate (“SOFR”) plus 1.4%) or the base rate (Prime plus 1.0%). The Company also pays a commitment fee equal to 0.2% of the average commitment not utilized. Interest payments are due monthly. As of December 31, 2022, there were no borrowings under the Revolver.

On December 21, 2022, the Company entered into a $12.0 million 2022 Term Loan. The 2022 Term Loan is payable in equal monthly installments, with the remaining balance payable at the maturity date of December 21, 2027. The Company may prepay the loan at any time with no penalty. As of December 31, 2022, the Company had no available borrowing capacity on the 2022 Term Loan.

Under the 2022 Term Loan, the Company elected the Secured Overnight Financing Rate ("SOFR") plus 1.4%. Interest payments are due monthly. As of December 31, 2022, the interest rate on the 2022 Term Loan was 5.7%.

The Company is subject to a number of restrictive covenants under the Credit Facility that, among other things, impose operating and financial restrictions on the Company.

Financial covenants include the following:

i. Senior Net Leverage Ratio, as defined, not to exceed: (a) 3.0:1.0 as of the end of the Fiscal Quarters ending March 31, 2023; June 30, 2023; and September 30, 2023; (b) 2.75:1.0 as of the end of the Fiscal Quarters ending December 31, 2023; March 31, 2024; June 30, 2024; and September 30, 2024; (c) 2.50:1.0 as of the end of the Fiscal Quarters ending December 31, 2024; March 31, 2025; June 30, 2025; and September 30, 2025; (d) 2.25:1.0 as of the end of the Fiscal Quarters ending December 31, 2025; March 31, 2026; June 30, 2026; and September 30, 2026; and (e) 2.0:1.0 as of the end of the Fiscal Quarters ending December 31, 2026; March 31, 2027; June 30, 2027; and September 30, 2027.

ii. Fixed Charge Coverage Ratio, as defined, of at least 1.20:1.0, as of the end of any Fiscal Quarter, commencing with the Fiscal Quarter ending March 31, 2023.

For the year ended December 31, 2022, the Company was in compliance will all non-financial and financial covenants. Starting on March 31, 2023, the Company will have financial covenants disclosed above that they will be required to comply with under the 2022 Credit Agreement.

Operating covenants include restrictions on indebtedness, liens, mergers, consolidations, investments, acquisitions, disposition of assets, and transactions with affiliates. Dividends, redemptions and other payments on equity (restricted payments) are generally limited. Customary events of default (with customary grace periods, notice and cure periods and thresholds) include payment default, breach of representation in any material respect, breach of certain covenants, default to material indebtedness, bankruptcy, ERISA violations, material judgments, change in control and termination or invalidity of guaranty or security documents.

The Credit Facility is secured by a security interest in substantially all of the Company's assets.

Notes Payable - Equipment Financing

The Company has multiple equipment financing notes. As of December 31, 2022, and 2021, the Company had equipment financing notes totaling $1.2 million and $1.6 million, respectively, which are collateralized by the associated equipment. The stated fixed rate of the equipment financing notes range from 4.89% to 6.94% and have a maturity date ranging from July 2023 to September 2026. The notes are collateralized by the original purchased equipment which have an aggregate net book value of $1.6 million as of December 31, 2022.

2022 Loan Agreement

On April 8, 2022, the Company entered into a loan agreement (the "Loan Agreement"), with an effective date of March 31, 2022. Under the terms of the Loan Agreement, the lender provided a revolving line of credit (the "Line of Credit') to the Company in the amount of $15.0 million. Under the Loan Agreement, the Company may repay principal amounts and reborrow them as necessary until the maturity date of March 31, 2027. Outstanding borrowings under the Loan Agreement will be subject to interest at a rate equal to the Bloomberg Short-Term Bank Yield Index rate (BSBY), plus 1.5%, adjusted on the first day of each month (the Adjustment Date). Interest is calculated on the basis of a 360-day year and the actual number of days elapsed. The Company agreed to pay interest on any outstanding borrowings monthly beginning April 30, 2022. The Line of Credit is subject to an Unused Commitment Fee equal to 0.2% per year and is payable monthly starting on May 1, 2022.

The Line of Credit is available for issuance of letters of credit to a specified limit of $6.0 million. Any outstanding and undrawn letters of credit shall be reserved under the Line of Credit and such amount shall not be available for borrowings. On December 21, 2022, the Loan Agreement was closed.

On October 29, 2021, the Company deposited $4.9 million into a restricted interest-bearing account with SMBC to fund the standby letter of credit and release the guarantees provided by Kirin and Mitsui. For the year ended December 31, 2021, the Company incurred total guarantee fee expense for the standby letter of credit of $0.1 million which was included in guarantee fees in the consolidated statements of operations. The $4.9 million letter of credit will be returned to the Company in exchange for $4.9 million of the Letters of Credit issued under the 2022 Credit Agreement. As of December 31, 2022, the standby letter of credit had not been returned, and the restriction on the deposit of $4.9 million into a restricted interest-bearing account with SMBC to fund the standby letter of credit had not been released. The $4.9 million deposit, which is associated with the Line of Credit, is expected to be released from restriction and returned to the Company in the first quarter of 2023. The amount is therefore recorded as restricted cash and classified within current assets as of December 31, 2022.

2021 Credit Agreement

On February 12, 2021, the Company entered into a new Uncommitted and Revolving Credit Line Agreement (2021 Credit Agreement) with SMBC to refinance and replace the 2020 Credit Agreement. The terms of the 2021 Credit Agreement are substantially similar to the terms of the 2020 Credit Agreement. Under the 2021 Credit Agreement, SMBC may in its sole discretion elect to make unsecured loans to the Company until February 11, 2022, in an aggregate principal amount up to, but not exceeding, $20.0 million at any time. Each loan made under the 2021 Credit Agreement may have a maturity date that is not less than one day and not more than twelve months after the date that such loan is disbursed, as the Company and SMBC mutually agree. SMBC may, in its sole discretion at any time, terminate in whole or partially reduce the unused portion of the credit line under the 2021 Credit Agreement. SMBC is not obligated to make any loan under the 2021 Credit Agreement.

Any loans under the 2021 Credit Agreement bears interest at a per annum rate quoted by SMBC and agreed to by the Company when such loan is made. Interest on a loan is payable in arrears on the maturity date of such loan. The interest accrued on a loan and paid to the bank is a variable interest rate, based on rates quoted by the bank. The Company can choose an interest rate, based on current market rates and on the number of days it chooses to lock in the interest rate. The number of days range from 30 days to 365 days.

Both the 2020 Credit Agreement and 2021 Credit Agreement were guaranteed by two significant Company stockholders, Kirin and Mitsui. Each stockholder guaranteed 50% of the total amount of the loan, or $10.0 million. On October 4, 2021, the Company repaid the $20.0 million of outstanding borrowings under the 2021 Credit Agreement, plus interest accrued and unpaid on the loan through the date of repayment. Upon repayment, the 2021 Credit Agreement was terminated. The Company incurred incremental fees related to the payoff totaling $7 thousand. Upon repayment of the outstanding borrowings under the 2021 Credit Agreement, the related Kirin and Mitsui guarantees were released and terminated.

Standby Letter of Credit

In 2018, an irrevocable standby letter of credit was issued by a bank on the Company’s behalf as required by the landlord of the South Carolina production facility, and guarantees were issued by related parties (see Note 9). The standby letter of credit is for $4.9 million and had an original expiration date of December 3, 2019, with automatic renewals until October 31, 2037. The guarantee fee is based on the 12-month USD LIBOR rate, plus 3% on the amount of the guarantee. The letter of credit has an annual fee of $20 thousand.

Debt Maturities

The contractual maturities of the Company's long-term debt as of December 31, 2022 are as follows:

Year Ending December 31,	Amount
2023	$ 523,510
2024	2,139,572
2025	1,862,456
2026	1,786,878
2027	6,857,143
Thereafter	—
	$ 13,169,559

14. Leases

The Company leases real estate, vehicle, and equipment for use in its operations. The Company's leases generally have lease terms of 1 to 30 years, some of which include options to terminate, or to extend leases. The Company includes options that are reasonably certain to be exercised as part of the determination of lease terms. The Company may negotiate termination clauses in anticipation of any changes in market conditions, but generally these termination options are not exercised. Residual value guarantees are generally not included within operating leases. In addition to base rent payments, the leases may require the Company to pay directly for taxes and other non-lease components, such as insurance, maintenance and other operating expenses, which may be dependent on usage or vary month-to-month.

The Company currently leases and operates three industrial facilities in Summerville, South Carolina and a fourth industrial facility located in Benicia, California.

The Company's primary manufacturing and administrative facility is located in Summerville, South Carolina. The 272,000 square-foot facility is located on 25.8 acres and houses manufacturing and production, research and development, medical affairs, engineering, quality management, laboratory testing, brand marketing, inside sales, customer service, finance, legal, human resources, warehousing and materials management, procurement and safety functions. The lease expires in October 2037. The Company has the right to renew for two additional terms of five years each.

On January 26, 2021, the Company entered into a five-year lease agreement for 115,500 square feet within a 136,500 square foot building for the Company's fulfillment and distribution operations, located in Summerville, South Carolina. Rent was abated for the first three months while the Company installed racking, packing stations and other required equipment, prior to the Company's shipping operations to this facility. This lease terminates in July 2026. The lease has two renewal options for three years each. The Company has funded a customary security deposit of $0.1 million upon execution of the lease, which has been recorded within other assets on the consolidated balance sheets as of December 31, 2022 and December 31, 2021.

On July 28, 2021, the Company entered into a lease agreement for a 360,320 square foot industrial building for the Company's finished goods warehousing and shipping operations, located in Summerville, South Carolina. The building is currently under construction and the lease will commence on the date of which the landlord completes construction of the facility and required tenant improvements, currently estimated to be during the second quarter of 2023 and will terminate upon the thirteenth anniversary of the commencement date. The lease has one renewal option for a five-year term. The lease provides for an allowance for tenant improvements of up to $1.3 million. The annual base rent for the first year will be $2.0 million and is subject to an annual escalation of 2.0% on each anniversary. The Company has funded a customary security deposit of $0.3 million upon execution of the lease which has been recorded within other assets on the consolidated balance sheets as of December 31, 2022 and December 31, 2021.

The Company maintains a 16,896 square-foot warehouse in Benicia, California for distribution and fulfillment operations. This lease terminates in January 2025. The Company has the right to renew for one additional term of five years.

On March 10, 2022, the Company amended the lease agreement for its headquarters in New York, New York. The amended agreement granted an additional right-of-use ("second substitute premises") to the Company in the future following the expiration of its current lease. The second substitute premises were substantially completed on October 3, 2022. The amendment commenced on October 3, 2022 and will terminate on the five year anniversary of the rent commencement date. The Company has funded a customary security deposit of $0.2 million for its headquarters, which has been recorded within other assets on the consolidated balance sheets as of December 31, 2022.

During the third quarter of 2022, the Company entered into a two-year lease for the purchase of equipment to be located within the Company's primary manufacturing and administrative facility in Summerville, South Carolina. The lease provides the Company with an option to purchase the equipment from the lessor at the expiration of the lease term in exchange for transfer of title to the $195 thousand security deposit funded by the Company to the lessor upon commencement of the lease. The Company initially classified the lease as an operating lease and recorded an operating lease right-of-use asset and operating lease liability of approximately $2.3 million in the consolidated balance sheets as of September 30, 2022. As of December 31, 2022, the amounts have been reclassified to properly present the lease as a financing lease for the purchase of equipment.

The Company also leases a 2,500 square-foot administrative and support facility in Madison, Wisconsin. The lease for this office expires in October 2024.

The balances for the operating and finance leases where the Company is the lessee are presented as follows within the consolidated balance sheets:

	December 31, 2022	December 31, 2021
Operating lease:		
Operating lease right-of-use assets, net	$ 17,546,240	$ 17,836,756
Current portion of operating lease obligations	1,504,433	2,633,236
Operating lease obligations, net of current portion	28,430,474	27,605,739
Total operating lease liabilities	$ 29,934,907	$ 30,238,975
Finance lease:		
Finance right-of-use assets	$ 3,143,592	$ 883,076
Current portion of finance lease obligations	1,660,404	413,487
Finance lease obligation, net of current portion	1,455,011	482,544
Total finance lease liabilities	$ 3,115,415	$ 896,031

The components of lease expense are as follows within our consolidated statements of operations:

	Years ended December 31,	
	2022	2021
Operating lease expense:		
Operating lease cost[(1)]	$ 4,923,387	$ 5,692,735
Finance lease expense:		
Amortization of leased assets	1,098,349	424,961
Interest on lease liabilities	109,439	52,511
Total lease expense	$ 6,131,175	$ 6,170,207

(1) Includes short-term leases and variable lease costs, which are immaterial.

The weighted average remaining lease term and weighted average discount rate at December 31, 2022 and December 31, 2021, were as follows:

	December 31, 2022	December 31, 2021
Weighted average remaining lease term (years)		
Operating leases	13.04 years	13.73 years
Finance leases	1.63 years	2.33 years
Weighted average discount rate applied		
Operating leases	8.6%	9.2%
Finance leases	6.2%	6.1%

Supplemental cash flow information related to leases where the Company is the lessee is as follows:

	Years ended December 31,	
	2022	2021
Operating cash outflows from operating leases	$ 5,132,133	$ 4,794,134
Operating cash outflows from finance leases (interest payments)	109,439	52,511
Financing cash outflows from finance leases	934,975	1,242,948
Leased assets obtained in exchange for finance lease liabilities	3,352,693	540,433
Leased assets obtained in exchange for operating lease liabilities	2,307,468	2,913,002

As of December 31, 2022, the maturities of the operating and finance lease liabilities are as follows:

Period	Operating leases	Finance leases
2023	$ 3,899,432	$ 1,818,062
2024	4,103,534	1,219,769
2025	4,069,997	47,063
2026	3,836,053	38,940
2027	3,421,442	—
Thereafter	32,964,888	—
Total minimum lease payments	$ 52,295,345	$ 3,123,835
Less: imputed interest	22,360,438	8,420
Total present value of lease liabilities	$ 29,934,907	$ 3,115,415
Less: current portion	1,504,433	1,660,404
Long-term portion of lease liabilities	$ 28,430,474	$ 1,455,011

In 2016, the Company entered into a new lease agreement for office, warehouse and production space in Summerville, South Carolina. The Company was required to provide the landlord with a $4.9 million irrevocable letter of credit as a security deposit (see Note 13). The required security deposit may be reduced upon the attainment of certain EBITDA levels.

15. Convertible Preferred Stock and Stockholders' Equity

On July 5, 2018, the Company issued 27,011,500 Series E convertible preferred stock to Kirin and Mitsui for $138.4 million.

A summary of the significant rights and privileges of the Series E convertible preferred stock is as follows:

Conversion - Each share of Series E preferred stock is convertible at the option of the holder into common stock on a one-for-one basis. Each share of Series E preferred stock shall automatically be converted into shares of common stock at the then effective conversion price immediately after the consummation of a qualified public offering. Additionally, each share of preferred stock is automatically converted immediately upon the conversion or vote to convert by the holders of a majority of the then outstanding preferred stock.

Liquidation - Upon any liquidation, dissolution, or winding-up of the business, the assets of the Company available for distribution to its stockholders shall be distributed first to the holders of shares of Series E convertible preferred stock up to their original issue prices.

Voting Rights - The holder of each share of preferred stock shall be entitled to vote on all matters and shall be entitled to that number of votes equal to the total number of shares of common stock into which the preferred stock are convertible.

Dividends - In the event the Board of Directors declares the payment of dividends, they shall be distributed first to the holders of shares of Series E convertible preferred stock up to their original issue prices. Thereafter, the amounts remaining shall be distributed pro rata based on the number of shares of common stock then held by each shareholder (assuming conversion of all outstanding shares of Series E convertible preferred stock into common stock).

The Company's Series E convertible preferred stock has been classified as temporary equity on the accompanying consolidated balance sheets in accordance with authoritative guidance for the classification and measurement of redeemable securities. Upon certain change in control events outside of the Company's control, including liquidation, sale, or transfer of control of the Company, holders of the Series E convertible preferred stock can cause its redemption. The Company has determined not to adjust the carrying values of the Series E convertible preferred stock to the liquidation preferences of such shares because the Series E convertible preferred stock is not currently redeemable and not probable of becoming redeemable due to the uncertainty of whether or when the contingent events would occur.

Immediately prior to the completion of the Company's IPO on September 22, 2021, all outstanding shares of the Series E convertible preferred stock automatically converted on a one-to-one basis into an aggregate of 27,011,500 shares of common stock. As of December 31, 2022 and December 31, 2021, there were no shares of Series E convertible preferred stock outstanding.

16. Warrants

On October 10, 2018, the Company issued to Kirin and Mitsui each 2,225,000 warrants, for a total of 4,450,000 warrants, to purchase the Company's common stock. The warrants have an exercise price of $5.12 and an expiration date of October 11, 2028. In July 2020, each shareholder exercised 2,168,485 warrants for a total of $22.2 million in gross proceeds. As of December 31, 2022, and 2021, 453,455, of the original 4,450,000 warrants, remain outstanding. These warrants are classified as equity within the consolidated balance sheets as of December 31, 2022, and 2021.

On June 23, 2010, the Company issued 2,532,000 warrants to a related-party stockholder, with a strike price of $6.74 and an original expiration date of June 23, 2020. In May 2019, the Board of Directors extended the term of the warrants for an additional 10 years to June 23, 2030. As of December 31, 2022, and 2021, none of the 2,532,000 warrants have been exercised and all common stock warrants remained outstanding. These warrants are classified as equity within the consolidated balance sheets at December 31, 2022, and 2021.

On May 10, 2011, the Company issued 453,455 warrants to purchase common stock to a related-party stockholder, with a strike price of $6.74 per warrant. In May 2019, the Board of Directors extended the term of the warrants for an additional 10 years to June 23, 2030. The extension was determined by management to be a modification of the warrant. Due to these warrants containing certain down-round protections, which are not associated with the underlying Company's equity that may trigger in the event of a modification of certain other outstanding warrant instruments, the Company has classified these warrants as liabilities within the consolidated balance sheets as of December 31, 2022 and 2021.

The warrant liability is remeasured at fair value at each reporting date and have a fair value of $1.1 million and $2.1 million as of December 31, 2022, and 2021, respectively.

To calculate the fair value of the warrants, certain assumptions were made, including the fair market value of the underlying common stock, risk-free interest rate, volatility, and remaining contractual life. Changes to the assumptions could cause significant adjustments to the valuation. Due to the fact that the Company had no publicly available stock price information prior to the IPO and limited publicly available stock price information subsequent to the IPO, the expected volatility assumption was determined by examining the historical volatilities of a group of industry peers whose share prices are publicly available. The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of the grant for treasury securities of similar maturity or expected term. The Company has not paid and does not anticipate paying cash dividends on its shares of common stock; therefore, the expected dividend yield is assumed to be zero.

The Black-Scholes model was used to value the liability-classified warrants. The following assumptions were used:

	December 31,	
	2022	2021
Fair market value	$ 2.34	$ 6.21
Exercise Price	$ 6.74	$ 6.74
Term	7.5	8.5
Volatility	75%	75%
Annual dividend	—	—
Risk-free interest rate	3.97%	1.48%

The fair value of financial instruments measured on a recurring basis is as follows:

	As of December 31, 2022			
Description	Total	Level 1	Level 2	Level 3
Liabilities:				
Warrant liability	$ 1,059,343	$ —	$ 1,059,343	$ —

	As of December 31, 2021			
Description	Total	Level 1	Level 2	Level 3
Liabilities:				
Warrant liability	$ 2,058,566	$ —	$ —	$ 2,058,566

Changes in the ability to observe valuation inputs may result in a reclassification of levels within the fair value hierarchy.

The following table summarizes the change in fair value, as determined by Level 3 inputs and transfers in or out of the Level 3 fair value hierarchy, for all assets and liabilities using unobservable Level 3 inputs:

	Warrant Liability
Balance at December 31, 2020	$ 3,930,930
Change in fair value for 2021	(1,872,364)
Balance at December 31, 2021	2,058,566
Change in fair value for 2022	(999,223)
Transfer to level two during the year ended December 31, 2022	(1,059,343)
Balance at December 31, 2022	$ —

17. Income Taxes

The provision for income taxes consisted of the following for the years ended December 31, 2022 and 2021:

	Years ended December 31,	
	2022	2021
Current income tax expenses:		
Federal	$ —	$ —
State	472,529	411,919
Total current income tax expense	472,529	411,919
Deferred income tax expenses:		
Federal	(7,936,507)	—
State	154,320	—
Total deferred income tax (benefit) expense	(7,782,187)	—
Income tax (provision) expense	$ (7,309,658)	$ 411,919

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets and liabilities are as follows at December 31, 2022 and 2021:

	December 31,	
	2022	2021
Deferred tax assets:		
Net operating losses	$ 9,221,189	$ 13,431,724
Federal and state tax credits	2,233,431	3,383,268
Lease liability ASC 842	7,541,756	7,271,783
Research and development	2,550,572	—
Stock options	1,705,609	—
Disallowed interest expense	—	164,921
Share-based compensation	—	495,960
Impairment	—	464,720
Other	593,254	691,010
Total deferred tax assets	$ 23,845,811	$ 25,903,386
Deferred tax liabilities:		
Basis difference on fixed assets	$ (4,551,953)	$ (4,114,426)
Basis difference on intangibles	(1,779,346)	(1,427,816)
Deferred revenue	(182,570)	—
Other accrued and prepaid expenses	(424,884)	(709,653)
Right-of-use asset ASC 842	(4,721,215)	(4,372,138)
Other	—	(72,714)
Total deferred liabilities	(11,659,968)	(10,696,747)
Net deferred tax asset	12,185,843	15,206,639
Less valuation allowance	(4,403,656)	(15,206,639)
Net deferred tax asset (liability) post valuation allowance	$ 7,782,187	$ —

If, based on the weight of available evidence, it is more likely than not that all deferred tax assets will not be realized, a valuation allowance must be recorded to reduce the recorded deferred tax assets to net realizable value. No valuation allowance was considered necessary as of December 31, 2022. Prior to the release of the valuation allowance in 2022, the Company identified an error in the 2021 valuation allowance. The Company assessed this error, deemed it to be immaterial, and has adjusted certain prior period amounts in the above table to align with the current period presentation.

The Company's income tax expense differs from the amount that results from applying the statutory U.S. Federal income tax rate to income before income taxes due to a variety of factors. The primary differences result from the following:

	Years Ended December 31,			
	2022		2021	
Book income before tax	$ 8,011,492		$ 8,815,776	
Federal rate	21.0%		21.0%	
Federal income tax at the statutory rate U.S. federal rate	1,682,413	21.0%	1,851,313	21.0%
State taxes, net of federal	527,618	6.6%	325,416	3.8%
Permanent items	557,075	7.0%	693,699	7.9%
Prior year true ups	514,707	6.4%	8,665	0.0%
Write off of Health Elements Federal NOL DTAs	—	0.0%	4,865,575	55.2%
Write off of Health Elements State NOL DTAs	—	0.0%	1,241,633	14.1%
Change in valuation allowance	(10,802,983)	(134.8%)	(8,490,499)	(96.3%)
Nondeductible expenses and other	211,512	2.6%	(83,883)	(1.0%)
Income tax (benefit) expense	$ (7,309,658)		$ 411,919	
Effective income tax rate	(91.2%)		4.7%	

As discussed in Note 2, Health Elements made a federal election during 2013 to be taxed as a Subchapter C corporation. Since that time, Health Elements has filed a consolidated income tax return. As such, separate tax returns are filed and therefore net operating losses are unique to each tax group.

As of December 31, 2021, the Company had federal and state net operating loss carryforwards of approximately $47.0 million and $50.9 million, respectively, including Health Elements. As of December 31, 2022, the Company had federal and state net operating loss carryforwards of approximately $29.1 million and $47.1 million, respectively. If not utilized, the federal operating loss carryforwards incurred before January 1, 2020 will begin to expire in 2030.The federal operating losses incurred in 2018 and beyond do not expire. The state operating loss carryforwards do not expire.

The Company has net operating loss carryforwards in various other state jurisdictions that are not material to the consolidated financial statements.

The Company's ability to utilize its net operating loss (NOL) and tax credit carryforwards may be substantially limited due to ownership changes that have occurred or that could occur in the future, as required by Section 382 of the Internal Revenue Code of 1986, as amended (the Code), as well as similar state provisions. These ownership changes may limit the amount of NOL and tax credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an "ownership change," as defined by Section 382 of the Code, results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percent of the outstanding stock of a company by certain stockholders or public groups. During 2021, the Company completed an analysis of the available NOL and tax credit carryforwards under Section 382 of the Code. As a result of this analysis, federal and state net operating losses were reduced by $31.3 million and $26.9 million, respectively.

During the course of preparing the Company's consolidated financial statements as of and for the year ended December 31, 2022, the Company identified that the previous assessment of Section 382 ownership changes incorrectly excluded Health Elements from the scope of the analysis. The Company completed a revised analysis during the current period, and after properly assessing the effects of upper tier shifts in ownership at the Company, it was determined that Health Elements also experienced a Section 382 ownership change. As a result of the identified ownership change, the portion of Health Elements NOL carryforwards attributable to the pre-ownership change periods are subject to a substantial annual limitation under Section 382 of the Code. The Company has adjusted its previously reported NOL carryforwards to address the impact of the 382 ownership change at Health Elements. This resulted in a reduction of previously disclosed available federal and state NOLs of $23.2 million and $18.8 million, respectively. The write down of the NOLs reduced the net operating losses line within the table of deferred tax assets as of December 31, 2021, as previously disclosed by $6.1 million, with a corresponding decrease in the valuation allowance. Additionally, previously, the Company had disclosed that the total reduction to federal and state NOL carryforwards resulting from the Section 382 study was $8.1 million and $8.1 million, respectively. As a result of the additional analysis performed during 2022, the Company has increased the amounts within the preceding paragraph by $23.2 million and $18.8 million, respectively.

Since the limitation affected the prior period, the Company has determined that its December 31, 2021 tax footnote presentation overstated the gross deferred tax asset and corresponding valuation allowance by $6.1 million. However, there was no net impact to the net deferred tax asset and tax expense as the decrease in the net operating loss and tax credit carryforwards was offset completely by a corresponding adjustment to the Company's overall valuation allowance. For comparative purposes, the Company's prior year tax footnote has been revised to reflect the adjustment to the net operating losses, tax credits and valuation allowance. The revision had no effect on the previously reported balance sheets, statements of operations and comprehensive loss, cash flows and stockholders' equity.

The Company is subject to taxation in the U.S. and various states. The Company does not have any unrecognized tax benefits. As of December 31, 2022, and 2021, there is no accrued interest or penalties recorded in the consolidated financial statements.

Cash paid for income taxes for the years ended December 31, 2022 and 2021 were as follows:

	Years Ended December 31,	
	2022	2021
Prior year extension payments made in current year	$ 515,650	$ 583,910
Amounts paid with prior year tax filings	—	—
First Quarter	—	—
Second Quarter	—	—
Third Quarter	—	—
Fourth Quarter	—	1,290
	515,650	585,200
Plus Notices Received	—	—
Less Refunds Received	—	—
Less Franchise Taxes included in amounts above	252,000	205,000
Total Cash Paid for Income Taxes	$ 263,650	$ 380,200

18. Employee Compensation Plans

The Company maintains a qualified defined contribution profit sharing plan (Profit Sharing Plan) for all eligible employees. Employees age 21 or older are eligible to participate on the first day of the following month from their hire date. The amount of contribution is determined annually by the Board of Directors. Effective January 1, 2019, the Company began making safe harbor contributions to the Profit Sharing Plan. The contribution will match 100% of the elective deferrals for the first 3% contributed by the employee, with another 50% of deferrals over 3% up to 5% of the compensation. This safe harbor plan requires that all matching contributions are 100% vested at the time of contribution. The total employer safe harbor contributions to the Profit Sharing Plan during the years ended December 31, 2022 and 2021 were $1.1 million and $0.9 million, respectively. Any profit-sharing contributions would be fully vested at the end of six or more years of service, with 20% each year starting in the second year of service. There were no profit-sharing contributions to the Profit Sharing Plan in 2022 or 2021.

The Company has a non-qualified deferred compensation plan for select groups of management that was established in August 2015 (Deferred Compensation Plan). The purpose of the Deferred Compensation Plan is to attract and retain a select group of management or highly compensated employees and to provide them an opportunity to defer compensation on a pre-tax basis and accumulate tax-deferred earnings. Each participant in the Deferred Compensation Plan has a fully vested and non-forfeitable interest in each year's contribution, including interest credited thereto, and in any Company matching contributions, if applicable. The Company may make discretionary credits to the deferred compensation account of each participant in an amount determined each plan year by the Company. The Company has not made any discretionary credits to the Deferred Compensation Plan since inception.

19. Stock-based Compensation

Prior to the Company's IPO, the Company's Board of Directors adopted, and the stockholders approved the Company's 2021 Equity Incentive Plan (2021 Plan). The 2021 Plan provides for the grant of incentive stock options, within the meaning of Section 422 of the Internal Revenue Code, to Company employees and parent and subsidiary corporations' employees, and for the grant of non-statutory stock options, stock appreciation rights, restricted stock awards (RSAs), restricted stock units (RSUs), and performance awards to employees, directors, and consultants and parent and subsidiary corporations' employees and consultants.

Subject to the adjustment provisions of and the automatic increase described in the 2021 Plan, as of December 31, 2021, a total of 3,480,510 shares of the Company's common stock is reserved for issuance pursuant to the 2021 Plan. In addition, subject to the adjustment provisions of the 2021 Plan, the shares reserved for issuance under the 2021 Plan will also include shares subject to awards granted under the Company's 2010 Equity Incentive Plan (2010 Plan) or the Company's Restated 2020 Onegevity Health Equity Plan, as amended (Onegevity Plan) that, on or after September 22, 2021 (the effective date of the IPO), expire or otherwise terminate without having been exercised or issued in full, are tendered to or withheld by the Company for payment of an exercise price or for satisfying tax withholding obligations, or are forfeited to or repurchased by the Company due to failure to vest (provided the maximum number of shares that may be added to the 2021 Plan, pursuant to outstanding awards under the 2010 Plan, or Onegevity Plan, is 10,615,030 shares). Subject to the adjustment provisions of the 2021 Plan, the number of shares available for issuance under the 2021 Plan will also include an annual increase on the first day of each fiscal year beginning with the 2022 fiscal year and ending on the tenth anniversary of the date the Company's Board of Directors approved the 2021 Plan, in an amount equal to the least of:

- 8,701,275 shares;
- five percent (5%) of the outstanding shares of the Company's common stock as of the last day of the immediately preceding fiscal year; or
- such other amount as the Company's Board of Directors may determine.

The 2021 Plan is administered by the Company's Compensation Committee, a sub-committee of the Board of Directors. Options are granted at the discretion of the 2021 Plan's administrator and have a term of not greater than 10 years from issuance. Options are exercisable when vested. Vesting requires continuous employment up to the vesting date and the vesting schedule is determined by the 2021 Plan. Options generally vest over a four-year period.

Prior to the 2021 Plan becoming effective, the Company previously issued stock-based awards under the 2010 Plan. The 2010 Plan was created by the Company's Board of Directors and has been amended from time to time to grant additional options. The plan provides for the grant of stock options, RSAs, RSUs, and performance awards to employees, directors, and consultants and parent and subsidiary corporations' employees and consultants. Options are granted at the discretion of the Company's Board of Directors and have a term of not greater than 10 years from issuance. Options are exercisable when vested. Vesting requires continuous employment up to the vesting date and the vesting schedule is determined by the Plan. Options generally vest over a four-year period.

On September 22, 2021, and upon the 2021 Plan becoming effective, the Company terminated the 2010 Plan, but all terms and conditions of the outstanding awards remained in effect with no changes. As of December 31, 2021, there were 949,510 shares available for issuance under the 2021 Plan and 13,106,416 share-based awards outstanding, comprised of 9,699,656 stock option awards and 3,406,760 restricted stock units.

On January 26, 2022, in accordance with the 2021 Plan's adjustment provisions, the Company increased the share reserve by 2,627,710 shares, as registered on Form S-8 and filed with the Securities and Exchange Commission (SEC) on January 26, 2022. As of December 31, 2022, a total of 5,479,220 shares of the Company's common stock is reserved for issuance pursuant to the 2021 Plan. As of December 31, 2022, there were 1,442,472 shares available for issuance under the 2021 Plan and 14,250,011 share-based awards outstanding, comprised of 9,337,503 stock option awards and 4,912,508 restricted stock units.

Stock Based Compensation Expense

The following table summarizes stock based compensation expense for the years ended December 31, 2022 and December 31, 2021:

	For the year ended December 31,	
	2022	2021
Stock options	$ 713,358	$ 2,793,316
Restricted stock units	10,621,941	1,760,708
Total stock-based compensation expense	$ 11,335,299	$ 4,554,024

Stock Options

During the years ended December 31, 2022 and 2021, there were no grants of stock options.

The following tables summarize all stock option activity for the years ended December 31, 2022 and December 31, 2021:

	Options Outstanding	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value [1]
Outstanding as of January 1, 2022	9,699,656	$ 5.28	6.22	$ 12.30
Granted	—	—		
Exercised	(304,303)	1.47		
Cancelled/forfeited	(57,850)	14.46		
Outstanding as of December 31, 2022	9,337,503	5.34	5.14	$ 1.94
Vested and Exercisable as of December 31, 2022	9,337,503	$ 5.34	5.14	$ 1.94

	Options Outstanding	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value [1]
Exercisable, December 31, 2021	5,691,541	$ 4.29	5.73	$ 10.9
Outstanding as of January 1, 2021	7,811,975	$ 4.66	6.30	N/A
Granted [2]	1,959,335	7.65		
Exercised	(39,614)	1.91		
Cancelled/forfeited	(32,040)	5.12		
Outstanding as of December 31, 2021	9,699,656	5.28	6.22	$ 12.30
Vested and expected to vest after December 31, 2021	9,699,656	$ 5.28	6.22	$ 12.30

(1) Aggregate intrinsic value represents the difference between the closing fair value of the underlying common stock and the exercise price of outstanding, in-the-money options on the date of measurement.

(2) During the year ended December 31, 2021, the Company issued 1,959,335 stock options in exchange for outstanding stock options of Onegevity at the time of, and in conjunction with the merger agreement as further discussed in Note 4. As a result of the stock option exchange being determined to be materially a "like-for-like" transaction, there was no incremental stock compensation expense recorded by the Company. The Company compared the fair value of the stock options immediately before and after the exchange and determined that the exchange did not result in incremental compensation expense. These stock options contain an accelerated vesting provision whereby upon the completion of an IPO by the Company or qualified change-in-control, any related and unvested stock options would become fully vested. Upon the Company's IPO on September 22, 2021, all 1,959,335 stock options issued in connection with the Onegevity merger fully vested.

The following table summarizes additional information related to stock options for the periods presented:

	For the year ended December 31,	
	2022	2021
Weighted-average grant date fair value of stock options granted [1]	N/A	N/A
Grant date fair value of stock options vested [2]	$ 951,144	$ 963,205
Intrinsic value of stock options exercised [3]	$ 1,265,470	$ 219,813

(1) During the years ended December 31, 2022 and 2021, there were no options granted by the Company. During the year ended December 31, 2021 and in connection with the Onegevity merger, the Company issued 1,959,335 options in exchange for outstanding stock options of Onegevity. As a result of the stock option exchange being determined to be materially a "like-for-like" transaction, there was no incremental stock compensation expense recorded by the Company. The Company compared the fair value of the stock options immediately before and after the exchange and determined that the exchange did not result in incremental compensation expense. These stock options issued in connection with the Onegevity merger have been excluded from the information presented for the year ended December 31, 2021.

(2) During the year ended December 31, 2021 and in connection with the Onegevity merger, the Company issued 1,959,335 options in exchange for outstanding stock options of Onegevity. These stock options contained an accelerated vesting provision whereby upon the completion of an IPO by the Company or qualified change-in-control, any related and unvested stock options would become fully vested. Upon the Company's IPO on September 22, 2021, all 1,959,335 stock options issued in connection with the Onegevity merger fully vested. These vested stock options issued in connection with the Onegevity merger have been excluded from the information presented for the year ended December 31, 2021.

(3) Shares of the Company's common stock, traded under the symbol "THRN," have been publicly traded since September 23, 2021, when the Company's common stock was listed and began trading on the Nasdaq Global Select Market (the "Nasdaq"). No market for the Company's stock existed prior to September 23, 2021. Accordingly, the total intrinsic value of stock options exercised excludes options exercised for the year ended December 31, 2020, prior to the IPO date. There were no stock option exercises prior to the IPO date during the year ended December 31, 2021.

During the year ended December 31, 2022, and 2021, the Company recorded stock-based compensation expense related to stock options of $0.7 million and $2.8 million, respectively. These amounts are classified as selling, general and administrative on the consolidated statements of operations. As of December 31, 2022, there was no unrecognized stock-based compensation expense related to outstanding stock options.

Restricted Stock Units

On July 29, 2021 and December 1, 2021, the Company issued RSUs to certain employees for an aggregate 875,760 and 2,531,000 shares, respectively, which vest ratably over a 4-year period. On April 4, 2022, April 26, 2022, and June 3, 2022, the Company issued RSUs to certain employees and directors for an aggregate of 2,143,000, 12,500, and 61,748 shares, respectively, which vest ratably over a 4-year period.

The following table summarizes all RSU activity for the year ended December 31, 2022:

	Number of Shares	Weighted-Average Grant-Date Fair Value
Outstanding as of December 31, 2021	3,406,760	$ 9.82
Granted	2,217,248	6.91
Vested	(629,000)	8.39
Cancelled/forfeited	(82,500)	7.13
Outstanding as of December 31, 2022	4,912,508	$ 8.73

During the year ended December 31, 2022, the Company recorded stock-based compensation expense related to RSUs of $10.6 million. The Company recorded stock-based compensation expense related to RSUs of $1.8 million during the year ended December 31, 2021. These amounts are classified as selling, general and administrative on the consolidated statements of operations. As of December 31, 2022, the unrecognized stock-based compensation expense related to outstanding RSUs was approximately $36.0 million and is expected to be recognized as expense over approximately 3.3 years.

The following table summarizes additional information related to RSUs for the periods presented:

	For the year ended December 31,	
	2022	2021
Weighted-average grant date fair value of RSUs granted [1][2]	$ 6.91	$ 9.99
Grant date fair value of RSUs vested [2][3]	$ 5,277,310	$ -
Intrinsic value of RSUs released [2][4]	N/A	N/A

(1) During the year ended December 31, 2021, there were 875,760 RSUs issued prior to the Company's IPO and an additional 2,531,000 RSUs issued after the IPO and prior to December 31, 2021. Shares of the Company's common stock, traded under the symbol "THRN," have been publicly traded since September 23, 2021, when the Company's common stock was listed and began trading on the Nasdaq Global Select Market (Nasdaq). Accordingly, no market for the Company's stock existed prior to September 23, 2021. Accordingly, the total intrinsic value of RSUs granted excludes the 875,760 RSUs granted prior to the IPO date.

(2) During the year ended December 31, 2021 and in connection with the Onegevity merger, the Company issued 472,590 RSUs in exchange for outstanding profits interest units held by employees of Onegevity. As a result of the RSU exchange being determined to be materially a "like-for-like" transaction, there was no incremental stock compensation expense recorded by the Company. The Company compared the fair value of the RSUs immediately before and after the exchange and determined that the exchange did not result in incremental compensation expense. These RSUs issued in connection with the Onegevity merger have been excluded from the information presented for the year ended December 31, 2021.

(3) During the years ended December 31, 2021 there were no RSUs that vested.

(4) During the years ended December 31, 2022 and 2021, there were no RSUs that were released.

20. Basic and Diluted Earnings per Share

Basic net income (loss) per share is calculated by dividing the net income (loss) available to common stockholders by the weighted-average number of common shares outstanding during the period, without consideration for common stock equivalents. Diluted EPS is computed by dividing the net income available to common stockholders by the weighted-average number of common stock and common stock equivalents outstanding for the period. For periods in which the Company incurs a net loss, outstanding common stock equivalents are not included in the calculation of diluted loss per share as their effect is anti-dilutive. Accordingly, basic and diluted net loss per share for those periods are identical.

Holders of Series E convertible preferred stock met the definition of participating securities, which required the Company to apply the two-class method to compute both basic and diluted earnings per share. The two-class method is an earnings allocation formula that treats participating securities as having rights to earnings that would otherwise have been available to common stockholders. The two-class method requires earnings for the period to be allocated between common stock and participating securities based upon their respective rights to receive dividends as if all earnings for the period had been distributed. In the event the Board of Directors declared dividends or any distributions, the available distributions would be distributed (i) first, to the Series E convertible preferred stock until such holders have received on a cumulative basis an amount per share equal to the Series E original issue price, and (ii) second, to the holders of common stock and Series E convertible preferred stock (on an as converted basis) on a pro rata, pari passu, basis. The attribution of earnings to the Series E convertible preferred stockholders was based on its contractual rights to receive dividends and, for the quarter in which they converted, the attribution was calculated using a weighted-average method. The Series E convertible preferred stock did not contractually participate in the Company's net losses, and therefore, undistributed losses were not allocated to Series E convertible preferred stock. Immediately prior to the completion of the Company's IPO on September 22, 2021, all outstanding shares of the Series E convertible preferred stock automatically converted on a one-to-one basis into an aggregate of 27,011,500 shares of common stock. See Note 15 for additional information related to the Series E convertible preferred stock.

The dilutive effect of stock options, warrants, and unvested nonparticipating restricted stock is based on the treasury stock method while the dilutive effect of the convertible preferred stock is based on the if-converted method. These potential common stock equivalents are only included in the calculations when their effect is dilutive. The Company presents the more dilutive of the two-class method or if-converted method as diluted net income (loss) per share during the period. For the year ended December 31, 2022, the Company presented diluted net income per share under the two-class method.

The following table presents information necessary to calculate net income (loss) per share for the years ended December 31, 2022 and 2021:

	Year Ended December 31,	
	2022	2021
Numerator:		
Net income attributable to Thorne HealthTech, Inc.	$ 15,674,040	$ 7,253,423
Undistributed earnings attributable to Series E convertible preferred stockholders	—	(3,507,892)
Numerator for basic EPS—net income available to Thorne HealthTech, Inc. common stockholders (A)	15,674,040	3,745,531
Effect of dilutive securities:		
Change in fair value of warrant liability	—	(1,872,364)
Undistributed earnings attributable to Series E convertible preferred stockholders—basic	—	3,507,892
Undistributed earnings attributable to Series E convertible preferred stockholders—diluted	—	(2,031,751)
	—	(396,223)
Numerator for diluted EPS—net income available to Thorne HealthTech, Inc. common stockholders (C)	15,674,040	3,349,308
Denominator:		
Denominator for basic EPS - weighted average shares (B)	52,757,834	27,478,411
Effect of Dilutive Securities [1]		
Stock options	—	3,608,128
RSUs	—	159,668
Warrants	—	1,082,358
Dilutive potential common shares	—	4,850,154
Denominator for diluted EPS—adjusted weighted average common stock and common stock equivalents (D)	52,757,834	32,328,565
Basic EPS (A/B) [2]	$ 0.30	$ 0.14
Diluted EPS (C/D) [2]	$ 0.30	$ 0.10

[1] Approximately 17.4 million warrants and stock-based awards were excluded from the computation of diluted EPS for the years ended December 31, 2022, because the effect would have been anti-dilutive under the treasury stock method.

[2] For the year ended December 31, 2022, diluted EPS is the same as basic EPS because the effects of potentially dilutive securities are anti-dilutive.

21. Commitments and Contingencies

Advertising - The Company has entered into an agreement that calls for future payments to a customer for advertising services to be performed. As of December 31, 2022, future annual minimum commitments under this agreement are $13.2 million in 2023 and $17.3 million in 2024. Total advertising fees paid during each of the years ended December 31, 2022, and 2021, were $9.5 million and $4.2 million, respectively.

Royalty Agreements -The Company has entered into various agreements that call for future payments to a major hospital for use of their trademarks and tradenames in advertising the benefits of supplements and provides the Company access to research information owned by the hospital and provides for the hospital to perform clinical trials and to support the Company's products. As of December 31, 2022, future annual minimum commitments under these agreements are $0.6 million in 2023.

The Company also has various royalty agreements, that are dependent on future sales. Total royalties paid during each of the years ended December 31, 2022, and 2021, were $0.3 and $0.6 million, respectively.

Other - In 2017, the Company received incentives totaling $0.8 million from Berkeley County, South Carolina, which includes certain performance obligations that must be met over the next seven years and maintained by the Company for five years once attained. The grant agreement includes the potential for repayment of proceeds in whole or in part for failure to satisfy the performance obligations. As of December 31, 2022, Berkeley County has not asked for repayment of these proceeds.

Contingencies

The Company, like other manufacturers of products that are ingested, faces an inherent risk of exposure to product liability claims if, among other things, the use of its product results in personal injury. The Company maintains product liability insurance to manage these risks. However, there can be no assurance the amount of insurance would be sufficient to cover all product liability claims.

In addition to the matter discussed below, occasionally the Company is involved in lawsuits arising in the ordinary course of its operations. The Company's management does not expect the ultimate resolution of pending legal actions to have a material effect on the consolidated financial statements of the Company.

The Company is aware of two third-party U.S. patents that have claims relating to compositions of nicotinamide riboside – an ingredient contained in several of the Company's nutritional supplement products – issued to the Trustees of Dartmouth College and licensed to ChromaDex Corporation (Chromadex), of Los Angeles, California. On December 1, 2020, and February 1, 2021, the Company filed separate petitions for inter partes review against U.S. Patent No. 8,383,086 and U.S. Patent No. 8,197,807, respectively, at the U.S. Patent Trial and Appeal Board to seek to invalidate these two patents.

On June 10, 2021, the Patent Trial and Appeal Board issued a decision granting institution of inter partes review against U.S. Patent No. 8,383,086. On May 31, 2022, the Patent Trial and Appeal Board issued a decision in which it invalidated the challenged claim in U.S. Patent No. 8,838,086. On August 2, 2022, the patent owner filed a "Patent Owner Notice of Appeal" with the U.S. Court of Appeals for the Federal Circuit. On December 29, 2022, the patent owner's appeal was dismissed.

August 12, 2021, the U.S. Patent Trial and Appeal Board issued a decision granting institution of inter partes review against U.S. Patent No. 8,197,807. On August 10, 2022, the Patent Trial and Appeal Board issued a decision in which it did not invalidate the challenged claims in U.S. Patent No. 8,197,807. The Company is appealing that decision.

On May 12, 2021, the Trustees of Dartmouth College and ChromaDex filed a complaint against the Company in the U.S. District Court for the Southern District of New York, alleging the Company's infringement of U.S. Patent Nos. 8,383,086 and 8,197,807. The complaint seeks to enjoin the Company from selling its nutritional supplement products that contain nicotinamide riboside and further seeks monetary damages for alleged infringement of the patents. On August 20, 2021, the trial judge in the patent infringement litigation issued an Order to Stay the litigation during the pendency of the two inter partes review. The Order to Stay remains in effect.

On September 21, 2021, in litigation that the Company is not party to, the U.S. District Court for the District of Delaware issued a summary judgment holding that U.S. Patent Nos. 8,383,086 and 8,197,807 are invalid. On February 13, 2023, that decision was upheld on appeal.

The Company has not recorded a loss in connection with this matter, because the Company believes that a loss is currently neither probable nor estimable.

22. Subsequent Events

The Company has evaluated subsequent events through the date the consolidated financial statements were issued.

Departure and Appointment of the Chief Financial Officer and Chair of the Audit Committee of the Board of Directors

On January 1, 2023, Bryan Conley tendered his resignation as the Company's Chief Financial Officer (CFO), effective immediately. On March 13, 2023, the Company announced that Saloni Varma, member of the Company's Board of Directors and Chair of the Audit Committee, will be appointed as the CFO of the Company, effective April 1, 2023. Also on March 13, 2023, Sarah Kauss, member of the Company's Board of Directors and Chair of the Compensation Committee, was appointed to serve as the Chair of the Audit Committee, effective April 1, 2023, to fill the vacancy created by Ms. Varma's appointment as CFO of the Company.

Acquisition of PreCon Health, Inc.

On January 11, 2023, the Company, entered into and consummated a Stock Purchase Agreement (the "PreCon Purchase Agreement") with PreCon Acquisition LLC ("PreCon Acquisition") which owns all of the issued and outstanding shares of capital stock of PreCon Health, Inc ("Precon Health"). Pursuant to the terms of the PreCon Purchase Agreement, the Company acquired PreCon Health's rights, title, and interest in certain nutritional supplement products (the "PreCon Products"), including certain complementary technology-related intangible assets including intellectual property, trade secrets, formulas, processes, recipes to produce the PreCon Products, and related ancillary contracts. The technology-related intangible assets represent substantially all of the fair value of the acquired assets. The technology-related intangible assets were acquired for (i) $4.0 million in cash paid at closing, (ii) $1.0 million in cash payable on or before ninety (90) days after January 11, 2023 (i.e., April 11, 2023), and (iii) a royalty payment to a related party of PreCon Acquisition in an amount equal to five percent (5%) of the gross sales revenue from the sale of the PreCon Products from and after such time as the Company achieves $5.0 million of gross profit, unless the second installment of the cash consideration of $1.0 million is not paid within ninety (90) days after January 11, 2023 (i.e., April 11, 2023), the royalty payment rate shall increase from five percent (5%) to seven percent (7%).

The acquisition has been accounted for as an asset acquisition in accordance with FASB ASC 805-50 because substantially all of the fair value of the assets acquired is concentrated in a single asset, the technology-related intangible assets for the Products, and are considered a single asset as they are inextricably linked. ASC 805-10-55-5A includes a screen test, which provides that if substantially all of the fair value of the assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets, the assets acquired are not considered to be a business. As an asset acquisition, the cost to acquire the group of assets, including transaction costs, is allocated to the individual assets acquired or liabilities assumed based on their relative fair values. The Company has not yet determined the relative fair values or the amortization period of the identifiable assets from the acquisition.

Amendment to Existing Lease Agreement

On February 7, 2023, an amendment to the Company's existing lease for approximately 240,800 square feet at 620 Omni Industrial Boulevard, Summerville, South Carolina (the Existing Premises), was executed. The amendment provides for the construction of a 74,400 square foot addition to the Existing Premises (the New Expansion), resulting in an amended total of 315,200 square feet under lease. The Company will receive an allowance of $8 million for the cost of the construction for the New Expansion. The Company anticipates completion of the New Expansion and commencement of the lease amendment during the fourth quarter of fiscal year 2023. We are still evaluating the accounting impact of this amendment.

Dissolution of Nutrativa LLC

On February 28, 2022, the Company acquired all of the outstanding membership interests of Nutrativa LLC (see Note 4 for further information over the Nutrativa LLC acquisition). On February 14, 2023, the Company entered into an Assignment Agreement with Nutrativa LLC. Under the terms of this agreement, Nutrativa LLC transferred all rights, title and interest in Nutrativa LLC's assets to the Company. On March 8, 2023, a Certificate of Cancellation was filed and executed with the office of the Secretary of State of Delaware, formally dissolving Nutrativa LLC.

Draw on Revolving Credit Promissory Note

On March 3, 2023, the Company drew $15 million of the $40.1 million available under the Revolver to partially fund an escrow account associated with the planned leasehold improvements and footprint expansion for our manufacturing and distribution facility located in Summerville, South Carolina. On March 16, 2023, together with $8 million of cash from operations, the Company transferred the funds received from the draw on the Revolver to the escrow account.

There were no other subsequent events requiring recognition or disclosure in the accompanying consolidated financial statements.

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

None.

Item 9A. Controls and Procedures.

a. Evaluation of Disclosure Controls and Procedures

As required by Rule 13a-15(b) of the Securities Exchange Act of 1934 (the "Exchange Act"), management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated, as of the end of the period covered by this report, the effectiveness of our disclosure controls and procedures as defined in Exchange Act Rule 13a-15(e). Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that due to material weaknesses in our internal control over financial reporting described below in Management's Report on Internal Control over Financial Reporting, our disclosure controls and procedures were not effective as of December 31, 2022.

Notwithstanding the identified material weaknesses, management believes the consolidated financial statements included in this Annual Report on Form 10-K fairly present, in all material respects, our financial condition, results of operations and cash flows as of and for the periods presented in accordance with U.S. generally accepted accounting principles.

b. Management's Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act). Management, including our Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2022. In making this assessment, our management used the criteria for effective internal control over financial reporting described in "Internal Control-Integrated Framework (2013)," issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting for external purposes in accordance with U.S. generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of 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 or procedures may deteriorate. Accordingly, even effective internal control over financial reporting can only provide reasonable assurance of achieving its control objectives.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis.

Based on our assessment which used the criteria noted above, management has concluded that our internal control over financial reporting was not effective as of December 31, 2022 due to the material weaknesses described as follows:

- We did not properly design or maintain effective controls over the financial reporting process to enable timely reporting of complete and accurate financial information. Specifically, we did not design and implement review controls with a sufficient precision to prevent or detect a material misstatement and to validate the completeness and accuracy of underlying data used in certain review controls, did not consistently perform independent reviews of journal entries or consistently retain adequate supporting documentation of the preparation and review of financial information supporting financial statement balances and the related footnote disclosures.

- We did not design and maintain sufficient information technology general controls ("ITGCs") in the areas of logical security access and change management in certain financially relevant systems, including adequate segregation of duties, and reinforcing independent journal entry review. Due to the pervasive impact of the ineffective ITGCs, certain control activities including manual controls that rely on data produced by and maintained within these IT system applications such as the management review control deficiencies described above, were also considered ineffective, potentially impacting all financial statement accounts.

- We did not properly design or maintain effective formal processes and controls related to the accounting for and disclosure of complex, non-routine, and significant and unusual transactions, including accounting for non-routine or unusual contracts with customers in accordance with ASC 606 and accounting for business combinations in accordance with ASC 805.

- We did not design and maintain effective controls related to the preparation and review of the annual income tax provision and related footnote disclosures in accordance with ASC 740.

- We did not design and maintain effective formal processes and controls to ensure the completeness and accuracy of our disclosures regarding related party transactions.

Although no material misstatements were identified in our consolidated financial statements, these control deficiencies create a reasonable possibility that a material misstatement of the Company's consolidated financial statements will not be prevented or detected on a timely basis. We have concluded that the deficiencies represent material weaknesses in our internal control over financial reporting and our internal control over financial reporting was not effective as of December 31, 2022.

Our independent registered public accounting firm will not be required to formally attest to the effectiveness of our internal controls over financials reporting as long as we are an “emerging growth company” pursuant to the provisions of the JOBS Act.

c. Remedial Measures

During the current year, management implemented significant changes to improve procedures relating to our internal control structure, including our ability to rely on system generated information. Specifically, management has:

- engaged an internal audit specialist to consult with management related to formalizing process documentation, performing risk assessments, consult on control design, provide training to control owners, and perform control testing to monitor the effectiveness of control performance and remediation;
- hired additional finance and accounting personnel with the requisite skill and experience to evaluate complex, non-routine, and unusual transactions and perform controls effectively;
- implemented user access reviews over all IT applications significant to the financial reporting processes;
- reinforced segregation of duties through logical access controls and mitigating manual controls;
- implemented reviews of SOC1 reports issued by the service auditors of the Company’s third-party software vendors;
- designed an updated IT change management process that reinforces and documents the requirement that only authorized, tested and approved changes are moved to the production application environments.

The remediation measures described above and their impact on the Company’s internal control over financial reporting is ongoing. The material weaknesses will not be considered remediated until the applicable controls operate for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively. We are focused on remediating these deficiencies during fiscal year 2023 and will strengthen our internal control over financial reporting and will prevent a reoccurrence of the material weaknesses described above.

d. Changes in Internal Control over Financial Reporting

Other than as discussed above, there were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the most recently completed fiscal quarter other than those described in the Remedial Measures section above that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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.

Except as set forth below, the information required by Item 10 of Part III is included in our Proxy Statement related to our 2022 Annual Meeting of Stockholders and is incorporated herein by reference.

The Company has adopted an ethics code of conduct (the "Code of Business Conduct and Ethics") that applies to all employees, including the principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A copy of that code is available on our corporate website under the heading "Corporate Governance" at investors.thornehealthtech.com, which does not form a part of this Annual Report on Form 10-K. You may obtain free of charge copies of the code from our website at the above internet address. To the extent permissible under Nasdaq rules, we intend to disclose amendments to our Code of Business Conduct and Ethics, as well as waivers of the provisions thereof, on our investor relations website.

Item 11. Executive Compensation.

Information required by Item 11 of Part III is included in our Proxy Statement relating to our 2022 Annual Meeting of Stockholders and is incorporated herein by reference.

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

Information required by Item 12 of Part III is included in our Proxy Statement relating to our 2022 Annual Meeting of Stockholders and is incorporated herein by reference.

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

Information required by Item 13 of Part III is included in our Proxy Statement relating to our 2022 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

Information required by Item 14 of Part III is included in our Proxy Statement relating to our 2022 Annual Meeting of Stockholders and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

The following documents are filed as part of this report:

(a) **Financial Statements -** For a list of all financial statements, refer to Consolidated Financial Statements Table of Contents in Item 8 - Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

(b) **Financial Statement Schedules -** All schedules are omitted as the required information is either not applicable, not present, not present in material amounts or presented within the consolidated financial statements or related notes.

(c) Exhibits - We make reference to the exhibits listed below:

Exhibit Number	Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
3.1	Amended and Restated Certificate of Incorporation of the Registrant, dated September 27, 2021.	10-Q	11/10/21	3.1	
3.2	Amended and Restated Bylaws of the Registrant, dated September 27, 2021.	10-Q	11/10/21	3.2	
4.1	Fourth Amended and Restated Registration Rights Agreement by and among the Registrant and certain of its stockholders, dated July 5, 2018.	S-1/A	9/21/21	4.1	
4.2	Fourth Amended and Restated Stockholders Agreement by and among the Registrant and certain of its stockholders, dated July 5, 2018.	S-1	7/16/21	4.2	
4.3	Specimen common stock certificate of the Registrant.	S-1	7/16/21	4.3	
4.4	Amended and Restated Common Stock Purchase Warrant issued to Kirin Holdings Company, Limited, dated as of July 15, 2020.	S-1/A	9/21/21	4.4	
4.5	Amended and Restated Common Stock Purchase Warrant issued to Mitsui & Co., Ltd, dated as of July 15, 2020.	S-1/A	9/21/21	4.5	
4.6	Amended and Restated Common Stock Purchase Warrant issued to Diversified Natural Products, Inc., dated as of May 10, 2011.	S-1/A	9/21/21	4.6	
4.7	Amended and Restated Common Stock Purchase Warrant issued to ELUS Holdings Corporation, dated as of May 10, 2011.	S-1/A	9/21/21	4.7	
4.8	Amendment to Warrant to Purchase Common Stock, between the Registrant and Diversified Natural Products, Inc., effective May 2, 2019.	S-1/A	9/21/21	4.8	
4.9	Amendment to Warrant to Purchase Common Stock, between the Registrant and ELUS Holdings Corporation, effective May 2, 2019.	S-1/A	9/21/21	4.9	
4.10	Description of the Registrant's Securities registered pursuant to Section 12 of the Securities Exchange Act of 1934.	10-K	3/16/22	4.10	
10.1+	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers.	S-1/A	9/21/21	10.1	
10.2+	2010 Equity Incentive Plan, as amended, and forms of agreement thereunder.	S-1/A	9/21/21	10.2	
10.3+	Restated 2020 Onegevity Equity Plan, and forms of agreement thereunder.	S-1/A	9/21/21	10.3	
10.4+	2021 Equity Incentive Plan and forms of agreements thereunder.	10-K	3/16/22	10.4	
10.5+	2021 Employee Stock Purchase Plan and forms of agreements thereunder.	S-1/A	9/21/21	10.5	
10.6(a)+	Form of Confirmatory Employment Letter with Paul F. Jacobson.	S-1/A	9/21/21	10.6(a)	
10.6(b)+	Form of Confirmatory Employment Letter with William C. McCamy.	S-1/A	9/21/21	10.6(b)	
10.6(c)+	Form of Confirmatory Employment Letter with Thomas P. McKenna.	S-1/A	9/21/21	10.6(c)	
10.7+	Employee Incentive Compensation Plan.	S-1/A	9/21/21	10.7	
10.8(a)+	Form of Change in Control and Severance Agreement with Paul F. Jacobson.	S-1/A	9/21/21	10.8(a)	
10.8(b)+	Form of Change in Control and Severance Agreement with William C. McCamy.	S-1/A	9/21/21	10.8(b)	
10.8(c)+	Form of Change in Control and Severance Agreement with Thomas P. McKenna.	S-1/A	9/21/21	10.8(c)	
10.9+	Outside Director Compensation Policy.	S-1/A	9/21/21	10.9	
10.10#	Lease Agreement between the Registrant and GPT Summerville Owner LLC, dated September 16, 2019, as amended.	S-1/A	9/21/21	10.10	
10.11	Agreement of Lease between the Registrant and Carnegie Hall Tower II L.L.C, dated March 14, 2013, as amended.	S-1/A	9/21/21	10.11	
10.12	Multi-Tenant Industrial Triple Net Lease between the Registrant and Icon Owner Pool 1 SF Non-Business Parks, LLC, dated October 25, 2019.	S-1/A	9/21/21	10.12	
10.13#	Vendor Agreement between the Registrant and BioTE Medical, LLC, dated December 1, 2020.	S-1/A	9/21/21	10.13	
10.14	Uncommitted and Revolving Credit Line Agreement between the Registrant and Sumitomo Mitsui Banking Corporation, dated February 12, 2021.	S-1/A	9/21/21	10.14	
10.15	Fee Letter between the Registrant and Mitsui & Co., Ltd., dated February 12, 2021.	S-1/A	9/21/21	10.15	
10.16	Fee Letter between the Registrant and Kirin Holdings Company, Limited, dated February 12, 2021.	S-1/A	9/21/21	10.16	
10.17	Uncommitted and Revolving Credit Line Agreement between the Registrant and Sumitomo Mitsui Banking Corporation, dated February 14, 2020.	S-1/A	9/21/21	10.17	
10.18	Fee Letter between the Registrant and Mitsui & Co., Ltd., dated February 14, 2020.	S-1/A	9/21/21	10.18	
10.19	Fee Letter between the Registrant and Kirin Holdings Company, Limited, dated February 14, 2020.	S-1/A	9/21/21	10.19	

10.20	Reimbursement Agreement between the Registrant and Sumitomo Mitsui Banking Corporation, dated November 30, 2018.	S-1/A	9/21/21	10.20	
10.21	Fee Letter between the Registrant and Kirin Holdings Company, Limited, dated November 30, 2018.	S-1/A	9/21/21	10.21	
10.22	Fee Letter between the Registrant and Mitsui & Co., Ltd., dated November 30, 2018.	S-1/A	9/21/21	10.22	
10.23	Unconditional Guaranty between the Registrant and Truist Bank, dated June 2, 2020.	S-1/A	9/21/21	10.23	
10.24#	Authorized Reseller Agreement between the Registrant and Pattern Inc., dated November 25, 2019, as amended.	S-1/A	9/21/21	10.24	
10.25#	First Amended and Restated Distribution Agreement between the Registrant and Emerson Ecologics, LLC, dated August 31, 2020, as amended.	S-1/A	9/21/21	10.25	
10.26	Nominating, Observer, and Secondment Agreement between the Registrant, Kirin Holdings Company, Limited, and Mitsui & Co., Ltd., dated September 27, 2021.	10-K	3/16/22	10.26	
10.27	Industrial Lease between Registrant and SFG Charleston Omni, LLC, dated July 28, 2021.	10-Q	11/10/21	10.1	
10.28	Lease Agreement between Registrant and SRE TKC Charleston IV, LLC, dated January 26, 2021.	10-K	3/16/22	10.28	
10.29	Loan Agreement, dated March 31, 2022, between Thorne HealthTech, Inc., as borrower, and Bank of America N.A., as lender.	8-K	4/12/22	10.1	
10.30	Security Agreement, dated March 31, 2022, between Thorne HealthTech, Inc. and Thorne Research, Inc., as pledgor, and Bank of America, N.A.	8-K	4/12/22	10.2	
10.31	Continuing and Unconditional Guaranty, dated March 31, 2022, by Thorne Research, Inc., as guarantor.	8-K	4/12/22	10.3	
10.32	Authorized Reseller Agreement between Registrant and Pattern, Inc., dated April 21, 2022.	10-Q	5/12/22	10.4	
10.33	Credit Agreement, dated December 21, 2022, between Thorne HealthTech, Inc., as borrower, and Fifth Third Bank N.A., as lender.	8-K	12/22/22	10.1	
10.34	Revolving Loan Promissory Note, dated December 21, 2022, between Thorne HealthTech, Inc., as borrower, and Fifth Third Bank N.A., as lender.	8-K	12/22/22	10.2	
10.35	Term Loan Promissory Note, dated December 21, 2022, between Thorne HealthTech, Inc., as borrower, and Fifth Third Bank N.A., as lender.	8-K	12/22/22	10.3	
10.36	Guaranty and Security Agreement, dated December 21, 2022, by Thorne HealthTech, Inc. and Thorne Research, Inc., as guarantor, together, grantors, in favor of Fifth Third Bank, N.A.	8-K	12/22/22	10.4	
10.37	Joint Venture Agreement, dated January 31, 2023, by Thorne HealthTech, Inc., as purchaser, and PreCon LLC, as Seller				X
10.38	Second Amendment to Lease Agreement, dated November 17, 2022, between Thorne HealthTech, Inc., as tenant, and Victoria Logisitics Assets LP, as landlord				X
21.1	Subsidiaries of the Registrant.				X
23.1	Consent of Independent Registered Public Accounting Firm.				X
31.1	Certification of the Chief Executive Officer, pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of the Chief Financial Officer, pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1†*	Certification of the Chief Executive Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
32.2†*	Certification of the Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.				X
101	The following financial information from Thorne HealthTech Inc.'s Annual Report on Form 10-K for the year ended December 31, 2022 formatted in Inline XBRL (Extensible Business Reporting Language) includes: (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Operations, (iii) the Consolidated Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit), (v) the Consolidated Statements of Cash Flows, and (vi) Notes to the Consolidated Financial Statements.				X

104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)	X

+ Indicated management contract or compensatory plan.
# Portions of the exhibit have been omitted as the Registrant has determined (i) the omitted information is not materials; and (ii) the Registrant customarily and actually treats the omitted information as private or confidential.
† The certifications attached as Exhibits 32.1 and 32.2 that accompany this Annual Report on Form 10-K, are deemed furnished and not filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report on Form 10-K, irrespective of any general incorporation language contained in such filing.

The agreements and other documents filed as exhibits to this report are not intended to provide factual information or other disclosure other than with respect to the terms of the agreements or other documents themselves, and you should not rely on them for that purpose. In particular, any representations and warranties made by us in these agreements or other documents were made solely within the specific context of the relevant agreement or document and may not describe the actual state of affairs as of the date they were made or at any other time.

Item 16. Form 10-K Summary

None.

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**.**

THORNE HEALTHTECH, INC.

Date: March 31, 2023

By: /s/ Paul F. Jacobson

Paul F. Jacobson
Chief Executive Officer

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 in the capacities and on the dates indicated.

Name	Title	Date
/s/ Paul F. Jacobson **Paul F. Jacobson**	Chief Executive Officer *(Principal Executive Officer; Principal Financial and Accounting Officer)*	March 31, 2023
/s/ Thomas P. McKenna **Thomas P. McKenna**	Chief Operating Officer and Director	March 31, 2023
/s/ Sarah M. Kauss **Sarah M. Kauss**	Director	March 31, 2023
/s/ Saloni S. Varma **Saloni S. Varma**	Director	March 31, 2023
/s/ Riccardo C. Braglia **Riccardo C. Braglia**	Director	March 31, 2023
/s/ Toshitaka Inuzuka **Toshitaka Inuzuka**	Director	March 31, 2023
/s/ Takeshi Minakata **Takeshi Minakata**	Director	March 31, 2023

Board of directors

Paul Jacobson
Chairman and Chief Executive Officer
Thorne HealthTech, Inc.

Sarah Kauss [1, 2, 3]
Founder
S'well Bottle

Riccardo Braglia [1, 2, 3]
Group Executive Chairman
Helsinn Group

Takeshi Minakata [2]
President and Chief Executive Officer
Kyowa Hakko Bio., Ltd. (Kirin Holdings Co. Ltd.)

Thomas McKenna
Chief Operating Officer
Thorne HealthTech, Inc.

Saloni Varma [2]
Chief Financial Officer
Thorne HealthTech, Inc.

Toshitaka Inuzuka [2]
General Manager
Mitsui & Co., Ltd.

1 Audit Committee
2 Compensation Committee
3 Nominating and Corporate Governance Committee

Stockholder information

Common Stock Listings
The Company's Common Stock (ticker: THRN) is listed on the NASDAQ Global Select Market ("NASDAQ")

Registrar and Transfer Agent Contact
Computershare Investor Services
P.O. Box 505005
Louisville, KY 40233-5005
1-800-311-4816 (U.S. and Canada)
1-201-680-6693 (International)
www.computershare.com/investor

Corporate Office Contact
Thorne HealthTech, Inc.
152 W. 57th Street
New York, NY 10019
1-929-251-6321
www.thorne.com

Annual Meeting of Stockholders
June 14, 2023
The annual meeting of Thorne HealthTech, Inc. will be in virtual format via live audio webcast. Stockholders can attend the meeting via the internet at:
www.proxydocs.com/THRN

Independent Registered Public Accounting Firm Contact
BDO USA, LLP
421 Fayetteville St, Suite 300
Raleigh, NC 27601
1-919-754-9370
www.bdo.com

Investor Relations Corporate
investors@thorne.com
investors.thornehealthtech.com/overview/

Thorne HealthTech

THRN