Table of Contents

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2023

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

For the transition period from _____to_____

Commission File No. 001-37704

DARIOHEALTH CORP.

(Exact name of registrant as specified in its charter)

Delaware	**45-2973162**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
322 W. 57th St. **New York, New York**	**10011**
(Address of principal executive offices)	(Zip Code)

(972)-4 770-6377
(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, par value $0.0001 per share	**DRIO**	**The Nasdaq Stock Market LLC**

Securities registered pursuant to Section 12(b) of the Exchange Act: None

Securities registered pursuant to Section 12(g) of the Act: Common Stock, par value $0.0001 per share; Warrants to purchase Common Stock

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the closing price as of the last business day of the registrant's most recently completed second fiscal quarter is $98,193,532.

As of March 22, 2024, the registrant had outstanding 29,442,532 shares of common stock, $0.0001 par value per share.

Documents Incorporated By Reference: None.

TABLE OF CONTENTS

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS AND SUMMARY RISK FACTORS

This Annual Report on Form 10-K, or the Annual Report, contains "forward-looking statements," which includes information relating to future events, future financial performance, financial projections, strategies, expectations, competitive environment and regulation. Words such as "may," "should," "could," "would," "predicts," "potential," "continue," "expects," "anticipates," "future," "intends," "plans," "believes," "estimates," and similar expressions, as well as statements in future tense, identify forward-looking statements. Forward-looking statements should not be read as a guarantee of future performance or results and may not be accurate indications of when such performance or results will be achieved. Forward-looking statements are based on information we have when those statements are made or management's good faith belief as of that time with respect to future events, and are subject to significant risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. Important factors that could cause such differences include, but are not limited to:

- our current and future capital requirements and our ability to satisfy our capital needs through financing transactions or otherwise;
- our ability to meet the requirements of our existing debt facility;
- our product launches and market penetration plans;
- the execution of agreements with various providers for our solution;
- our ability to maintain our relationships with key partners, including Sanofi U.S. Services Inc. ("Sanofi");
- our ability to complete required clinical trials of our product and obtain clearance or approval from the United States Food and Drug Administration (the "FDA"), or other regulatory agencies in different jurisdictions;
- our ability to maintain or protect the validity of our U.S. and other patents and other intellectual property;
- our ability to retain key executive members;
- our ability to internally develop new inventions and intellectual property;
- general market, political and economic conditions in the countries in which we operate, including those related to recent unrest and actual or potential armed conflict in Israel and other parts of the Middle East, such as the recent attack by Hamas and other terrorist organizations from the Gaza Strip and Israel's war against them;
- interpretations of current laws and the passages of future laws; and
- acceptance of our business model by investors.

The foregoing does not represent an exhaustive list of matters that may be covered by the forward-looking statements contained herein or risk factors that we are faced with that may cause our actual results to differ from those anticipated in our forward-looking statements. Please see "Risk Factors" for additional risks that could adversely impact our business and financial performance.

Moreover, new risks regularly emerge and it is not possible for our management to predict or articulate all the risks we face, nor can we assess the impact of all risks on our business or the extent to which any risk, or combination of risks, may cause actual results to differ from those contained in any forward-looking statements. All forward-looking statements included in this Annual Report are based on information available to us on the date of this Annual Report. Except to the extent required by applicable laws or rules, we undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise. All subsequent written and

oral forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the cautionary statements contained above and throughout this Annual Report.

When used in this Annual Report, the terms "Dario," "DarioHealth," "the Company," "we," "our," and "us" refer to DarioHealth Corp., a Delaware corporation and our subsidiary LabStyle Innovation Ltd., an Israeli company, PsyInnovations Inc., a Delaware company, Twill, Inc., a Delaware company, and DarioHealth India Services Pvt. Ltd., an Indian company. "Dario" is registered as a trademark in the United States, Israel, China, Canada, Hong Kong, South Africa, Japan, Costa Rica, and Panama. "DarioHealth" is registered as a trademark in the United States and Israel.

Summary of Risk Factors

Our business is subject to a number of risks, including risks that may adversely affect our business, financial condition and results of operations. These risks are discussed more fully below and include, but are not limited to, risks related to:

Risks Related to Our Financial Position and Capital Requirements

- Risks associated with our relatively new business;
- our future capital needs and their potential impact on our existing stockholders;
- our history of losses and stockholder's inability to rely upon our historical operating performance;

Risks Related to Our Business

- the acceptance of our products in the market and our exposure to market trends;
- our risks of basing our business on the sale of our principal technology;
- our reliance on manufacturers and distributors;
- the impact of a failure of our digital marketing efforts;
- our reliance on the Apple App Store and Google's Android platform;
- the risks associated with conducting business internationally;
- potential errors in our business processes and product offerings;
- our reliance on the performance of key members of our management team and our need to attract highly skilled personnel;
- the integration of Upright and PsyInnovations into our business;
- the volatility of capital markets and other macroeconomic factors, including due to inflationary pressures, geopolitical tensions or the outbreak of hostilities or war;

Risks Related to Product Development and Regulatory Approval

- the expense and time required to obtain regulatory clearance of our products;
- our limited clinical studies and the susceptibility to varying interpretations of such studies;
- our ability to complete clinical trials;
- the failure to comply with the FDA's Quality System Regulation or any applicable state equivalent;
- our reliance on third parties to conduct clinical trial work;
- the impact of legislation and federal, state and foreign laws on our business, including protecting the confidentiality of patient health information;
- the potential impact of product liability suits;

Risks Related to Our Intellectual Property

- the risks relating to obtaining or maintaining our intellectual property;
- potential litigation relating to the protection of our intellectual property;
- our limited foreign intellectual property rights;
- Our reliance on confidentiality agreements and the difficulty in enforcing such agreements;

Risks Related to Our Industry

- the intense competition we face in the markets we operate;
- our need to respond quickly to technological developments;
- the risks relating to obtaining or maintaining our intellectual property;
- the risks relating to third-party payors not providing for adequate coverage and reimbursement for our products;

Risks Related to Our Operations in Israel

- the risks relating to the political, economic and military instability that may exist in Israel;
- the potential for operations to be disrupted as a result of obligations of Israeli citizens to perform military service;
- the difficulty in enforcing judgements against us or certain of our executive officers and directors;

Risks Related to the Ownership of Our Common Stock and Warrants

- the ability for our officers, directors and founding stockholders to exert influence over our affairs;
- the potential lack of liquidity, or volatility, of our common stock and warrants;
- the impact of analysts not publishing research or reports about us;
- the expense relating to our requirements as a U.S. public company;
- the potential failure to maintain effective internal controls over financial reporting;
- the existence of anti-takeover provisions in our charter documents and Delaware law; and
- that we do not intend to pay dividends on our common stock.

PART I

Item 1. Business

Dario is revolutionizing how people with chronic conditions manage their health through the innovation of a new category of digital health: Digital Therapeutics as a Service ("DTaaS"). We believe that our innovative approach to digital therapeutics disrupts the traditional provider-centered system of healthcare delivery by offering user-centric care that is continuous, customized supportive of better overall health. Our solutions combine the power of technologies and behavior science to make better health accessible, affordable, and easy for all by solving for what people need, when and where they want it, with hyper-personalized care that is always connected – to services, devices, and people – and delivered continuously. Our solutions are proven to drive savings for health plans and employers by improving the health of their populations.

Twill, a company which we recently acquired, is a global, digital-first solution with a mission to improve the mental and physical health of people everywhere. Through Twill, we provide personalized and connected care that accelerates access to mental health and well-being through highly engaging evidence-based programs, supportive communities, human-led coaching and therapy. Twill's solution is used by enterprises, health plans, pharmaceutical companies, and individuals around the world, and is available globally in 10 languages, covering more than 18 million lives.

During the last few years, our strategy has been to evolve from point solution to a comprehensive multi condition platform. We have pursed this strategy since 2021, resulting in various acquisitions and the recent acquisition of Twill.

We believe that digital health is undergoing a massive transformation, as innovators evolve from offering point solutions to more integrated approaches. We believe that we are uniquely poised to answer that call and usher in the next generation of digital health.

Twill Acquisition

With the integration of Twill, we believe that we can achieve multiple advantages as well as synergies in multiple fronts:

1. Product offering
2. Commercial channels
3. Improved clients and member experience and economics
4. Improved financial profile with accelerated path to profitability.

Product Offering

With Twill, we believe we have created the most comprehensive and engaging digital health platform to provide best-in-class support for mental well-being, maternal health, and the costliest chronic conditions. We believe that this unified approach will meet people where they are on their health journey and accelerate access to personalized support and connected care.

With the combination of Twill, we also plan to tap into navigation technology "Twill Care" that helps take over the top of the funnel and help employers and health plans to enroll more members into the platform. With a unified platform, we believe that our platform addresses multiple health needs in a seamless user experience and represents a significant step forward to unlock the value of digital health for our members, clients, and partners. In addition, following the acquisition of Twill, we now have a combined wealth of data and insights across individual care journeys to guide strategy across a wide range of health needs. As a result, we believe that our unified set of solutions, delivering best-in-class outcomes, are now ready to optimize and scale for greater impact.

Commercial Channels

Following the acquisition of Dario and Twill, we are sharing the exact same channels for product offering delivery:

- Employers
- Health Plans
- Pharma

In our experience over the last few years, we believe that payers would like to utilize one integrated solution. We now have synergies with Twill where we can offer such an integrated solution. In addition, our acquisition of Twill creates immediate scale, with four of the five top health plans, multiple Fortune 100 employers, and several major pharmaceutical companies as customers.

Improved client and member experience and economics

Following the acquisition of Twill, we believe we will see a significant improvement in higher revenue per every dollar invested into sales and marketing. We expect improvement in all metrics: more eligible lives to support, improved enrollment rate, higher engagement, and also higher revenue per user on average from total lives.

It all starts with the ability to deliver a streamlined and holistic member journey. With industry-leading activation rates, Twill's immediate access to mental health and well-being support significantly expands our reach across populations. We are then able to keep members engaged through a variety of health and condition areas to meet their dynamic needs. We use billions of consumer data insights to drive 80% retention after one year.

Addressing each person's well-being is the key to delivering lasting behavior change. We are aiming to reach more people by providing them with an approachable entry point to care and a more holistic solution to whole body health. The acquisition of Twill allows us to do more in one place, incorporating some of the most common and interconnected health conditions, to drive more value for both members and customers.

Not only does the combination of our complementary solutions address the market need for more integrated solutions but the combination of two digitally led companies enables us to continue innovating without the usual requirements for deep investment to deliver the ultimate value for our stakeholders' better outcomes at lower cost to accelerate profitability.

Improved financial profile

We believe that the synergies following our acquisition of Twill are also on the organization and operations levels, as both companies are technology companies operating in the health care industry and focusing on the consumer to achieve clinical performance.

Given the synergies above we anticipate improvement in the combined entity financial profile including the potential for 30% annualized cost synergies within two years, a potential increase in revenues on a pro forma basis, an increase in margins and an accelerated path to profitability in 2025 through revenue scale, increased gross margins and cost synergies.

Overview

We began as a direct-to-consumer digital therapeutics company, solving first for the problem of how to engage users and support behavior change to improve clinical outcomes in diabetes. Beginning in 2020, Dario enacted a strategic shift to transform the business model by deploying a business-to-business-to-consumer ("B2B2C") approach, leveraging the strengths of our consumer solution platform to enable commercial growth opportunities in traditional health business channels by selling to health plans and employers.

At the same time, we expanded from a single-condition platform to a multi-condition platform, creating a robust suite of solutions to address the five most commonly co-occurring, behaviorally driven, and expensive chronic conditions, which are also representative of some of the most sought-after digital health solutions: diabetes, hypertension, pre-diabetes/weight management, musculoskeletal and behavioral health. After building weight loss and hypertension management into the legacy diabetes platform, we made three acquisitions in order to expand into musculoskeletal ("MSK") and behavioral health ("BH"). In that regard, we acquired Upright Technologies Ltd. ("Upright"), PsyInnovations Inc. ("PsyInnovations") and Physimax Technology assets to expand into the fields of MSK and BH. Our approach to integrating all solutions into one digital therapeutics platform follows the "best-of-suite" offering design principal which provides the user one place to monitor all identified chronic conditions and to deliver a seamless user experience for commonly co-occurring chronic conditions.

These two shifts led to the rapid expansion of our B2B2C business over the last two years and positioned the company for success in commercial markets. We continue to achieve key benchmarks as we rapidly scale our B2B2C model, including more than 100 total signed contracts as of today and the shift in our commercial pipeline where more than 50% of the contracts signed in the second half of 2022 are for multi-chronic solutions. We believe we have a unique and defensible position in the market thanks to our unique solution origin in consumer markets. In that regard, we have worked with various health care plans, including Aetna, to provide our platform to their members. In January 2024, we launched the Aetna platform with several customers, and we have continued to add customers that are planned for launches through the second quarter of 2024. We have already seen a strong start to the 2024 employer sales cycle with larger opportunities compared to 2023. We anticipate additional health plan customers in 2024 directly and through our partners that cover more than 87 million members.

We continue to generate a significant number of clinical publications. In that regard, we have published 47 real world data studies with total of 10 generated in 2022, 10 generated in 2023, and several more planned for 2024.

Recent Developments

Dario Published Research

In November 2023, we announced new research presented at the Diabetes Technology Society 2023 Meeting on November 7, 2023. The new research demonstrated the value of associating physical activity tracking alongside blood

sugar tracking for people living with diabetes and pre-diabetes. The new study examined the blood glucose and walking data of 989 Dario users to understand the impact of integrating clinical and behavioral data in a single digital app-based experience. The results demonstrated significantly reduced blood glucose levels in the first four months of using Dario and increased step levels in the same timeframe maintained for 12 months. In addition, the results demonstrated clinically significant reductions in blood glucose levels in users who tracked at least 400 steps per day.

In November 2023, we announced two new analyses recently presented by Sanofi U.S. demonstrating two mediators associated with improved clinical and economic in Dario users. Presentations by Sanofi U.S. at the Diabetes Technology Society (DTS) annual conference examined real-world data from matched Dario users and non-users with type 2 diabetes to determine the association of medication adherence from Dario's digital health solution with blood glucose control. Dario users saw an overall clinically significant reduction in HbA1c and an associated 10.6% improvement in medication adherence. The new research helps explain the results of a previously reported study on reductions in HbA1c, because medication adherence is one behavioral component of self-care needed to achieve improved clinical outcomes. In addition, Sanofi also presented research at ISPOR Europe 2023 of a new analysis showing more frequently engaged Dario users were associated with 10% reduction in all-cause healthcare resource use over 100 days and were 15% less likely to incur related charges. Engagement was defined by activities meaningful to diabetes management, such as taking a blood glucose reading; inputting an insulin dose; recording physical activity or tagging a meal. This new analysis provides additional information from previously reported study results demonstrating Dario's ability to contribute to a reduction in all-cause healthcare utilization by 9% including inpatient hospitalizations by 23% compared to non-users at 12 months.

Employer Contracts

In November 2023, we announced a new contract to provide its cardiometabolic solution to an employer beginning in January 2024. The employer, a national financial and business services company, selected Dario to improve the cardiometabolic health of its population with an integrated solution for diabetes, pre-diabetes, weight management and hypertension along with tailored support for employees taking a GLP-1, or anti-obesity, medications.

In December 2023, we announced today a new contract to provide cardiometabolic and GLP-1 solutions to a national employer beginning in January 2024. The employer, a national logistics company, selected Dario to deliver integrated support for employees living with diabetes, pre-diabetes, weight management and hypertension, while also providing a tailored experience for employees taking a GLP-1 medication.

In January 2024, we announced today a new contract to provide its cardiometabolic solution to a regional union, expected to begin in the first quarter of 2024. The Union, representing food industry workers, selected Dario to deliver integrated support for employees living with diabetes, pre-diabetes and weight management needs along with special support for those taking a GLP-1, or anti-obesity medication. The Union joins a growing set of public and labor clients using Dario's solution to provide highly personalized chronic condition management solutions to their members.

Market Landscape

The traditional healthcare industry is siloed and service-centric, and it is difficult for people to access care and support, while the healthcare experience itself remains cumbersome and disconnected. The future of health care is being shaped by digital health technologies that are rapidly becoming more important as access to traditional health care for the management of whole health becomes more difficult. As a direct-to-consumer pioneer, we presciently identified shifting healthcare consumer behaviors early and designed solutions with the intent of enabling users with easy-to-use technologies that support adoption and engagement.

Our members demanded ease of access and personalization, generally absent in health care but a standard in other consumer service experiences, and our unique approach significantly exceeds those expectations with excellent ratings from our members. Commercial digital health solutions currently perform poorly in this area, which leads to low engagement and weak outcomes.

As we expand our commercial business, we believe our consumer-centric solutions position us as a leader in digital health through a best-of-suite platform proven to deliver the experience people are demanding. This enables our service-oriented business model by delivering the engagement our clients demand and yields a stable form of revenue through an Annual Recurring Revenue ("ARR") model.

Longer term, as the market for digital health solutions faces economic pressures, we believe our consumer origins arm has several natural advantages that will help propel our growth and cement our leadership position. First, we amassed a trove of billions of data points from our consumer engagement and dozens of clinical publications including multiyear studies with approximately 50,000 participants.

Second, we built what we believe is the best-in-market clinical platform built with a focus on the overlapping chronic health needs present in our user base. This shift from a single condition platform to a multi-condition platform enables our best-of-suite approach.

Competitive Strengths

We believe that we are proving the value of our solutions as enterprise business sales continue to grow. With more than 100 signed contracts to date, we have solid evidence on the key differentiators that lead to new business opportunities: a consumer-friendly approach that drives engagement; deep integration capabilities; and best-in-class clinical outcomes.

Consumer Friendly Approach

Most digital health solutions are built to address the needs of a business and then sold directly to the business, bypassing the difficult step of achieving consumer buy-in with respect to the product. Our experience as a direct-to-consumer company now leverages those insights to drive B2B2C commercial growth by working with health plans, employers, and provider groups and providing them with a solution that their end users are more likely to utilize. Our current and potential customers recognize that consumer engagement insights are critical to success, and they are prioritizing solutions with more of a consumer-focused experience. We believe that impaired user engagement in competitor solutions could also drive enterprise customers to switch to us.

Deep Integration Capabilities

Our platform was designed with a flexible, open-framework that yields multi-faceted benefits for our members and partners including their clinical health and user experience. Our experience is a best of suite platform that leverages four points of integration to drive a connected, dynamic and adaptive user journey:

- User data is being captured and integrated across the experience, driving a personalized member experience across applications.
- User interface, including mobile applications, have been integrated to support a unified member experience.
- Clinical integration informs recommendations across conditions.
- This is all supported by a fully integrated coaching experience which provides one coach who supports the member across their entire journey.

The native integration of data across our solutions, providing a single view of a member data across all conditions and interactions, fuels our consumer-centric approach to engagement and leads to a more seamless user experience.

Our ability to allow integrations at the platform-level, easily allowing for the ingestion and exportation of data, also positions us as uniquely able to support the more connected healthcare experience that members and our partners increasingly demand. The recent integration of Dexcom CGM data into our platform is one example of the utility of our open-platform, positioning us as an attractive choice for clients and partners interested in building towards the future state of digital health.

Clinical Outcomes

We believe that we lead the digital therapeutic market in published outcomes with 38 studies across our suite of solutions, including the first clinical research demonstrating the positive impact of managing multiple chronic conditions with one digital health solution. Our ability to use large, real-world, longitudinal data-sets gives us a natural advantage in the scope and type of studies that can be conducted compared to competitors.

This capability enables one of the unique elements of our partnership with Sanofi, allowing our data to be consumed by a third party for independent analysis and eventual publication.

Our Product Offering

Our user-centric software platform integrates digital therapeutics, coaching, professional human support and medical devices to drive superior clinical and financial outcomes. Our best-of-suite suite of offerings is modular, allowing for enterprise clients to purchase one or more of our chronic condition management solutions, while enjoying the same best-in-class experience supported by our behavior change journey engine so our partners can be confident in achieving sustainable outcomes and value. Our suite of digital offerings includes:

Dario Metabolic ("Dario Evolve")

Our metabolic solutions are designed to address some of the most commonly co-occurring metabolic health needs - diabetes, pre-diabetes, hypertension, and weight management - through a combination of software, our smartphone-connected tools, interaction with live coaches, and real-time data analysis to help inform and educate users of the relationship between their behaviors and their health outcomes to drive changes that last.

Dario Musculoskeletal ("Dario Move")

Our unique approach addresses the most common MSK conditions, including chronic pain, by dealing with the cause and empowers users to create behavioral change. Dario Move's digital physical therapy programs and posture training help people improve strength and mobility by using a combination of software, wearable biofeedback sensors, and coaching to drive sustainable improvements in musculoskeletal health. The inclusion of posture training in the solution supports ongoing engagement in support of prevention and maintenance outside of an exercise therapy program.

Dario Behavioral Health ("Dario Elevate")

Our behavioral health solution optimizes access to evidence-based care by using an AI-driven screener to triage users and connect them to the most appropriate support across a wide range of mental health needs, including our integrated digital tools and coaching, giving users a seamless path to proven mental health support.

Dario Full Suite ("Dario One")

Our full suite of chronic condition management solutions offers the maximum benefit for our partners with a completely seamless and holistic approach to managing chronic conditions. In addition to a better unified member experience, our partners deploying Dario One enjoy several benefits from purchasing the entire suite of solutions: better overall health as evidenced by recent research published by us; the convenience and ease of a single vendor to manage; less strain on internal resources spread across several chronic condition management programs; and a more affordable program launches due to lower costs of implementation.

Dario's Solution Main Components

Users vary significantly in their interests and preferences, and unique user preferences also vary over time with respect to the optimal timing, tone, content, channel, frequency, and interventions required to produce sustained behavior change. Users' interactions with devices, smartphones, coaches, providers, and third-party solutions must be personalized

along these axes to ensure optimal engagement, retention, and outcomes. Furthermore, to engage and sustain user interest and participation, and drive outcomes, platforms must be dynamically responsive. Due to a lack of responsiveness to these types of variances, most digital health platforms that achieve high initial engagement often fail to retain users over time.

Key to our ability to accommodate user behavioral changes is our mature AI-driven user journey engine. While several in-market solutions now integrate health signals across a range of categories to apply limited, nominal personalization, primarily in the form of nudges, our solution is informed by years of user experience data from over 142,000 users that joined our chronic-condition platform, enabling us to continually personalize and adapt user journeys themselves (and not just messages) over time. Our journey engine drives our multichannel targeted outreach and enrollment campaigns, informs specific recommendations around a range of categories such as diet, physical activity, self-care, coaching interventions, and provider engagement, and evolves in real time in response to the data exhaust from a user's interaction with the care ecosystem.

Our journey engine combines complex behavioral science insights with data from hundreds of thousands of users over several years to recommend AI-driven initial and updated care journeys in response to a user's engagement with the platform. Most digital health solutions consist primarily of tracking, content, and nudges. These are often perceived by users as non-rewarding work, and often do not feel relevant to their concerns, particularly as they evolve over time. We believe that current in-market solutions trivialize within person changes over time and do not appropriately respond to the dynamically evolving interests of users. This results in reduced engagement and impaired outcomes. Our journey engine adapts user journeys to drive engagement, retention, and clinical outcomes by optimizing timing, tone, channel, content, frequency and intervention to deliver dynamically personalized user journeys that are more likely to result in the behavior changes needed to drive improved outcomes across a range of conditions. As we partner with solutions in additional conditions or categories, we engage new populations and generate fresh insights, enhancing the engagement and efficacy of these partnered solutions to deliver additional value to our users. The engine is designed for integration and scale; as we add populations and conditions for which behaviors are primary drivers of outcomes, our engine becomes more adept at customizing a user's evolving preferences and needs.

Software Applications

Our chronic condition management solutions are designed as three separate software applications to provide the best possible user experience across metabolic, MSK and behavioral health needs. Each application is integrated with Dario's single digital therapeutics platform and behavior change journey engine to ensure the same hyper-personalized experience across each person's unique health needs and preferences to keep them on track with healthy changes over time.

Dario Evolve

Dario Evolve helps users change their behaviors and help better manage their diabetes, blood pressure and weight. Using real-time data and analysis, the app helps users track their progress and offers real-time feedback and customized content to support each individual's needs and goals. Integration with the Dario journey engine ensure that each user receives holistic support and a highly personalized experience that keeps them on track for long-lasting results.

Dario Move

Dario Move helps users improve strength and mobility to help address chronic pain and improve overall musculoskeletal health. After completing an online assessment, each user receives a personalized, evidence-based exercise program that can be adjusted throughout their journey based on sensor data or self-reported feedback to a coach or in the app. Dario Move guides members through their tailored program with educational content to support long-term outcomes.

Dario Elevate

Dario's Elevate helps people get the help they need to address common mental health needs. Starting with a responsive, AI-driven screener, elevate triages users to understand the need and recommend the most appropriate support

to help them feel better. Our integrated, evidence-based digital tools and coaching help people learn proven techniques to better manage their emotional health.

Live Coaching

Live coaching is available as part of the Dario experience to give members a human point of contact for support and motivation, and also provide a level of accountability that is proven to help improve engagement and outcomes. As an integrated component of our suite of solutions, our professionally trained and certified health coaches serve as a personal support for each member throughout their journey across all solutions and are able to connect members with clinical experts when members need additional support. Our clinical coaches include Certified Diabetes Educators ("CDCES"), Registered Nurses, Pharmacists and Mental Health Clinicians who are able to assist members throughout their journey.

Dario User Devices

Our product offerings include integrated devices to capture relevant clinical and biofeedback data to support continuous, real-time monitoring of member health. Our native devices include:

- All-in-one smart glucose meter
- Bluetooth connected blood pressure cuff
- Digital Scale
- Biofeedback sensor device

Our Commercial Channels

We are focusing the go-forward business strategy around three key market opportunities: direct sales to employers and payers and partnerships with the ability to multiply our growth opportunities. We believe that our scalable business model selling digital therapeutics as a service through multi-year contracting relationships establishes a pipeline of ARR and has the potential to improve our gross margins over time.

Our software solutions are sold across a range of channels to create multiple growth engines and support rapid adoption across all segments of the market. Our integrated product suite is designed to address a common and growing sentiment from enterprise customers expressing frustration with the large number of condition-specific solutions, lack of transparency, lackluster results and poor member experiences. Our integrated solution aligns with these key buyer pain points and is proven to deliver value to strategic partners through our differentiated approach in the market. Finally, our consumer-centric legacy remains a key component of our commercial strategy, bolstering our ongoing solution development by serving as an innovation laboratory for new services and product enhancements.

Health Plans: Although health plans represent the longest and most complex purchasing cycle across our client base, these contracts often represent sizeable opportunities as they typically offer much larger potential member populations. We currently have three live contracts with health plans, two are regional payers and one is a large national plan, with several additional plans in negotiation and contracting at present day.

Employers: Our most robust growth in 2022 came from the employer market, a key buyer to help demonstrate our ability to deliver results. Today, we have approximately 120 employer populations actively on our platform, and growth of our employer pipeline continues to grow and mature.

Partnerships: Strategic partnerships play a key role in helping to expand our reach across markets quickly and efficiently. Our consumer-centric platform, the rate at which we have evolved our product, added and integrated solutions and provided product improvements and ability to easily share data and support a multitude of integrations makes Dario an attractive choice of partner for many in the market. One such significant partnership agreement is our collaboration with Sanofi, a global leader in health care, a relationship that resulted after an extensive search determined we are uniquely capable of providing the robust data and analytics required by Sanofi. The multi-year, $30 million-dollar agreement, is

helping to accelerate commercial adoption of our full suite of digital therapeutics through the promotion of our solutions in Sanofi's sales channels and the collaborative development of new products. We also entered into partner agreements with several large employer benefits platforms such as Virgin Health Pulse in 2021, helping expand our reach within the employer market.

In addition to our partnership with Sanofi, Dario is actively pursuing distribution partnerships in both the payer and employer verticals. In 2022, we partnered with Solera to establish a payer channel through their large network of plans. We also entered into partnership agreements with several large platforms such as Virgin Health Pulse, Alliant Insurance Services, and Vitality Group, helping expand our reach within the employer market. Dario is actively pursuing new partnerships in both markets to enhance our opportunities with a one-to-many approach.

Consumers: Our ability to engage members and improve health begins with our consumer-centric approach, and this audience remains key to our commercialization at the enterprise client level. Our direct-to-consumer channel continues to attract members to our platform and provides a neutral audience to test innovative product ideas, something traditional B2B companies are unable to do given limitations on commercial membership. These insights inform both our AI-driven behavior change journey engine, helping continuously improve engagement and retention, and inform product design to ensure our solutions remain at the forefront of consumer expectations.

Sanofi U.S. Agreement

On February 28, 2022, we entered into an exclusive preferred partner, co-promotion, development and license agreement (the "Agreement") with Sanofi for a term of five (5) years. Pursuant to the Agreement, we and Sanofi will co-promote certain of our products and services, including devices and accessories, and to develop new products and services based on insights derived from our data relating to the use of those devices and services. In addition, we granted Sanofi a license to access and use certain of our data, and Sanofi granted us a license under certain intellectual property of Sanofi for purpose of developing and promoting certain products and services for Sanofi in the United States.

Pursuant to the Agreement, in consideration of the preferred co-promotion and development rights granted by us, Sanofi agreed to pay us an aggregate amount of up to $30 million over the initial term of the Agreement, consisting of (i) an upfront payment, (ii) annual compensation for development costs per annual development plans to be agreed upon annually and (iii) certain contingent milestone payments upon meeting certain net sales and enrollment rate milestones at any time during the term of the Agreement. The Agreement also provides for us to make certain revenue sharing payments to Sanofi in a percentile beginning in the low double digits to low twentieth percentile of specified revenues upon qualifying sales through Sanofi introductions achieving a minimum revenue amount, and provided that the qualifying sales through Sanofi introductions remain above a specified percentage of total sales after year 3 of the agreement. Revenue sharing in the thirtieth percentile will apply with respect to new solutions or services developed under the agreement.

The Agreement has a term of five (5) years and may be renewed for a subsequent five (5) year term upon the mutual agreement of the parties. The Agreement may be terminated (i) by either party for a material breach, force majeure or insolvency; (ii) by us if net sales requirements are not reached; (iii) by either party for convenience, upon sixty days' prior notice, beginning in the third year of the Agreement; or (iv) by Sanofi if we fail to complete a development plan within nine (9) months of the Effective Date, or upon our change of control.

In July 2023, we entered into an amended and restated strategic agreement with Sanofi, an innovative global healthcare company. In this amendment, the parties adjusted certain pre agreed economic parameters, to better align the common interests of the parties in light of the developments in the digital health market after the first year of partnership, including revenue share adjustments that align with both parties' strategic goals. The changes apply to certain customers in exchange for additional promotional activities to be performed by Sanofi. The parties also agreed to allow the acceleration of certain development milestones agreed upon in the initial agreement. This multi-year, $30 million agreement, which is subject to certain contingencies, will help accelerate commercial adoption of our full suite of digital therapeutics and drive the expansion of digital health solutions on our platform. We and Sanofi will collaborate on promoting our multi-condition digital therapeutics solution, significantly increasing our sales reach in the health plan market and selectively in the employer channel. In addition, the agreement calls for us and Sanofi to develop new or

enhanced solutions leveraging our platform, and for the parties to generate robust evidence to support future commercialization in the health plan channel.

Clinical Studies

Main Highlights

Our studies below demonstrate the clinical value of our legacy digital therapeutic devices and the ability of our solutions to deliver sustainable outcomes over time.

Dario reported an Average Reduction in Estimated HbA1C of 1.4% for High-Risk type 2 Diabetes Users.

We presented at the 77th ADA session a study that was titled "Reducing A1C Levels in Individuals with High-Risk Diabetes Using the Mobile Glucose Meter Technology." In the study we reported an average reduction in estimated HbA1C of 1.4% for high-risk type 2 Diabetes users.

At the ADA 2018 session, Dario presented three real-world-data analysis studies, as detailed below.

Type 2 Diabetes Users of Dario Digital Diabetes Management System Experience a Shift from Greater than 180 mg/dL to Normal Glucose Levels with Sustainable Results

- *Reduction of 19.3% in high glucose readings within 12 months*
- *Increase of 11.3% in in-range readings within 12 months*

***Methods**: A retrospective data evaluation study was performed on the Dario™ cloud database. A population of all active Type 2 Diabetic (T2D) users that took measurements with Dario™ Blood Glucose Monitoring System ("BGMS") on average of 20 measurements per month during 2017. The study assessed the ratio of all high blood glucose readings (180-400 mg/dL) and the ratio of all normal blood glucose readings (80-120 mg/dL) in their first month of use to their last month of use during 2017 as recorded in the database.*

***Results**: For 17,156 T2D users activated during 2017 the average ratio of high events (180-400 mg/dL) was reduced by 19.3% (from 28.4% to 22.9% of the entire measurements). While at the same time, the ratio of normal range readings (80-120 mg/dL) was increased by 11.3% (from 25.6% to 28.5% of the entire measurements).*

***Updated Analysis** combining 2017 and 2018 data totals 38,838 Type 2 Diabetes active users and 3,318,014 measurements show 14.3% decrease in high readings (180-400 mg/dL) and 9.2 % increase in In-range (80-120 mg/dL) readings.*

A decrease in High Readings and Severe Hyperglycemic Events for People with T2D over the Full Year of 2017 in Users Monitoring with Dario Digital Diabetes Management System

- *Reduction of 20% of High events (180-400 mg/dL) in T2D sustained within 12 months*
- *Reduction of 58% of Hyper events (>400mg/dL) in T2D within 12 months*

***Methods:** A retrospective data evaluation study was performed on the Dario™ cloud database. A population of active Type 2 Diabetic (T2D) users that continuously measured their blood glucose using Dario™ BGMS during the full year of 2017 was evaluated. The study assessed the ratio of high (180-400 mg/dL) and hyperglycemic (>400mg/dL) blood glucose readings during full year of 2017 as recorded in the database. The average of high and hyperglycemic glucose readings were calculated in periods of 30-60, 60-90, 90-120, 120-150, 150-180, 180-210, 210-240, 240-270, 270-300, 300-330, 330-360 days and compared to first 30 days as a starting point of analysis.*

***Results:** For 225 T2D active users the ratio of high events (180-400 mg/dL) was reduced gradually in 19.6% (from 23.4% to 18.8% of the entire measurements) from baseline compared to the 12th month of the year. Moreover, the*

ratio of severe hyperglycemia events (>400 mg/dL) was decreased in 57.8% (from 0.90% to 0.38% of the entire measurements) at the same period.

Continuous Reduction of Blood Glucose Average during One Year of Glucose Monitoring Using Dario Digital Monitoring System in a High-Risk Population

- *The study presented a reduction of 14% Blood Glucose average was observed in T2D within 12 months*
- *76% of the population showed 24% improvement in Blood glucose average within 12 months*

***Methods**: An exploratory data analysis study reviewed a population of high-risk active type 2 Diabetic users with initial 30 days glucose average above 180 mg/dL during a full calendar year. The study assessed the average blood glucose readings along a year of usage. The average glucose readings was calculated per user in periods of 30 days intervals from 30-60 to 330-360 days and compared to the first 30 days as the starting point baseline of analysis.*

***Results:** Overall of 238 highly engaged T2D users (more than one daily measurement in average) whose average blood glucose level was above 180mg/dL in the first 30 days of measurements (225±45 mg/dL) showed continuous reduction in glucose level average vs. baseline. Reduction in blood glucose average level was demonstrated gradually, in the succeeding 3, 6 and 12 months showing average decrease of 7%, 11% and 14% vs. baseline, respectively. Furthermore, 76% of the entire population (180 out of 238 users) improved their average blood glucose level over a year. Those 180 users (average blood glucose 228±46) showed an average decrease of 10%, 16% and 24% in their glucose average following 3, 6 and 12 months, respectively.*

At the American Association of Diabetes Educators (AADE) 2018 Dario presented a study titled "Decrease in Estimated A1C for people in High-risk over a full year of users monitoring with a digital Diabetes management system."

A reduction of 1.4% in estimated HbA1C in Type 2 Diabetes high risk users from baseline after one year of the Dario system use.

***Methods**: A retrospective data evaluation study was performed on the Dario™ cloud database. A population of high-risk (with baseline A1C > 7.5 percent), active users that continuously measured their blood glucose using Dario™ BGMS during a full year was evaluated. The study assessed estimated A1C values based on blood glucose readings during a full year as recorded in the database. The estimated A1C values were calculated in periods of 3, 6, 9 and 12 months and compared to first 30 days as a starting point of analysis.*

***Results**: A group of 363 high-risk Dario BGMS users (A1C>7.5) with greater than two blood glucose measurements taken per day in the first 30 days and in the 12th month of the year was selected. Estimated A1C was improved by -0.7, -0.8 and -1 percent from baseline to 3, 6 and 9 months respectively, and remained -1 percent lower following 12 months of usage (8.65±0.96 vs.7.65±1.0). Moreover, subgroup analyses by diabetes type revealed substantial estimated A1C improvement among people with T2D showing improvement of -1 percent from baseline to 3, 6 months and 1.4 percent following 12 months (8.5 ± 0.91% vs. 7.14% ± 0.98%).*

An additional study evaluated the potential improvement in glycemic variability in Type 2 diabetes over six months in patients monitoring with Dario Digital Diabetes Management System. Dario presented the study results at the Advance Technologies and Treatment for Diabetes (ATTD) conference in February 2019 in Berlin. We presented two additional studies outcomes at ADA 2019 conference.

Decrease in Glycemic Variability for T2D over Six Months in Patients Monitoring with Dario Digital Diabetes Management System

- *The study demonstrated a reduction of 14%-18% in measurements variability was observed in T2D within 6 months*
- *Hypo events (<70 mg/dL) remained <1 event on average*

Methods: *A retrospective data evaluation study was performed on the Dario™ database. A population of T2D high-risk patients (blood glucose measurements average (GM_{avg}) >180 mg/dL) measuring more than 20 times in the first 30 days (analysis baseline) was evaluated on days 60-90 (3 months) and 150-180 days (6 months). Standard deviation (SD) and GM_{avg} were calculated and compared to the baseline.*

Results: *A group of 698 T2D high-risk Dario™ users was selected. GV was reduced by 10% and 14% from baseline through 3 and 6 months, respectively (SD of 55.7, 58.4 vs.65.0). GM_{avg} was reduced by 8% and 12% from baseline through 3 and 6 months, respectively (201.1±25.57, 192.8±54.3 vs. 219.5±38.5) while patient's hypoglycemic event (<70mg/dL) was in average, less than one (<1) during this period. Subgroup analyses (355 patients) revealed substantial GV improvement among non-Insulin T2D patients. The GV was reduced by 14% and 18% from baseline through 3 and 6 months, respectively (SD of 52.8, 50.7 vs.61.7).*

T2D Users of Dario Digital Diabetes Management System Experience an Increase of in-range Glucose Levels Linked to App Engagement

Relative Increase of 10 % In-range linked to App engagement

Methods*: A retrospective data evaluation study was performed on the Dario™ cloud database. A population of active Type 2 Diabetic (T2D) users (>15 measurements per month on average) was evaluated. The study assessed the ratio of in-range blood glucose readings (70-140 mg/dL) as a function of App engagement level for 6 months as recorded in the database compared to first 30 days as a starting point of analysis.*

Results*: A population of 4917 T2D non-insulin users measuring more than 15 times per month on average during 6 months in a row was evaluated. The ratio of in-range (70-140 mg/dL) readings was increased following 3 months in correlation to the level of tagging meal reference/carbs/physical activity occurrences (4.0%, 9.1% and 11.9% for tagging 0-1, 1-2 and >2 times per day on average, respectively) and sustained for 6 months.*

Reduction of Blood Glucose Average Less than 140mg/dL in People with Type2 Diabetes Using Dario Digital Diabetes Management System

30-40% of T2D Dario users experienced Reduction of Blood Glucose Average below 140 mg/dL

Methods: *A retrospective data evaluation study was performed on the Dario™ cloud database. A population of active T2D users that continuously measured for 6 months was evaluated. The study assessed their BG avg and estimated A1C (eA1C) values based on blood glucose readings as recorded in the database. Values were calculated in periods of 3 and 6 months and compared to their first 30 days as a starting point analysis.*

Results: *A group of 1248 Dario BGMS T2D active users (1.98 measurements per day on average during 6 months in a row) with BG avg >140mg/dL (eA1C>6.5) was evaluated. All 1248 (100%) reduced their BG avg along 6 months on average.*

A group of 31% (387) achieved BG avg of <140 mg/dL (eA1C<6.5) following 3 months showing 19% reduction on average from baseline (132.38±13.36 vs.162.79±25.41 mg/dL and eA1C 6.24±0.46 vs 7.3±0.88) and sustained their glycemic control during a 6 month period (131.57±13.86 mg/dL and eA1C 6.21±0.48).

Subgroup analyses of 568 non-insulin users revealed that 40% (226) achieved a BG avg <140 mg/dL following 3 months (131.95±13.21 vs.161.67±24.18 mg/dL and eA1C 6.22±0.46 vs 7.26±0.84) and sustained for 6 months period (131.03±13.70 mg/dL and eA1C 6.19±0.47). Along the 6 months period, hypo events (<50mg/dL) per user per month on average remained stable.

In August 2019 another study was presented at the AADE 2019 in Atlanta. The study evaluated the "Impact of Digital Intervention on In-range Glucose Levels in Users with Diabetes." The study results showed 6% improvement in average blood glucose levels over 3 months intervention program for a group of 162 users. A 39% increase in the in-range (80-130 mg/dL; <180mg/dL post-meal) measurements was observed in a subgroup of 101 patients who started with average blood glucose levels of over 140mg/dL. In November 2019, another analysis was presented in Diabetes Technology conference "The Effect of Digital Intervention on Glycemic Control in Users with Diabetes" looking on total in-range measurements ratio 70-180 mg/dL showing increase of 19% following 3 months on the Dario Engage platform.

In In February 2020, we presented an additional clinical study at the ATTD conference in Madrid, Spain. The presented data shows the Dario digital therapeutics platform successfully assists insulin dependent patients with diabetes in reducing hypoglycemic events.

Decrease in Hypoglycemia Events Over Two Years in Patients Monitoring with Dario's Digital Diabetes Management System

***Methods*:** A retrospective data analysis was performed on the Dario real-world database. Insulin dependent of users with type 1 or type 2 diabetes population was evaluated for two years of continuous system use. Average numbers of level 1 hypoglycemia (<70mg/dL) and level 2 hypoglycemia (<54 mg/dL) events were calculated monthly and compared to baseline (first month).

***Results*:** For 1481 type 1 and type 2 insulin dependent users, average of level 1 hypoglycemia events and level 2 were reduced by 24% and by 17% after 6 months and by 50% and 57% after 2 years vs. baseline respectively. Users with type 1 diabetes (N=363) reduced level 1 hypoglycemia events by 50% and Level 2 by 55% after 2 years. Moreover, a 40% reduction in high blood glucose readings was observed as well after 2 years.

In June 2020, we presented two clinical studies at the ADA Virtual conference. The presented data from these studies showed:

Estimated A1C Reduction in High-Risk Patients Over Two Years of Using a Digital Diabetes Management Platform

This study presented data indicated the potential for a digital diabetes management solution to effect and sustain glycemic control improvements and demonstrated long term reduction of blood glucose average (eA1c) and glycemic variability in type 2 diabetes over two years. The system assists users through a variety of mechanisms including behavior modification in diabetes self-management and in long-term routines for self-care.

***Methods*:** A retrospective study of high-risk users (BG avg >180 mg/dL equivalent to e A1c 8.0) 2 with type 2 diabetes that measured their blood glucose using the Dario® platform database over two consecutive years was performed. The minimum engagement level for inclusion was at least two blood glucose measurements per day on average taken in Month 1 and Month 24. Actual blood glucose readings were taken by the Dario meter and loaded into the cloud database. These were evaluated for the blood glucose average (BGavg), estimated A1c (eA1c) values and glycemic variability (by Standard Deviation; SD) following 24 months compared to the first month (baseline).

***Results*:** 368 high-risk, T2D active and engaged users for at least consecutive 2 years were identified and assessed for their risk-level and insulin usage. A group of 148 T2D, non-Insulin users that started with a blood glucose average (BG avg) >180 mg/dl (equivalent to eA1c>8.0) consistently reduced their BG avg by 18% on average and sustained these values (179±45 vs. 219±56 mg/dL) following 2 years on the Dario platform. Glycemic variability was reduced over two years by 20% on average (SD:45 vs. 56). Substantial reductions were observed for higher risk groups (insulin and non-insulin treated). The subset that started with average BG levels > 212 mg/dL (eA1c >9.0) and average BG levels >240 mg/dL (eA1c>10) reduced their average BG by 22.5% and 25.7% respectively on average over two years. The equivalent reductions in eA1c were 1.95% and 2.42%.

Users with type 2 diabetes using a digital platform experienced sustained improvement in blood glucose levels.

***Methods*:** A retrospective data evaluation (Q1:2018-2019) was performed on the Dario® data base. A population of active users (18 measurements per month with the Dario® System on average) with T2D, non-Insulin treated was evaluated over a full year. High blood glucose readings (180-400 mg/dL, >250 mg/dL), fasting readings (<126 mg/dL) and post-meal readings (<180mg/dL) ratios were assessed in their first month of use until the 12th month.

***Results*:** For 9,200 users with T2D, non-Insulin users, the average ratio of high glycemia events (180-400 mg/dL) from entire set of measurements was reduced by 26% (18.62% vs. 23.43%) while readings of >250mg/dL were reduced by 33% (4.65% vs. 6.93%) over a year. Fasting measurements analysis revealed an increase of 16% in ratios of readings <126 mg/dL per entire set of fasting measurements (40.59% vs. 34.92%) on average.

In August 2020, we presented an additional clinical study at the Virtual Association of Diabetes Care & Education Specialists (ADCES) conference. The presented observational study data demonstrated better glycemic and blood pressure control. Patients using an integrated chronic disease management digital platform have the potential to improve user activation which may assist to better manage their blood glucose and blood pressure levels and sustain behavioral change.

Impact of Digital Management on Clinical Outcome in Patients with Chronic Conditions: diabetes and hypertension.

The study presented Hypertension and Diabetes clinical outcomes.

Hypertension: Increase in normal level % measurements from 6% to 12% while hypertension stage 2 measurements decreased from 53% to 45%. 70% of the users (243 out of 345) improved their blood pressure levels by 8.4 mmHg Systolic and 6.2 mmHg Diastolic, on average.

Glucose levels: A reduction of 33% in high readings (>250 mg/dL) and 67% in severe events (>400 mg/dL) was observed over six months.

Methods: A retrospective data evaluation study was performed on the Dario™ cloud database. A population of active users that measured both blood pressure and blood glucose for at least 3 months was observed. Blood pressure and blood glucose levels were evaluated. First month measuring on Dario platform was used as study baseline. Clinical outcomes examined were blood pressure values, percentage of blood pressure categories, average blood glucose (BGavg) and high blood glucose readings (>250 mg/dL, >400 mg/dL) ratios.

Results: A group of 345 active users started at baseline with Hypertension stage 1, 2 or hypertensive crisis levels and measured following 3 months was evaluated.

- Blood pressure outcomes:
  - Normal levels increased from 6% to 12% and percentage of users with hypertension stage 2 decreased from 53% to 45%
  - 70% of the users (243 out of 345) improved their blood pressure levels in 8.4 mmHg Systolic and 6.2 mmHg on average (Systolic 134.2±12 vs.142.6±14; Diastolic 89.9 ±11 vs.83.7 ±8.7)
- Blood Glucose outcomes:

- A group of 345 users measured with Dario their blood glucose in addition to blood pressure, 89% are type 2 and pre-diabetes - average age is 60.4.
- For the group of 345 users a reduction of 33% (5.4% vs.8.0%) in high readings ratio (>250 mg/dL) and 67% (0.3%vs.0.9%) in severe events ratio (>400 mg/dL) was observed following six months on average.

A subset of 114 users with diabetes in higher risk started with BG average >160 mg/dL improved their average blood glucose by 14% (207±47 vs.177±50 mg/dL) following six months compared to baseline.

In November 2020, we presented additional clinical study data at the Virtual Diabetes Technology Society (DTS) meeting.

The Effect of a Digital Therapeutic Platform on Glycemic Control in Adults above Age 65 with Type 2 Diabetes.

This study showed reduction of 13% blood glucose average in age group ≥65 (N=298) at six months sustained for 12 months, and reduction of 38.1% in high readings ratio (>250 mg/dL) in the ≥65 age group at six months and by 41.5% at 12 months.

In Feb 2021 we published in the first time in a peer-reviewed journal "*Journal of Medical Internet research (JMIR) Diabetes",* the article:

"Role of Digital Engagement in Diabetes Care Beyond Measurement: Retrospective Cohort Study"

This study sheds light on the source of the association between user engagement with a diabetes tracking app and the clinical condition, highlighting the importance of within-person changes versus between-person differences. Our findings underscore the need for and provide a basis for a personalized approach to digital health.

***Methods*:** This retrospective real-world analysis followed 998 people with type 2 diabetes who regularly tracked their blood glucose levels with the Dario digital therapeutics platform for chronic diseases. Subjects included "nontaggers" (users who rarely or never used app features to notice and track mealtime, food, exercise, mood, and location, n=585) and "taggers" (users who used these features, n=413) representing increased digital engagement. Within- and between-person variabilities in tagging behavior were disaggregated to reveal the association between tagging behavior and blood glucose levels. The associations between an individual's tagging behavior in a given month and the monthly average blood glucose level in the following month were analyzed for quasicausal effects. A generalized mixed piecewise statistical framework was applied throughout.

***Results*:** Analysis revealed significant improvement in the monthly average blood glucose level during the first 6 months (t=−10.01, P<.001), which was maintained during the following 6 months (t=−1.54, P=.12). Moreover, taggers demonstrated a significantly steeper improvement in the initial period relative to nontaggers (t=2.15, P=.03). Additional findings included a within-user quasicausal nonlinear link between tagging behavior and glucose control improvement with a 1-month lag. More specifically, increased tagging behavior in any given month resulted in a 43% improvement in glucose levels in the next month up to a person-specific average in tagging intensity (t=−11.02, P<.001). Above that within-person mean level of digital engagement, glucose levels remained stable but did not show additional improvement with increased tagging (t=0.82, P=.41). When assessed alongside within-person effects, between-person changes in tagging behavior were not associated with changes in monthly average glucose levels (t=1.30, P=.20).

In February 2021, we also presented two studies virtually in ATTD.

Impact of a Digital Intervention Engine on Diabetes Self-management

A digital diabetes platform has the potential to consistently interact with users, improve self-management and sustain among users who had not recently measured their blood glucose.

Methods: A retrospective study was performed on a population of 246 Dario active members who had not measured blood glucose for a 7-day period. 127 of these users were randomly assigned to a Test group and experienced a digital intervention flow, and the remaining 119 users were assigned to a Control group.

***Results*:** Digital engagement levels were observed following 60 days in both groups. Differences between Test group and Control group were observed. In the Test group, the percent of users who measured blood glucose was significantly higher ($P<0.001$): 14% in first 30 days and 22% in 30-60 days; average number of measurements was 6% higher in the first 30 days and 17% in 30-60 days; number of interactions (e.g. logging fasting glucose) with the digital platform was 10% higher in first 30 days and 15% in 30-60 days. Difference in average days between measurements, defined as "recency" was 30% lower in the test group.

Impact of a Digital Therapeutic on Insulin Self-Management

The potential benefit of a digital diabetes management platform in the self-management required from insulin treated users, incorporating its use on a daily base, and sustaining behavioral change.

***Methods*:** A retrospective study was performed on a population of 285 active Dario users (85% with type 2) under insulin therapy, that measured with Dario for at least three months and logged basal insulin usage. The group included 112 users whose starting average blood glucose >180 mg/dL. Among this group the average age was 50±20.8. The group also included 173 users whose starting average blood glucose was <180 mg/dL with average age 54±19.9. First month measuring on platform was used as study baseline.

***Results*:** In the sub-group of 112 users the average amount of basal insulin increased by six units after three months (45 vs.39). Their fasting blood glucose was significantly reduced (9%) after three months (186±57 vs. 204±62) without change in hypoglycemia events ratio (<70 mg/dL) on average, and 15% of the users reduced their fasting average to <126 mg/dL. However, in the sub-group of 173 users, basal insulin usage and fasting glucose levels remained stable following three months.

In May 2021, a prospective pilot study was published in a peer reviewed journal "Journal of Diabetes Science and Technology":

"Digital Therapeutics for Type 2 Diabetes: Incorporating Coaching Support and Validating Digital Monitoring"

The study suggests that a diabetes digital platform with real-time feedback and access to coaching improved diabetes outcome measures such as HbA1c with a reduction in GV. Importantly, we provide clinical validation for digital self-monitoring to deliver personalized care for patients with type 2 diabetes mellitus ("T2DM"). Future research should replicate our findings using a larger sample.

***Methods*:** In this study (ClinicalTrials.gov: NCT04057248), 12 participants with baseline HbA1c >8.5% were provided with Dario digital therapeutic platform (connected blood glucose meter, test strips, mobile app and access to live CDCES). At both study enrollment and completion, participants completed blood testing and a satisfaction report. During 3-month intervention, participants tracked their blood glucose levels through the app and were routinely contacted by CDCES. Clinical outcomes and self reported data before and after intervention were compared.
***Results*:**

- Significant reduction in lab values such as HbA1C (2 points), Fasting Blood Glucose (18%) and Body Mass Index (BMI) (10%)
- Statistically significant improvement in glucose variability (21%)
- Significant improvement in self-reported evaluation in weight and glucose control satisfaction
- Weekly engagement with CDCES predicted reduction of participants' GV during the following week

In June 2021, two studies were presented in 81th ADA:

Impact of Digital Intervention Tools on Engagement and Glycemic Outcomes

Product updates to digital platforms that guide on healthy eating and help users understand their glucose readings in context may assist users in improving the management of their diabetes.

***Methods*:** A retrospective data evaluation study was performed on Dario ™ members during the time before and after product modification. Digital engagement and clinical outcomes were measured on first to six months per each period to examine if habit formation was achieved.

***Results*:** A group of total 9794 users who had enrolled in a membership for 6 months or longer was evaluated. The digital engagement was improved. The ratio of measurements logged with context (fasting, pre-meal, post-meal, bedtime) was increased significantly by 56% in the first month following product modification on average (51.3%. vs. 32.8%) (P<0.001). Differences in the level of digital engagement remained stable over a 6 month period. The average number of days between measurements, i.e. "recency" decreased by 21% on average (2.71 vs. 3.45). Average ratios of high readings (180-400 mg/dL) were reduced by 12% on average over six months.

Users with high-risk type 2 diabetes using a digital therapeutic platform experience a change in blood glucose levels

Digital diabetes platform has the potential to enhance self-care behaviors across socioeconomic statuses and among different language speakers.

***Methods*:** A retrospective data evaluation study was performed on the Dario™ data base. A population ("high-risk users") of all users with type 2 diabetes activated during 2017-2020 who took measurements with Dario in the first 2 months and who started with an average blood glucose above 180 mg/dL was evaluated. The ratios assessed were target range (70-180 mg/dL) and high blood glucose (>180 mg/dL) readings over a year. Socioeconomic status was matched by applying zip code data to census.gov data.

***Results*:** For 11,101 users, the average ratio of target range readings (70-180 mg/dL) was significantly increased from 28.4% to 54.8% (P<0.001). Average high events ratio (>180 mg/dL) was significantly reduced from 71.3% to 44.4% over a full year usage (P<0.001). The change appeared in the earliest months and was maintained over a year. Average number of days between measurements, i.e., "recency" was 3.3 days. A subset of Spanish language app users (N=169) was also evaluated, and comparable trends were observed. Matching Census.gov data on study population showed that 20% of users resided in low income zip codes, 70% in middle and 10% in upper income zip codes.

In August 2021, we presented additional clinical study data at the ADCES meeting.

Efficacy of a tailored digital intervention tool targeting patients with clustered recurrent high glucose readings

The potential benefit of implementing a real-time digital diabetes intervention journey to recognize episodes of high blood glucose measurement clusters and assist patients in improving self-management and clinical outcomes.

Methods: A retrospective data evaluation study was performed on a population of 3,609 users who experienced a cluster event of frequent high blood glucose levels above 250 mg/dL (>=4 times in 4 different days along 7 days) and measured with Dario at least one month before and after the event during 2021. A group of 1,084 users was assigned to a Test group who experienced a digital intervention flow with personalized messages via various channels. The remaining 2,525 users were assigned to a Control group. The clinical outcome examined was the monthly average of high blood glucose readings ratio calculated as the number of blood glucose measurements >250 mg/dL per total number of measurements in a month. This was measured during the event month and in the following month. T-test was used to compare the changes in high readings ratio in the Test group and Control group in the following month versus event month.

***Results*:** A significant difference of 19% vs. control group (N=3,609), 18% for the group with type 2 (N=2307) and 42% for the group with type 2 non-insulin, in the reduction in average monthly ratio of high readings (above 250 mg/dL) per total blood glucose measurements in the following month. The results indicate personalized communications are effectively influencing positive lifestyle behavior change

A group of 454 users experienced the cluster event in a 6-month period before the digital journey was activated and after. A significant difference was observed after the digital journey versus before the digital journey in the following month's change in high readings ratio (-8% vs. +5%; P-value <0.03)

In February 2022, another manuscript was published in "*Journal of Medical Internet research (JMIR)"*

"Blood Pressure Monitoring as a Digital Health Tool for Improving Diabetes Clinical Outcomes: Retrospective Real-world Study"

The results of this study shed light on the association between BG and BP levels and on the role of BP self-monitoring in diabetes management. Our findings also underscore the need and provide a basis for a comprehensive approach to understanding the mechanism of BP regulation associated with BG.

***Methods*:** In this retrospective, real-world case-control study, we extracted the data of 269 people with type 2 diabetes (T2D) who tracked their BG levels using the Dario digital platform for a chronic condition. We analyzed the digital data of the users who, in addition to BG, monitored their BP using the same app (BP-monitoring [BPM] group, n=137) 6 months before and after starting their BP monitoring. Propensity score matching established a control group, no blood pressure monitoring (NBPM, n=132), matched on demographic and baseline clinical measures to the BPM group. A piecewise mixed model was used for analyzing the time trajectories of BG, BP, and their lagged association

***Results*:** Analysis revealed a significant difference in BG time trajectories associated with BP monitoring in BPM and NBPM groups (t=–2.12, P=.03). The BPM group demonstrated BG reduction improvement in the monthly average BG levels during the first 6 months (t=–3.57, P<.001), while BG did not change for the NBPM group (t=0.39, P=.70). Both groups showed similarly stable BG time trajectories (B=0.98, t=1.16, P=.25) before starting the use of the BP-monitoring system. In addition, the BPM group showed a significant reduction in systolic (t=–6.42, P<.001) and diastolic (t=–4.80, P<.001) BP during the first 6 months of BP monitoring. Finally, BG levels were positively associated with systolic (B=0.24, t=2.77, P=.001) and diastolic (B=0.30, t=2.41, P=.02) BP.

In February 2022, we presented virtually in ATTD:

Impact of a digital therapeutic platform on weight loss and diabetes self-management

This observational study demonstrates the potential for digital platforms to durably improve diabetes and weight self-management among users with BMI of ≥30 kg/m^2.

***Methods*:** A retrospective study was performed on 715 Dario active members who started with a baseline BMI of ≥30 kg/m^2 (51% male; 48% female; 80% with type 2 diabetes) and who recorded weight measurements for at least 12 months. Weight measurements and blood glucose readings were observed over 12 months.

***Results*:** The total population of 715 users who participated in the study improved their weight level on average ($p<0.05$). Nearly two-thirds of the population improved their weight, with an average reduction of 7.4% ($p<0.05$) and an average reduction in BMI of 2.8 kg/m^2. Over 30 percent achieved weight loss of 5% or greater over 12 months. A subset of 237 engaged users who started with BMI of ≥35 kg/m^2 achieved weight loss of 5% over 12 months ($p<0.05$). The subgroup of 108 users that started at high-risk blood glucose levels (average blood glucose >180 mg/dL) reduced their weight by 4.9%, average blood glucose by 16.1% and high readings ratio by 38% over 12 months ($p<0.05$).

In June 2022, three retrospective data analysis studies were presented in 82th ADA:

Persons with high-risk diabetes, depression and stress using a Digital health platform experience improvement in glycemic management

The use of a multi-condition digital therapeutic platform may be associated with improved glucose management for persons with "high risk" glycemia who cope with depression and stress. The present study revealed that a digital multi-condition platform has the potential to enhance self-care behaviors among people with diabetes that suffer from stress and depression.

***Methods*:** A retrospective data analysis on the Dario^{TM} database of users who activated the mobile app during 2019-2021 and who self-reported stress and depression in the app questionnaire. Participants who took at least 5 measurements during their 1st and 12th months with Dario and who started with an average blood glucose >180 mg/dL were termed "high-risk". A statistical analysis (T-test) was used to evaluate the differences in average blood glucose and high blood glucose (>180 mg/dL) readings ratio over a year.

***Results*:** The high-risk group of 491 users significantly reduced their average blood glucose by 13% (204±60 vs. 234±55) ($P<0.001$). A subset of high-risk users with type 2 (N=379) was also evaluated and significantly reduced their average blood glucose by 14% ($P<0.001$) (201±66 vs. 233±53). Moreover, high glucose events ratio (>180 mg/dL) was significantly reduced from 72.6% to 55.8% over a full year of usage ($P<0.001$) (N=343).

Hypertension control among persons with diabetes using a self-management multicondition digital platform

A multi-condition digital therapeutic platform may promote behavioral modifications and result in sustainable improvements in both glycemic control and blood pressure levels. The study demonstrates an improvement in multiple chronic conditions (diabetes and hypertension) for people using one digital platform.

***Methods*:** A retrospective data evaluation was performed on the Dario database. A population of active users who started with hypertension stage 1 (Systolic ≥130 mmHg or Diastolic ≥ 80mmHg) as their baseline since 2019 was identified. Blood glucose and blood pressure readings were assessed at first and sixth month of use. A subgroup of users who started at hypertension stage 2 was evaluated as well. A statistical analysis (T-test) was used to evaluate differences in Systolic and Diastolic pressures and average blood glucose.

***Results*:**

For the 2554 users with diabetes and hypertension stage 1 and above, more than two thirds improved their systolic blood pressure by 13 mmHg ($P<0.001$; 144±14 to 131±13) and diastolic blood pressure by 8 mmHg ($P<0.001$; 91±12 to 83±10) over six months.
Additionally, a group of 38.7% (N=990) moved to a lower hypertensive stage ($P<0.001$) according to American Heart Association definitions.

The subset of 1367 users with stage 2 hypertension improved their systolic blood pressure from 150±12.4 to 141±15.2 mmHg on average and 43.9% (N=600) improved their blood pressure by more than 10 mmHg over six months (P<0.001).

The subgroup of 306 users who started at high-risk blood glucose levels significantly reduced their blood glucose average by 15% over 6 months (232.4±46 to 198±65 mg/dL) (P<0.001).

Blood Glucose Levels in High-Risk Type 2 Diabetes Users of a Digital Therapeutic Platform by Race/Ethnicity

Digital therapeutic platforms may promote behavior modification in high-risk patients with type 2 diabetes to create sustainable outcomes and allow the users to become more active participants in their chronic condition. The study revealed that the digital diabetes platform has the potential to enhance self-care behaviors across diverse populations.

Methods: A retrospective data study was performed on the Dario database. A group of Dario digital therapeutic users with type 2 diabetes that was active during 2019-2021 and took at least three blood glucose measurements in the first and 12th months was evaluated. The group started with average blood glucose above 180 mg/dL in the first month and reported Ethnicity in the app: White, Latino, Black, or Asian. The baseline was defined as the first month's average blood glucose. A statistical analysis (Wilcoxon and Kruskal – Wallis tests) was used to evaluate the difference between groups in their average blood glucose levels over a year.

***Results*:**

A group of 1,000 users was analyzed, male 483 (48%) and female 517 (52%). Average blood glucose was significantly reduced in all users and per ethnic group over a year: All users by 14% (230±58 vs. 197±47) (p<0.001); White by 14% (229±58 vs. 197±47)) (p<0.001); Latino by 15% (237±59 vs. 202±48) (p<0.001); Black by 15% (230±63 vs. 196±48) (p<0.001) and Asian by 15% (229±55 vs.195±43) (p<0.005).

No difference between the groups was found at 12th month(P=0.751).

In August 2022, we presented a retrospective data analysis study in the ADCES.

Digital therapeutic platforms improve blood glucose management across rural/nonrural groups.

The study supports the hypothesis that digital diabetes platforms have the potential to enhance self-care behaviors across challenging population from varied socioeconomic statuses in high-risk patients with T2DM.

Methods: A retrospective data study was performed on the Dario database. A group of T2DM "high-risk" users started with an average blood glucose of 180 mg/dL and above in the first month (baseline), was evaluated. The group of Dario users were active at 2019-2021 and took at least six blood glucose measurements in the first, 6th and 12th months. Members residency was defined as rural or nonrural based on whether their community was eligible to apply for Rural Health Grants by the Federal Office of Rural Health Policy ("FORHP") (10). Nonparametric tests were used to evaluate the differences in average blood glucose levels over a year.

Results:

- A group of 1333 users was analyzed with demographic characteristics as follows: Nonrural 1157 (87%) and Rural 176 (13%).

- The blood glucose average mg/dl was significantly reduced (Friedman tests) in all users and in each rural/nonrural group over a year: Nonrural reduced by 17% from T_0 to T_{12} (228±59 vs. 190±47) (P<0.001); Rural reduced by 13% from T_0 to T_{12} (224±60 vs. 196±51) (P<0.001).

- No significant difference between Rural/Nonrural groups was found at first, 6th and 12th months periods (Kruskal-Wallis, P=0.235/0.163/0.142 respectively).

In August 2022, we published in the first-time two retrospective data analysis on behavioral health outcomes, Depression and Anxiety in the American Psychology Association (APA).

Effectiveness of a Digital Behavioral Health Solution for Depression Symptoms

This study provides preliminary insights into the effectiveness of a digital chronic condition platform to facilitate symptom reduction in individuals screened for depression.

- ***Methods:*** A retrospective data evaluation study was performed on the Dario database. The Patient Health Questionnaire-9 ("PHQ-9") was utilized to screen for depression severity and track progress over time. The current sample is based on individuals who used the Dario Behavioral Health platform between 2019-2021, and completed at least two PHQ-9 assessments, one at baseline and the second between baseline and 12 weeks of platform utilization. Scores were calculated based on PHQ-9 scoring guidelines. Users were stratified based on severity as minimal-mild (score 0-9), mild-moderate and severe-moderate (10-19), or Severe (>=20).

Results:

- A group of 496 platform users (376 women, 108 men, 12 other) who completed two assessments of PHQ-9 was evaluated. The population included 269 users who started at minimal-mild severity and 227 who started at moderate or severe severity (175 moderate; 52 severe).The minimal-mild group mostly maintained at the same level of average PHQ-9 score post assessment. The moderate-severe group significantly improved their average PHQ-9 score (P<0.001).

- A proportion of 72% of moderate-severe users showed improvement in their post PHQ-9 assessment and 38% of moderate-severe users reported scores in the minimal-mild range over the study period. Moreover, 44% of the moderate-severe population experienced a clinically significant score reduction (reduction of >5) in the full PHQ-9 over the study period. Out of 175 users who started at a moderate depression level, and 162 (93%) improved or maintained their level and out of 52 users who started at a severe depression level, 30 (58%) users reduced their level to moderate or minimal-mild.

Effectiveness of a Digital Behavioral Health Solution for Anxiety Symptoms

This study provides preliminary insights into the effectiveness of a digital chronic condition platform to facilitate symptom reduction in individuals screened for anxiety.

Methods: A retrospective data evaluation study was performed on the Dario database. The Generalized Anxiety Disorder Assessment (GAD-7) was utilized to screen for anxiety severity and track progress over time. The current sample is based on individuals who used the Dario Behavioral Health platform between 2019-2021, and completed at least two GAD-7 assessments, one at baseline and the second between baseline and 12 weeks of platform utilization. Scores were calculated based on GAD-7 scoring guidelines. Users were stratified based on severity as minimal-mild (score 0-9), moderate (10-14), or Severe (>=15).

Results:

- The group of 523 platform users who completed two assessments of GAD-7 was evaluated; 297 users had baseline scores in the minimal-mild range and 226 were moderate or severe. The severe group significantly improved their average GAD-7 score (P<0.001; paired t-test). A proportion of 68% from the severe users improved their score, and 42% of the severe users reported scores in minimal-mild range over the study period (P<0.001). Moreover, 40% of the severe population experienced a clinically significant score reduction (reduction of >5) in GAD-7 over the study period.

- The minimal-mild group mostly maintained their levels and hence did not escalate to higher severity while using the care platform. Additionally, out of 100 users who started at a moderate anxiety level, 84 (84%) improved or maintained their level (P<0.001), and out of 126 users started at a severe anxiety level, 69 (55%) reduced their level to moderate or minimal-mild (P<0.001).

In September 2022, a retrospective data analysis study was published in "International Association for the Study of Pain" (IASP) large conference.

Pain level reduction mediated by perceived posture quality and training duration in patients using digital therapeutic biofeedback technology

The study sheds light on the nature of the linkage between posture biofeedback technology and pain reduction. Based on the findings of our mediation model constructed on a lagged association between training duration, perceived posture quality, and pain levels, we suggest that posture quality is a potential mechanism for posture training-related analgesia.

Methods: A retrospective real-world study examined 981 users who used the Dario posture trainer. Training duration, defined as the time the device is worn (hours), was recorded. This study utilized the Dario posture trainer, Upright in Dario Health, a wearable postural biofeedback device.

Results: Posture biofeedback training duration was significantly associated with pain levels (B=-0.0002, p<0.001). Also, the training duration predicted the following week's posture quality (B=0.0004, p<0.001) and in turn posture quality predicted the following week's pain. Finaly, posture quality mediated the effect of weekly training duration on the pain levels in two weeks.

In December 2022, the first manuscript was published in a peer-reviewed journal "*Frontiers in Physiology*" on retrospective data analysis on UpRight posture biofeedback platform.

The two-stage therapeutic effect of posture biofeedback training on back pain and the associated mechanism: A retrospective cohort study

The study findings provided a better understanding of the therapeutic dynamic during digital biofeedback intervention targeting pain, modeling the associated two-stage process. Moreover, the study sheds light on the biofeedback mechanism and may assist in developing a better therapeutic approach targeting perceived posture quality.

Methods: This retrospective real-world evidence study followed 981 users who used the UpRight posture biofeedback platform. Piecewise mixed models were used for modeling the two-stage trajectory of pain levels, perceived posture quality, and weekly training duration following an 8-week biofeedback training. Also, the mediation effect of perceived posture quality on the analgesic effect of training duration was tested using Monte Carlo simulations based on lagged effect mixed models.

Results: The analysis revealed significant pain level reduction of 50% (p <.0001) and posture quality improvement (p <.0001) during the first 4 weeks of the training, maintaining similar pain levels and perceived posture quality during the next 4 weeks. In addition, weekly training duration demonstrated an increase during the first 3 weeks (p <.001) and decreased during the next 5 weeks (p <.001). Moreover, training duration predicted following-week perceived posture quality (p <.001) and in turn perceived posture quality predicted following-week pain (p <.001) (p = 0.30). Finally, perceived posture quality mediated the effect of weekly training duration on the pain levels in 2 weeks (p <.0001).

In January 2023, a manuscript was published in a peer-reviewed journal "*MDPI-Applied sciences*" on retrospective data analysis glycemic management across Racial/Ethic groups:

Glycemic Management by a Digital Therapeutic Platform across Racial/Ethnic Groups: A Retrospective Cohort Study

Our findings demonstrate improvement in blood glucose levels in high-risk racial/ethnic minority populations with T2DM, showing that in this group of users who are motivated to use a digital device there appears to be no difference in the outcomes between racial/ethnic groups.

Methods: The retrospective real-world analysis followed a group of 1,000 people with Type 2 diabetes who used the Dario digital therapeutic platform over 12 months. Participants included in the study had a blood glucose average > 180 mg/dL (hyperglycemia, high-risk) in their first month. The differences between/within the groups' average blood glucose level (Avg.bg) and glycemic variability were evaluated. Furthermore, three general linear models were constructed to predict the Avg.bg by the number of blood glucose measurements (Bgm) in Model 1 (with the moderator White persons ("WP")/people from racial and ethnic minority groups ("REM")) and by the frequency of measurements by months (F.m) within REM and WP in Model 2 and Model 3, respectively.

Results: The Avg.bg was significantly reduced in each group over a year with no differences between REM/WP users. Blood glucose measurements in Model 1 and frequency of measurements by months in Model 2 and Model 3 predicted the Avg.bg. Findings indicate a positive association between digital engagement and glycemia, with no differences between REM and WP participants.

In February 2023, a manuscript was published in a peer-reviewed journal "*PAIN reports*" on an analytical framework of retrospective data for personalized pain management using piecewise mixed-effects model trees:

Personalizing digital pain management with adapted machine learning approach

This analytical framework offers an opportunity for investigating the personalized efficacy of digital therapeutics for pain management, taking into account users' characteristics and boosting interpretability and can benefit from including more users' characteristics.

Methods: We demonstrated the implementation of the model with posture biofeedback training data of 3610 users collected during 8 weeks. The users reported their pain levels and posture quality. We developed personalized models for nonlinear time-related fluctuations of pain levels, posture quality, and weekly training duration using age, gender, and body mass index as potential moderating factors.

Results: Pain levels and posture quality demonstrated strong improvement during the first 3 weeks of the training, followed by a sustained pattern. The age of the users moderated the time fluctuations in pain levels, whereas age and gender interactively moderated the trajectories in the posture quality. Train duration increased during the first 3 weeks only for older users, whereas all the users decreased the training duration during the next 5 weeks.

In February 2023, we presented two additional clinical studies at the ATTD conference in Berlin, Germany:

Decrease in Hypoglycemia Events over Year in Older adults with Diabetes Monitoring with Digital Diabetes Management System

Older adults using a digital diabetes management platform have the potential to promote behavioral change and prevent hypoglycemia, demonstrating better glycemic outcome.

Methods: A retrospective data analysis was performed on the Dario database. A cohort of users aged 67 or older with Type 1 or Type 2 diabetes and using Dario over a year was evaluated. Average numbers of Hypoglycemia Level 1 (<70mg/dL) and Level 2 (<54 mg/dL) events as defined by the ADA were observed monthly and compared to baseline (first month).

Results: In the cohort of 2844 users, hypoglycemia level 1 events were reduced by 31% and 35% from baseline (0.54, 0.51 vs. 0.78) on average within 6 months and sustained over a year ($p<0.05$). Hypoglycemia level 2 events were reduced by 53% (0.08, 0.08 vs. 0.17) on average within 6 months and sustained over a year (<0.05). The ratio of hypoglycemia readings per total measurements significantly reduced as well. Subgroup analyses (1353 patients) of Dario users aged 67 or older with Type 1 or Type 2 using Insulin revealed a substantial reduction of severe hypoglycemia Level 2 of 42% (0.11 vs. 0.19) ($p<0.05$) and significant reduction in hypoglycemia events ratio as well over a year.

Impact of Digital Coaching on Diabetes Self-management and Glycemic Outcomes for People with Type 2 Diabetes

Self-monitoring blood glucose and digital engagement have a mediating role in the effect of digital coaching on blood glucose levels. Coaching interactions have the potential to lead to behavioral change, which can positively impact the trajectory of a low-engaged user. By constantly learning from the user's data, the digital therapeutic platform can continually improve and adapt to the user's individual needs, leading to better outcomes. The study demonstrated that our platform is digital first where the human coaching intervention is provided to the right user at the right time and with the right intervention.

Methods: Retrospective data analysis was performed on a sample size of 712 users with type 2 diabetes with baseline average >180 mg/dL measured blood glucose over 12 months on the platform. 534 did not use a coaching service and 178 users interacted with a coach over a year.

Results: Monthly Average blood glucose level significantly reduced in both groups w and w/o coach interaction over a year (18% vs. 11%). Blood glucose measurements and digital engagement activities mediated the effect of coaching on average blood glucose levels. For individuals who are less inclined to measure their blood glucose, coaching can help establish regular monitoring habits and to understand the importance of monitoring their levels.

In June 2023, we presented three clinical studies at the 83th ADA conference:

Blood Glucose Reduction and Long-term Sustainability in High-risk Patients with Type 2 Diabetes Over Three Years Using a Digital Platform

The study showed that digital diabetes monitoring has the potential to enhance users' awareness and affect and sustain glycemic control improvements over 3 years. Moreover, it is highly expected that engagement to app features in a chronic condition management may help users with type 2 diabetes consistently taking care of their lifestyle behaviors to maintain better clinical outcomes.

Methods: A retrospective data analysis was performed on users with T2D in high-risk (baseline BG avg>169 mg/dL in month1; equivalent to A1C 7.5) who activated between 2017-2020 and measured their BG using Dario platform over three consecutive years (at months 1,6,12,24 and 36). The outcomes assessed were average blood glucose (BG avg) and high BG readings ratio (>180 mg/dL). Digital engagement was assessed by additional parameters including measurement type (fasting/premeal/post meal/bedtime), carbohydrate intake, meal type and physical activity alongside glucose measurement.

Results: A group of 1,239 users significantly reduced their BG avg consistently over three years by 15.6% (179±55 vs. 212±42) ($p<0.05$) and high readings ratio by 39% ($p<0.05$). A subset of users who completed at least one engagement type following months 12, 24, and 36 (N=433) demonstrated significantly greater reductions versus the complementary group (N=806): BG avg by 18.8% (172±51 vs. 212±45) and high readings ratio by 45% ($p<0.05$).

Digital Platform Users Managing Three Chronic Conditions Diabetes, Hypertension and Overweight Experience Better Outcomes than those Who Manage One Condition Following Six Months

Monitoring several conditions on an integrated platform may have the potential to offer a greater means for a person with diabetes to effectively manage glycemia, engage with the treatment and improve outcomes. This study can illuminate the relative contribution of multi chronic conditions management driving behavioral change to successful diabetes outcomes.

Methods: A retrospective data analysis was performed on users who were active during 2019-2022 and measured blood glucose (BG) using Dario platform for at least six months. The test group included users who measured blood pressure (BP) and weight within 6 months from their first BG measurement; a matched control group of users who measured BG only in the first six months was generated. BG levels were assessed by average BG (BG avg) and BGMS engagement was assessed by counting BG measurements per month. High-risk users were defined as those with baseline BG avg>180mg/dL in Month 1.

Results: A total number of 17,108 users were included in the study: a test group of 2154 users measured BG, BP and Weight in the first six months on the platform and a control group of 14,954 users measured BG only in the first six months on the platform. The test group (N=2,154) demonstrated significantly greater (1.7-fold) engagement evaluated by higher number of BG measurements, than the control group (N=14,954) in Month 1 and Month 6 ($p<0.01$). A subgroup of the test group, 343 users at high-risk who measured 3 conditions BG, BP and weight was evaluated. A matched control group of 1,579 high-risk users was generated. The high-risk test group (N=343) demonstrated significantly greater reduction in BG avg versus the control subgroup (N=1579) measured BG only, after 6 months (17% vs.11%) ($p<0.01$). Moreover, the ratio of population that reduced their BG avg to lower than 180 mg/dL after 6 months (equivalent to A1C 8.0; HEDIS measure) was significantly higher in the test subgroup versus control subgroup in high-risk (by 30%; $p<0.01$).

Impact of a Digital Health Educational Feature on Engagement and Glycemic Outcomes

The present study demonstrates that by providing improved knowledge, increased motivation, and personalized learning digital health educational features can help users feel more empowered to manage their diabetes effectively.

Methods: A retrospective data evaluation study was performed on Dario ™ members with type 2 (T2D) and prediabetes who experienced the educational feature. Engagement (blood glucose measurements and logging carbs to Dario mobile app) and glycemic outcomes were assessed three months pre-post experiencing the feature. Glycemic outcomes were assessed by average blood glucose (mg/dL) and glycemic variability (SD).

Results: A group of 994 people with type 2 and prediabetes who were active in the mobile app and measured their blood glucose three months before using the new feature and in the following three months after, was evaluated. The average number of blood glucose measurements increased by 34% ($p<0.05$) following the introduction of the new learning feature. A subgroup of 303 users with type 2 and prediabetes that reported depression in the app as a co-existing condition increased carbs logging event by 39%. In a subgroup of 234 high-risk users (baseline >180 mg/dL) the average blood glucose and glucose variability were significantly reduced by 13% and 11% on average, respectively ($p<0.05$).

In August 2023, we presented an additional clinical study on the benefits of engagement with a digital therapeutic for better clinical outcomes at the Association of Diabetes Care & Education Specialists (ADCES) conference.

Users managing Diabetes with Large-scale Digital Therapeutics Platform Experience a Change in Blood Glucose and Engagement Over Two Years.

*T*he present study demonstrates the benefits of engagement with a digital therapeutic platform for diabetes management in high-risk patients, demonstrating an improvement in glycemic outcomes and sustainment for a significant period.

***Methods*:** A retrospective real-world data study was performed on the Dario database. The current sample is based on active users since 2019 with at least two months measurements for two years. Engagement was assessed by blood glucose (BG) and weight measurements. Clinical outcomes assessed were average BG and high readings (>180mg/dL) ratios. Linear mixed effects models investigated changes in engagement and clinical outcomes.

***Results*:** A population of 119,482 platform users was included, Age: 53 ± 15; Gender: 51% women. High-risk subgroup included 31,562 users with first month (baseline) average BG>180 mg/dL. Total users' engagement increased significantly by 29% (14.3 to 18.5) over two years (p<0.001). High readings ratio (>180mg/dL) in high-risk subgroup decreased significantly by 38% (38.8% vs. 63.1%) over two years (p<0.001). The monthly average BG of the high-risk subgroup was reduced significantly by 16% (218.1mg/dL to 183.4mg/dL) over two years (p<0.001). A negative interaction effect was found with monthly engagements and the monthly average BG, as users with increased engagements (+1 SD) demonstrated stronger reductions in monthly average BG.

In September 2023, a manuscript was published in a peer-reviewed journal "*Journal of Medical Internet research (JMIR) Diabetes"* on the contribution of specific digital engagement tools to mental health conditions – Depression and Anxiety.

Specifying the Efficacy of Digital Therapeutic Tools for Depression and Anxiety: Retrospective, 2-Cohort, Real-World Analysis

This study demonstrated general improvement followed by a period of stability of depression and anxiety symptoms associated with cognitive behavioral therapy–based digital intervention. Interestingly, engagement with a coaching session but not a breathing exercise was associated with a reduction in depression symptoms. Moreover, breathing exercise but not engagement with a coaching session was associated with a reduction of anxiety symptoms. These findings emphasize the importance of using a personalized approach to behavioral health during digital health interventions.

***Methods*:** Depression and general anxiety symptoms were evaluated in real-world data cohorts using the digital health platform for digital intervention and monitoring change. This retrospective real-world analysis of users on a mobile platform–based treatment followed two cohorts of people: (1) users who started with moderate levels of depression and completed at least 2 depression assessments (n=519) and (2) users who started with moderate levels of anxiety and completed at least 2 anxiety assessments (n=474). Levels of depression (Patient Health Questionnaire-9) and anxiety (Generalized Anxiety Disorder-7) were tracked throughout the first 16 weeks. A piecewise mixed-effects model was applied to model the trajectories of the Patient Health Questionnaire-9 and the Generalized Anxiety Disorder-7 mean scores in 2 segments (1-6 weeks and 7-16 weeks). Finally, simple slope analysis was used for the interpretation of the interactions probing the moderators: coaching sessions and breathing exercises in both depression and anxiety cohorts.

***Results*:** Analysis revealed a significant decrease in depression symptoms (β=–.37, 95% CI –0.46 to 0.28; $P\leq$.001) during the period of weeks 1-6 of app use, which was maintained during the period of 7-16 weeks. Coach interaction significantly moderated the reduction in depression symptoms during the period of weeks 1-6 (β=–.03, 95% CI –0.05 to –0.001; P=.02). A significant decrease in anxiety symptoms (β=–.41, 95% CI –0.50 to –0.33; $P\leq$.001) was revealed during the period of 1-6 weeks, which was maintained during the period of 7-16 weeks. Breathing exercises significantly moderated the reduction in anxiety symptoms during the period of 1-6 weeks (β=–.07, 95% CI –0.14 to –0.01; P=.04).

In November 2023, we presented additional clinical study data at the virtual Diabetes Technology Society (DTS) meeting that investigated the association between monthly aggregated blood glucose measurements and walking activity (number of steps).

Non-linear Association between Blood Glucose Levels and Walking in an Integrated Digital Health Platform for Diabetes Management

*T*his study sheds light on the importance of walking in diabetes management. Our findings highlight the potential of digital health platforms in promoting physical activity using a diabetes tracking app to improve clinical outcomes. By integrating the information that counts steps people with diabetes can access a single platform that helps them feel supported in their daily diabetes care and lifestyle management.

***Methods*:**
In this retrospective real-world study, a cohort of 989 platform users with Type 2 diabetes and pre-diabetes, who regularly tracked their blood glucose levels for 12 months using the Dario digital platform was evaluated. The association between blood glucose levels and the number of steps was examined over time. A piecewise linear mixed effects model was applied to test the trajectories over time of monthly average blood glucose and monthly average number of steps a day in two time periods defined by previous research[3] as well as to test non-linear association between them.
***Results*:** The sample included 437 (44%) women, 546 (55%) men and 6 (0.6%) others. The average age was 62.5 (SD ±12.7) and the average BMI was 32.5 (SD ±6.9). The baseline average BG was 142.5 mg/dL (SD ±37.7). 808 (82%) users have type 2 diabetes and 181 (18%) have pre-diabetes. Analysis revealed that during the first 4 months there is a positive trend of monthly average steps (B=.02, P<.001) while there is a negative trend of blood glucose levels (B= -2.00, P<.001) in the same time frame. Significant improvement in monthly average blood glucose was observed in users with at least 400 steps a day (B= -2.26, P<.001), while for those with less than 400 steps a day there was no significant change.

Certain clinical studies were published by Sanofi on our data in 2023.

The first poster was published at ISPOR May 2023.

Comparison of All-Cause Healthcare Resource Utilization Rates between Patients with Type 2 Diabetes Who Use a Digital Diabetes Solution Versus Non-Users: A 12-Month Retrospective Cohort Study

*I*n this retrospective cohort study, utilizing Dario Diabetes Solution (DDS) demonstrated a significantly greater reduction in all-cause HCRU and inpatient hospitalization rates during 12-month follow-up compared with non-users receiving usual care.

***Methods*:** This retrospective cohort study (January 2017–April 2021) included adults (≥18 years) with T2DM receiving anti-diabetic medication(s) with ≥1 inpatient or ≥2 outpatient visits ≥30 days apart during baseline period. Baseline was 12 months before index date (first DDS registration [users] or first medical encounter in the quarter with medical claims [non-users]); follow-up was 12 months. User and non-user cohorts were matched 1:3 using exact and propensity score matching. Analysis included patients with access to care 12 months pre- and post-index date. Primary endpoint was all-cause HCRU (inpatient hospitalizations + ER visits) rates during follow-up. Data were analyzed using a generalized linear model with negative binomial distribution.

***Results*:** Of 9779 patients, DDS users (n=2445) and non-users (n=7334) were matched; mean±SD age was 58.2±10.6 and 58.3±12.5 years, respectively. At 12 months, mean (95% CI) all-cause HCRU rate (inpatient hospitalization + ER visits) was 0.475 (0.438–0.516) and 0.524 (0.500–0.549) events/year for users and non-users, respectively. Users had 9.3% lower HCRU rate compared with non-users (incidence rate ratio [IRR], 0.907 [0.826–0.996]; P=0.04). Mean all-cause inpatient hospitalization rate was 0.166 (0.147–0.186) and 0.216 (0.203–0.230) events/year for users and non-users, respectively. Users had 23.5% lower inpatient hospitalization incident rate versus non-users (IRR, 0.765 [0.671–0.873]; P<0.0001); ER visit rates were similar in both cohorts (IRR, 1.01 [0.907–1.125]; P=0.86).

Three studies were presented by Sanofi at the 83th ADA conference:

Impact of Digital Diabetes Solution on Glycemic Control in Adults with Type 2 Diabetes Mellitus in the United States—A Retrospective Cohort Study

*T*he study showed adults with uncontrolled T2DM using Dario Diabetes Solution (DDS) had better outcomes at 6 months, with more significant HbA1c reductions than matched nonusers across various BL HbA1c levels, showing incremental improvements to usual care.

***Methods*:** This retrospective cohort study included adults with type 2 diabetes mellitus (T2DM) with a baseline (BL) HbA1c ≥7% who used DDS (users) or received usual care (nonusers) between January 1, 2017, to October 31, 2021. BL period was 1 year before index date (first DDS registration [users] or first claim date in the quarter [nonusers]); follow-up period was 6 months. DDS user and nonuser cohorts were matched 1:3 using exact and propensity score matching. Primary endpoint was change in HbA1c from BL to 6 months, with subgroup analyses of patients (pts) with BL HbA1c >7.5%, >8%, >9%, and ≥1% drop from BL. Difference-in-difference results are reported using least squares (LS) means from linear models.

***Results*:** The study included 568 DDS users and 1699 nonusers. For all 2267 pts, mean ± SD age was 57.5±11.3 years and HbA1c was 9.14±1.83% at BL. At 6 months, LS mean difference between groups was −0.23% (mean HbA1c change vs BL: users, −1.02% [95% CI, −1.15, −0.89]; nonusers, −0.79% [−0.87, −0.71]; *P*=0.004). HbA1c drop ≥1% from BL to 6 months was achieved by 47% of users vs 37% nonusers (difference: 10%; *P*<0.001). Subgroup analysis at all BL HbA1c showed users achieved more significant HbA1c reductions vs nonusers (*P*<0.05). For pts with BL HbA1c >9%, the healthcare effectiveness data and information set performance measure, mean difference between groups was -0.47% (users, -2.25% [-2.50, -1.99]; nonusers, -1.78% [-1.92, -1.63]; *P*=0.002).

Use of Digital Diabetes Solution Is Associated with Improved Glycemic Control without Increased Risk of Severe Hypoglycemia in Adults with Type 2 Diabetes Mellitus in the United States—Retrospective Cohort Study

In this retrospective study, a larger proportion of adults with uncontrolled T2DM (BL HbA1c ≥8%) achieved HbA1c <8% after using DDS vs nonusers, with no increased risk of severe hypoglycemia (SH).

Methods: This retrospective cohort analysis included adults with T2DM who used DDS (users) and nonusers from 1JAN2017 to 31OCT2021. BL period was 1 year before index date (users, first DDS registration; nonusers, first claim date in the quarter); follow up was 6 months. DDS users and nonusers were sequentially matched 1:3 using exact and propensity score matching. Secondary endpoints included SH (event requiring medical intervention) rates for all patients (pts) and for pts with BL HbA1c ≥8% who achieved predefined target HbA1c <8%. SH incidence in users vs nonusers was examined.

Results: Overall cohort included 568 DDS users and 1699 nonusers: mean age, 57.5±11.3 years; mean BL HbA1c, 9.14±1.83%; oral antidiabetic drugs, 51%; insulin, 6%. BL SH was rare (users, 7/568; nonusers, 12/1699). There were 387 users and 1089 nonusers with BL HbA1c ≥8% (mean BL HbA1c, 10.0±1.7%). In this subgroup, HbA1c <8% was achieved by 9% more DDS users (174/387 [45%]) vs nonusers (393/1089 [36%]) at 6 months; P=0.002. At 6 months, overall SH rate was 38.8 (users) vs 10.6 (nonusers) events/1,000 pts per year (incidence rate ratio, 0.9; P=0.9). No observed increase in SH risk was associated with DDS in this population. SH was rare in pts who achieved HbA1c <8% (users, 1/174; nonusers, 3/393).

Effect of a Digital Diabetes Solution on All-Cause Health Care Resource Utilization Charges for Patients with Type 2 Diabetes—A Retrospective Cohort Study

In this retrospective cohort study, pts with T2DM who utilized DDS incurred significantly lower all-cause HCRU and OV charges vs nonusers.

Methods: This retrospective cohort study (pt selection window: 1JAN2017 - 31APR2021) included adults (≥18 years) with T2DM receiving antidiabetic medication(s) with ≥1 inpatient or ≥2 outpatient visits ≥30 days apart during the baseline (BL) period. BL was 1 year before index date (users, 1st DDS registration; nonusers, 1st claim date in the quarter); follow up was 1 year. User and nonuser cohorts were matched 1:3 using exact and propensity score matching. Study assessed HCRU rates and charges. A 2-part gamma distribution model was used to determine 1) likelihood (odds ratio, OR) of users vs nonusers to incur charges, then 2) total charges per patient per year (PPPY) including all-cause HCRU and office visit (OV) charges.

***Results*:** Of 9779 pts, 2445 DDS users and 7334 nonusers were matched; mean age, 58.2±10.6 and 58.3±12.5 years, respectively. At 1 year, users were 9% less likely to incur all-cause HCRU charges vs nonusers (OR, 0.91; *P*=0.07). All-cause HCRU charges were 26% lower for users vs nonusers (*P*<0.0001; $12552 [adjusted] PPPY savings). Users were more likely to incur all-cause OV charges vs nonusers (*P*=0.04). However, users had 19% lower all-cause OV charges vs nonusers (*P*<0.0001; $1790 [adjusted] PPPY savings). The percentages of pts who incurred T2DM related HCRU charges were low (users, 3.1%; nonusers, 3.0%).

Three posters were published at AMCP-Nexus, in October 2023:

The impact of a digital health technology on healthcare quality measures and clinical outcomes in adults with type 2 diabetes mellitus

In this retrospective study, in adults with T2DM, a greater proportion of Dario Diabetes Solution (DDS) users with BL A1c greater than or equal to 8% achieved A1c less than 8% and a smaller proportion with BL A1c greater than 9% remained greater than 9%, compared with a matched cohort of nonusers, without increasing the risk of severe hypoglycemia. DDS offers improved quality outcomes based on HEDIS A1c criteria.

Methods: Cohorts of 568 DDS users and 1,699 nonusers were compared. Inclusion criteria were as follows: adults with a diagnosis of T2DM, receiving at least 1 diabetes medication, A1c greater than or equal to 7.0%, and not using a continuous glucose monitor between January 1, 2017, and October 31, 2021. The primary endpoint was a change in A1c from baseline (BL) during a 180-day follow-up period, with subgroup analyses of people with BL A1c greater than 7.5%, greater than 8%, and greater than 9%. Exploratory analyses were conducted to evaluate whether DDS use could facilitate a lowering of BL A1c from greater than or equal to 8% to less than 8% and from greater than 9% to less than 9% in adults with T2DM. Secondary endpoints included severe hypoglycemia (event requiring medical intervention) rates for all included DDS users and nonusers and for those with BL A1c greater than or equal to 8% who achieved a predefined target A1c of less than 8%.

Results: Overall, DDS user and nonuser cohorts were well matched , including by payer type (70% commercial and 18% Medicare for both groups). Among 387 DDS users with BL A1c greater than or equal to 8%, 174 (45%) had A1c less than 8% during follow-up, compared with 393 (36%) of 1,089 nonusers (P=0.0021). In a subgroup analysis of people with BL A1c greater than 9%, among 237 DDS users, 86 (36%) had follow-up A1c greater than 9%, compared with 347 (49%) of 713 nonusers (P=0.0009). There was no increase in rates of severe hypoglycemia comparing groups (P>0.4).

Association between more frequent engagement with the Dario Diabetes Solution, a digital health technology, and a reduction in HbA1c in adults with type 2 diabetes mellitus

Higher DDS engagement was associated with a significantly greater reduction in A1c in adults with T2DM. The highest engagement was in the first 2 months of follow-up and correlated with the greatest reductions in HbA1c. Engagement decreased over time during follow-up. Further research is needed to assess additional interventions that may sustain engagement over time.

***Methods*:** This analysis included DDS users receiving at least 1 diabetes medication, with A1c ≥7.0%, and not using a continuous glucose monitor between January 1, 2017, and October 31, 2021. Baseline (BL) was 1 year before the index date (first registration for DDS), with follow-up of 180 days from the index date. Engagement activities were collected via the DDS app. Engagement activity was measured in active days (ie, number of days when a user performed any engagement activity). Ten DDS engagement activities were evaluated, including measuring BG, tagging (timing of BG measurement or meal type), food logging, and sharing logbook. Associations between overall DDS engagement and change in A1c were analyzed over 180 days using a linear regression method, and associations were evaluated at 60- day intervals over those 180 days. Individual components of engagement were also analyzed.

Results: 568 DDS users were included. At BL, their mean age was 57.3 years (SD ±11.3) and mean A1c was 9.14±1.78%. Median engagement activity was 65 active days of 180. Each day with any DDS engagement activity was associated with a 0.01% change in A1c (P<0.0001). Users in the most engaged quartile had 5× greater reduction in A1c than the least engaged quartile. Individual engagement activities with significant associations with reduced A1c were BG measurement, tagging (meal type), and inputting insulin dose.

A retrospective cohort study comparing health care resource utilization, length of stay and 30-day readmissions in users and non-users of a digital diabetes health intervention for patients with type 2 diabetes mellitus.

In this real-world analysis, all-cause HCRU, inpatient, and 30-day readmission rates were significantly lower among DDS users vs nonusers (9%, 23%, and 36%, respectively), and LOS was significantly shorter (1.6 days).

Methods: In this retrospective cohort study, adults (aged >18 years) receiving therapy for type 2 diabetes who used DDS from January 1, 2017, to April 30, 2021, were identified; index date was defined as the date of first DDS registration. Anonymized DDS user data were linked to patient-level claims data within the Symphony Health Integrated Dataverse. The DDS cohort was matched 1:3 using exact and propensity score matching to a nonuser cohort from the Symphony Health Integrated Dataverse with medical claims for type 2 diabetes mellitus during the study period. For nonusers, the index date was the first medical claim date in the matched quarter. All patients were required to have 12 months' post-index follow-up and to have at least 2 outpatient claims (>30 days apart) or at least 1 inpatient claim within this period. This analysis compared all-cause HCRU rates (inpatient + emergency department), LOS, and 30- day readmission rates in DDS users and nonusers. Negative binomial generalized linear models adjusting for baseline rates were used to generate incidence rates (per personyear) and incidence rate ratios (IRRs) and corresponding 95% Cis for all-cause HCRU and 30-day readmission rates. LOS was compared between groups using a two-sample t-test.

***Results*:** DDS users (n=2,445) and nonusers (n=7,334) were well matched (mean+SD age: 58.2+10.6 vs 58.3+12.5 years; sex, 53.3% female for both). At follow-up, the all-cause HCRU rate was 0.47 (95% CI= 0.44-0.52) in DDS users and 0.52 (95% CI= 0.50-0.55) in nonusers (IRR=0.91; 95% CI=0.83-1.00; P=0.041). The mean all-cause inpatient event rate was 0.17 (95% CI= 0.15-0.19) in DDS users and 0.22 (95% CI= 0.20-0.23) in nonusers (IRR= 0.77; 95% CI= 0.67-0.87; P<0.0001); there was no significant difference in emergency department visits. DDS users with an inpatient event (users, n=327; nonusers, n=1,196) had a shorter LOS (7.2 vs 8.8 days; P=0.017) and lower 30-day readmission rate (IRR= 0.64; 95% CI= 0.45-0.92; P=0.014) vs nonusers.

Additional poster was presented at ISPOR EU, in November 2023.

The Impact of Patient Engagement with a Digital Diabetes Solution on All-Cause Healthcare Resource Utilization Rates and Charges

Overall engagement with DDS was associated with a reduction in all-cause HCRU and lower likelihood of incurring HCRU-related charges.

Methods: Patient-level claims data for adult DDS users (>18 years; registered 01-Jan-2017 to 30-Apr-2021) receiving therapy for T2DM were retrieved from Symphony Health Integrated Dataverse. All patients had >2 outpatient (>30 days apart) or >1 inpatient visit within 12 months prior to index (date of first DDS registration). This analysis reports all-cause HCRU (inpatient + emergency room visits) and odds of incurring HCRU-related charges >$0 based on user engagement with any of 10 DDS activity metrics ('components' of activity metrics: measuring BG, measuring blood pressure, measuring weight, tagging [BG timing and meal type], food logging, inputting insulin dose, recording physical activity, sharing logbooks, reading articles, coach interaction). Overall engagement was defined as number of days any component was used within 12 months post-index. All-cause HCRU rates and charges per 100 days of engagement were adjusted for baseline values with a negative binomial generalized linear model and logistic model, respectively; incidence rate ratios (IRR) for HCRU and odds ratios (OR) for charges >$0 were derived.

Results: We identified 2445 DDS users (mean+SD age, 58.2+10.6 years; 53.3% female). Overall engagement (use of any DDS component) was associated with a 10% reduction in all-cause HCRU (IRR: 0.90; p=0.0048). Overall DDS engagement was associated with 15% decreased odds of incurring all-cause HCRU-related charges >$0 (OR: 0.85; p=0.0004).

Another poster was presented at Diabetes Technology Society at Nov 2023, the abstract will be published in JDST early 2024. The title is: "Impact of a Digital Diabetes Solution on Medication Adherence in Adults in the United States with Type 2 Diabetes Mellitus".

Government Regulation

The principal markets that we have initially targeted for Dario are the United States, Canada, the European Union, Australia, and New Zealand. The following is an overview of the regulatory regimes in these jurisdictions.

United States Regulation Generally

In the United States, medical devices are subject to extensive regulatory control at the federal level by the FDA under the Federal Food, Drug, and Cosmetic Act ("FDCA") and its implementing regulations. Under Section 201(h) of the FDCA, a medical device is an article, which does not achieve its intended purpose through chemical action or metabolism in or on the body and, among other things, is intended (i) 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 or (ii) to affect the structure or any function of the body of man or other animals. The Dario Blood Glucose Monitoring System is classified as a medical device and subject to regulation by numerous agencies and legislative bodies, including the FDA and its foreign counterparts. FDA regulations govern, among other things, device design and development, nonclinical and clinical testing, manufacturing, packaging, labeling, storage, pre-market clearance or approval, establishment registration and device listing, advertising and promotion, sales and distribution, recalls and field actions, servicing and post-market surveillance. A number of U.S. states also impose licensing and compliance regimes on companies that manufacture or distribute prescription devices into or within the state.

The FDA classifies medical devices into one of three classes. Classification of a device is important because the class to which a device is assigned determines, among other things, the necessity and type of FDA review required prior to marketing the device. Unless an exemption applies, each medical device commercially distributed in the United States will require a clearance through the pre-market notification (or 510(k)) process, De Novo classification, or pre-market approval ("PMA") from the FDA.

Class I devices are those for which reasonable assurance of safety and effectiveness can be maintained through adherence to general controls, which include compliance with the applicable portions of the FDA's Quality System Regulation ("QSR"), as well as regulations requiring facility registration and product listing, reporting of adverse medical events, and appropriate, truthful and non-misleading labeling, advertising, and promotional materials. The Class I designation also applies to devices for which there is insufficient information to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish special controls to provide such assurance, but that are not life-supporting or life-sustaining or for a use which is of substantial importance in preventing impairment of human health, and that do not present a potential, unreasonable risk of illness or injury.

Class II devices those for which general controls alone are insufficient to provide reasonable assurance of safety and effectiveness and there is sufficient information to establish "special controls." These special controls can include performance standards, post-market surveillance requirements, patient registries and FDA guidance documents describing device-specific special controls. While most Class I devices are exempt from the pre-market notification requirement, most Class II devices require a pre-market notification prior to commercialization in the United States; however, the FDA has the authority to exempt Class II devices from the pre-market notification requirement under certain circumstances.

Class III devices are intended to be life sustaining or life supporting, devices that are implantable, devices that present a potential unreasonable risk of harm or are of substantial importance in preventing impairment of health, and

devices that are not substantially equivalent to other lawfully marketed devices and for which safety and effectiveness cannot be assured solely by the general controls and special controls.

Pre-market Notification (510(k)) Clearance Process. Manufacturers of most Class II devices must submit premarket notifications to the FDA under Section 510(k) of the FDCA (21 U.S.C. § 360(k)) in order to obtain the necessary authorization to market or commercially distribute such devices. To obtain 510(k) clearance, manufacturers must submit to the FDA adequate information demonstrating that the proposed device is "substantially equivalent" to a "predicate device" that is already on the market. A predicate device is a legally marketed device that is not subject to PMA, meaning, (i) a device that was legally marketed prior to May 28, 1976, or pre amendments device, and for which a PMA is not required, (ii) a device that has been reclassified from Class III to Class II or I, or (iii) a device that was found substantially equivalent through the 510(k) process. The FDA typically issues a decision within 90 days of receipt of a 510(k) submission but may stop the review clock for up to 180 days to request that the applicant respond to the agency's requests for additional information about the proposed device. If the FDA agrees that the device is substantially equivalent to the predicate device identified by the applicant in a premarket notification submission, the agency will grant 510(k) clearance for the new device, permitting the applicant to commercialize the device. Premarket notifications are subject to user fees, unless a specific exemption applies.

After a device receives 510(k) clearance, any modification 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 could even require a premarket application approval. The FDA requires each manufacturer to make this determination in the first instance, but the FDA can review any such decision. If the FDA disagrees with the determination, the agency may retroactively require the manufacturer to seek 510(k) clearance or premarket application approval. The FDA also can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or premarket application approval is obtained.

De Novo Classification. This device regulatory pathway allows a manufacturer whose novel device is automatically classified into Class III to request that the FDA classify such device as Class I or Class II based on evidence that the device in fact presents low or moderate risk, instead of following the typical Class III device pathway requiring the submission and approval of a PMA application. If the manufacturer seeks reclassification into Class II, the classification request must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. The FDA typically issues a decision within 150 days of receipt on a De Novo classification request but, as with 510(k) submissions, may stop the review clock for up to 180 days to request that the applicant respond to the agency's requests for additional information. If FDA grants the De Novo request, the device may be legally marketed in the United States. However, the FDA may reject the classification request if the agency identifies a suitable legally marketed predicate device that provides a reasonable basis for review of substantial equivalence or determines that the device is not low to moderate risk or that general controls would be inadequate to control the risks and adequate special controls cannot be developed. De Novo classification requests are subject to user fees, unless a specific exemption applies.

Premarket Approval (PMA). The PMA process is more demanding than the 510(k) and De Novo classification processes. For a PMA, the manufacturer must demonstrate through extensive data, including data from nonclinical studies and one or more clinical trials, that the device is safe and effective for its proposed indication. The PMA application must also contain a full description of the device and its components, a full description of the methods, facilities and controls used for manufacturing, and proposed labeling. Following receipt of a PMA submission, the FDA determines whether the application is sufficiently complete to permit a substantive review. If the FDA accepts the application for review, it has 180 days under the FDCA to complete its review and determine whether the proposed device can be approved for commercialization, although in practice, PMA reviews often take significantly longer, and it can take up to several years for the FDA to issue a final decision. Before approving a PMA, the FDA generally also performs an on-site inspection of manufacturing facilities for the product to ensure compliance with the QSR.

The FDA may refer any PMA submission, including applications for novel device candidates or device candidates that present difficult questions of safety or efficacy, to an advisory committee for review. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and, if so, under what conditions. The FDA is not bound

by the recommendation of an advisory committee, but it considers such recommendations when making final decisions on approval.

If the FDA's evaluation of the PMA application and inspection of the manufacturing facility is favorable, the FDA may issue an approval order authorizing commercial marketing of the device, or an "approvable letter," 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 met to the satisfaction of the FDA, the agency will issue a PMA approval order, subject to the conditions of approval and the limitations established in the approval order. If the FDA's evaluation of a PMA application or manufacturing facility is not favorable, the FDA will deny approval of the PMA or issue a "not approvable letter." The FDA may also determine that additional studies are necessary, in which case the PMA approval may be delayed for several months or years while such additional studies are conducted and data is submitted in an amendment to the PMA. The PMA process can be expensive, uncertain and lengthy, and each PMA submission is subject to a substantial user fee unless a specific exemption applies. PMA approval may also be granted with post-approval requirements such as the need for additional patient follow-up or requirements to conduct additional clinical trials.

After approval of a premarket application, a new PMA application or PMA supplement may be required in the event of a modification to the labeling, manufacturing process, specifications, materials or design of the device. PMA supplements often require submission of the same type of information as an initial PMA application, except that the supplements are 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 clinical data or the convening of an advisory committee. The PMA pathway is much more costly, lengthy and uncertain.

In general, software that is intended for a medical purpose, whether it is included with a hardware device or is standalone software, is considered a medical device and subject to the same regulatory pathways described above, as long as it meets the definition of a "device" in Section 201(h) of the FDCA. However, the 21st Century Cures Act, which became law in December 2016, expressly excluded from the FDCA's device definition some software functions, such as software to support healthcare facility administration, general wellness software, electronic health records and certain clinical decision support software. In September 2019, the FDA published a revised guidance, *General Wellness: Policy for Low Risk Devices*, describing its approach to general wellness products, including software, which states that the agency does not intend to examine the compliance of low risk general wellness products, as long as they are intended to (i) maintain or encourage general health or healthy activity and do not make any claims relating to specific diseases or conditions, or (ii) encourage a healthy lifestyle to help reduce the risk or impact of or help the user live well with certain chronic diseases or conditions where there is an established connection between a healthy lifestyle and the disease or condition. In addition, the FDA has published the *Policy for Device Software Functions and Mobile Medical Applications* guidance, which describes the agency's approach to regulating software device functions, and in particular, the types of software that are the focus regulatory enforcement, under enforcement discretion, or not considered medical devices. Our Smart Diabetes Management Solution software and wireless blood pressure monitor software are considered medical devices under the FDCA and such software products have received the required marketing authorizations and are listed with FDA. We believe that our other current software products either are not intended for a medical purpose or meet the applicable criteria to be considered low risk general wellness products.

The FDA issued a Final Rule on February 2, 2024 describing amendments to harmonize the QSR with the 2016 edition of the International Organization for Standardization publication *Medical Devices: Quality management systems—Requirements for regulatory purposes* (ISO 13485:2016), which will become effective on February 2, 2026. The harmonization process is not expected to have a significant impact on the quality system compliance operations of device manufacturers because most requirements described in the QSR correspond to requirements set forth in ISO 13485:2016. However, device manufacturers will likely need to revise certain quality system procedures to ensure compliance with the harmonized regulations and any failure to make such revisions or adapt to the harmonized regulations, once they become effective, may result in observations of noncompliance during facility inspections by the FDA or comparable regulatory authorities.

European and Non-European Regulation Generally

Sales of medical devices outside the United States are subject to foreign regulatory requirements that vary widely from country to country. These laws and regulations range from simple product registration requirements in some countries

to complex clearance and production controls in others. As a result, the processes and time periods required to obtain foreign marketing clearance may be longer or shorter than those necessary to obtain FDA clearance.

For example, the European Union (EU) has adopted specific directives and subsequently regulations regulating the design, manufacture, clinical investigations, labeling, conformity assessment, post-market surveillance and vigilance reporting for medical devices. The EU rules described below are generally applicable in the European Economic Area (EEA). Other countries, such as Switzerland, have entered into Mutual Recognition Agreements and allow the marketing of medical devices that meet EU requirements.

The EU presently requires that all medical products be certified to meet the EU's safety and performance requirements for such products and bear a CE mark, an international symbol of adherence to quality assurance standards and demonstrated clinical effectiveness. Prior to May 26, 2021, all medical devices placed on the EU market had to meet the relevant essential requirements laid down in Council Directive 93/42/EEC, or the Medical Device Directive (MDD), and if applicable, the Council Directive 90/385/EEC, or the Active Implantable Medical Device Directive (AIMD), or for in vitro diagnostic devices, Council Directive 98/79/EC, or the In Vitro Diagnostic Directive (IVDD). Active Implantable Medical Devices (AIMD) are defined as medical devices that rely on a source of electrical energy or any source of power other than that generated by the body, which are totally or partially introduced, either surgically or medically, into the human body and intended to remain after the procedure.

On May 26, 2021, the Medical Devices Regulation, EU 2017/745, (MDR) became effective, repealing and replacing the MDD and the AIMDD. The MDR is directly applicable in all EU member states. The MDR changed several aspects of the regulatory framework for medical device marketing in Europe in order to increase regulatory oversight of all medical devices marketed in the EU (which, in turn, increased the costs, time and requirements to place innovative or high-risk medical devices on the European market). The MDR among other things (i) strengthens the rules on placing devices on the market and reinforces post-market surveillance; (ii) establishes explicit provisions on a manufacturer's responsibilities for the follow-up of the quality, performance and safety; (iii) improves the traceability of medical devices through a unique identification number; and (iv) sets up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU.

An overarching requirement under the MDR is that any device must be designed and manufactured in such a way that it will not compromise the clinical condition or safety of patients, or the safety and health of users and others. In addition, the device must meet the performance specifications intended by the manufacturer and be designed, manufactured and packaged in a suitable manner. To that effect, the European Commission has adopted various standards applicable to medical devices. These include standards governing common requirements, such as sterilization and safety of medical electrical equipment and product standards for certain types of medical devices. There are also harmonized standards relating to design and manufacture. While not mandatory, compliance with harmonized standards is a way for manufacturers to demonstrate that products comply with relevant EU legislation.

To demonstrate compliance with the General Safety and Performance Requirements (GSPRs) set forth in the MDR, medical device manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Conformity assessment procedures require an assessment of the technical documentation, including the device description, the design stages, the manufacturing process, available clinical evidence, literature data for the product, and post-market experience in respect of similar products already marketed. Except for low-risk medical devices (Class I non-sterile, non-measuring devices), where the manufacturer can self-declare the conformity of its products with the GSPRs (except for any parts which relate to sterility or metrology), a conformity assessment procedure requires the intervention of a Notified Body. Notified Bodies are independent organizations designated by EU member states to assess the conformity of devices before being placed on the market. A Notified Body typically audits and examines a product's technical dossiers and the manufacturer's quality management system (which must, in particular, comply with ISO 13485). If satisfied that the AIMD or other medical device conforms to the relevant GSPRs, the Notified Body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE-Mark to the device, allowing the device to be legally marketed throughout the EU.

Notified Body certificates of conformity are valid for a fixed duration (which shall not exceed five years). Throughout the term of the certificate, the manufacturer will be subject to periodic surveillance audits to verify continued

compliance with the applicable requirements. In particular, there will be a new audit by the Notified Body before it renews the relevant certificate(s).

Devices lawfully placed on the market pursuant to the MDD and the AIMDD prior to May 26, 2021 could initially continue to be made available on the market or put into service until May 26, 2025. Nevertheless, the European Parliament recently adopted legislation to extend this transitional period to give manufacturers more time to switch from the previously applicable provisions to the new certification requirements for medical devices as laid down by the MDR. For high risk, class III and class IIb implantable devices the transitional period is extended until December 31, 2027. For medium and low risk, class IIb devices and class IIa, Im, Is and Ir devices the transition period is extended until December 31, 2028.

In May 2022, the IVDD was replaced by the In Vitro Diagnostic Device Regulation, EU 2017/746, (IVDR) and given a 5-year transition period until its full implementation on May 26, 2022. Unlike the IVDD, the IVDR has binding legal force throughout every EU member state. The major goal of the IVDR was to standardize diagnostic procedures within the EU, increase reliability of diagnostic analysis and enhance patient safety. Under the IVDR, IVDs are subject to additional legal regulatory requirements. Among other things, the IVDR introduces a new risk-based classification system and requirements for conformity assessments. Under the IVDR and subsequent amendments, IVDs already certified by a Notified Body under the IVDD may remain on the market until May 26, 2025, and IVDs certified without the involvement of a Notified Body may be placed on, or remain in, the market for up to three additional years (until May 26, 2028) depending on the classification of the IVD. The manufacturers of such devices remaining on the market must comply with specific requirements in the IVDR, but ultimately, such products, as with all new IVDs, will have to undergo the IVDR's conformity assessment procedures. In addition, the IVDR imposes additional requirements relating to post-market surveillance and submission of post-market performance follow-up reports.

In September 2013, we obtained ISO 13485 certification for our quality management system and CE Mark certification to market Dario, and in May 2015 Dario was cleared to fulfill the criteria according to EN ISO 15197:2013. The granting of the CE Mark allows Dario to be marketed and sold in 32 countries across Europe as well as in certain other countries worldwide. On November 21, 2014, MDSS, our European Authorized Representative, completed the registration of the Dario Blood Glucose Monitoring System with the German Authority as required by Article 10 of Directive 98/79/EC on in vitro diagnostic medical devices. We commenced an initial soft launch of the product in Europe in 2014, created initial demand for the product and established brand awareness and marketing techniques to reach our target market with a goal to continue expansion to new markets and territories.

We achieved regulatory clearance to market Dario in other countries that do not rely on the CE Mark. To date, the non-CE Mark jurisdictions which we have begun to market Dario include the United States, New Zealand, Canada, and Australia.

To the extent that we seek to market our product in other non-CE Mark countries in the future, we will be required to comply with the applicable regulatory requirements in each such country. Such regulatory requirements vary by country, and complying with such regulations may require substantial time and effort. As a result, no assurance can be given that we will be able to satisfy the regulatory requirements to sell our products in any such country. If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension of clinical trials, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, and criminal prosecution.

Clinical Trials

Clinical trials are almost always required to support PMA applications and are sometimes required to support 510(k) and De Novo classification submissions. All clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA's good clinical practice (GCP), regulations, including the investigational device exemption (IDE) regulations that govern investigational device labeling, prohibit promotion of investigational devices, and specify recordkeeping, reporting and monitoring responsibilities of trial sponsors and investigators. If the device presents a "significant risk," as defined by the FDA, the agency requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical studies. 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 patient. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that the device has a safety profile appropriate for human testing and that the trial protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA, unless the FDA expressly approves or denies the application in writing or notifies the sponsor that the investigation is on hold and may not begin until the sponsor provides supplemental information about the investigation that satisfies the agency's concerns. If the FDA determines that there are deficiencies or other concerns with an IDE that require modification of the trial, the FDA may permit a clinical trial to proceed under a conditional approval or the sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. In addition, the trial must be approved by, and conducted under the oversight of, an institutional review board, or IRB, for each clinical site. If the device presents a non-significant risk to the patient according to criteria established by FDA as part of the IDE regulations, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate authorization from the FDA, but must still comply with abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and labeling and record-keeping requirements.

As part of its clinical trial oversight responsibilities, an IRB must review and approve, among other things, the trial protocol and informed consent information to be provided to clinical trial subjects. An IRB must operate in compliance with FDA regulations. Information about certain clinical studies, including details of the protocol and eventually trial results, also must be submitted within specific timeframes to the National Institutes of Health (NIH), for public dissemination on the ClinicalTrials.gov data registry. Information related to the product, patient population, phase of investigation, trial sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial. Sponsors are also obligated to disclose the results of their clinical studies after completion. Disclosure of the results of these studies can be delayed in some cases for up to two years after the date of completion of the trial. Failure to timely register a covered clinical study or to submit study results as provided for in the law can give rise to civil monetary penalties and also prevent the non-compliant party from receiving future grant funds from the federal government. The U.S. Department of Health and Human Services' Final Rule and NIH's corresponding policy on ClinicalTrials.gov registration and reporting requirements became effective in 2017, and the government has brought enforcement actions against non-compliant clinical trial sponsors.

Progress reports detailing the results of the clinical studies must be submitted at least annually to the FDA and more frequently if unanticipated serious adverse events, or SAEs, occur. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the clinical protocol, GCP, or other IRB requirements or if the investigational product has been associated with unexpected serious harm to patients.

In the Consolidated Appropriations Act for 2023, Congress amended the FDCA to require the sponsor of any pivotal clinical trial that will be used to demonstrate the safety and effectiveness of a medical device marketing authorization submission to develop a diversity action plan for such trial, and if submission of an IDE application is required, to submit such diversity action plan to the FDA. The action plan must include the sponsor's diversity goals for enrollment, as well as a rationale for the goals and a description of how the sponsor will meet them. The FDA may grant a waiver for some or all of the requirements for a diversity action plan. It is unknown at this time how the diversity action plan may affect device pivotal clinical trial planning and timing or what specific information FDA will expect in such plans, but if FDA objects to a sponsor's diversity action plan and requires the sponsor to amend the plan or take other actions, it may delay trial initiation.

There is no assurance that a clinical study at any given site will progress as anticipated; the interim results of a study may not be satisfactory leading the sponsor or others to terminate the study, there may be an insufficient number of patients who qualify for the study or who agree to participate in the study or the investigator at the site may have priorities other than the study. Also, there can be no assurance that the clinical study will provide sufficient evidence to assure regulatory authorities that the product is safe, effective and performs as intended as a prerequisite for granting market clearance. See "Clinical Trials" above for clinical trials performed to date.

Post-Clearance Matters

Even if the FDA or other non-US regulatory authorities approve or clear a device, they may limit its intended uses in such a way that manufacturing and distributing the device may not be commercially feasible. After clearance or approval to market is given, the FDA and foreign regulatory agencies, upon the occurrence of certain events, are authorized under various circumstances to withdraw the clearance or approval or require changes to a device, its manufacturing process or its labeling or additional proof that regulatory requirements have been met.

A manufacturer of a device approved through the premarket approval application process is not permitted to make changes to the device which affects its safety or effectiveness without first submitting a supplement application to its premarket approval application and obtaining FDA clearance for that supplement. In some instances, the FDA may require a clinical trial to support a supplement application. A manufacturer of a device cleared through a 510(k) submission or a 510(k)+ "de-novo" submission must submit another premarket notification if it intends to make a change or modification in the device that could significantly affect the safety or effectiveness of the device, such as a significant change or modification in design, material, chemical composition, energy source or manufacturing process. Any change in the intended uses of a premarket approval application device or a 510(k) device requires an approval supplement or cleared premarket notification. Exported devices are subject to the regulatory requirements of each country to which the device is exported, as well as certain FDA export requirements.

Ongoing Regulation by FDA

Even after a device receives clearance or approval and is placed on the market, numerous regulatory requirements apply. These include:

- establishment registration and device listing;
- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation, and other quality assurance procedures during all phases of the product life-cycle;
- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or "off-label" uses, and other requirements related to promotional activities;
- medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur;
- corrections, 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 regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device.

The medical device reporting requirements also extend to healthcare facilities that use medical devices in providing care to patients, or "device user facilities," which include hospitals, ambulatory surgical facilities, nursing homes, outpatient diagnostic facilities, or outpatient treatment facilities, but not physician offices. A device user facility must report any device-related death to both the FDA and the device manufacturer, or any device-related serious injury to the manufacturer (or, if the manufacturer is unknown, to the FDA) within 10 days of the event. Device user facilities are not required to report device malfunctions that would likely cause or contribute to death or serious injury if the malfunction were to recur but may voluntarily report such malfunctions through MedWatch, the FDA's Safety Information and Adverse Event Reporting Program.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following sanctions: warning letters, fines, injunctions, civil or criminal penalties, recall or seizure of our current or future products, operating restrictions, partial suspension or total shutdown of production, refusing our request for 510(k) clearance or PMA approval of new products, rescinding previously granted 510(k) clearances or withdrawing previously granted PMA approvals.

We may be subject to announced and unannounced inspections by the FDA, and these inspections may include the manufacturing facilities of our subcontractors. If, as a result of these inspections, the FDA determines that our or our subcontractor's equipment, facilities, laboratories or processes do not comply with applicable FDA regulations and conditions of product clearance, the FDA may seek civil, criminal or administrative sanctions and/or remedies against us, including the suspension of our manufacturing and selling operations.

Ongoing Regulation by International Regulators

International sales of medical devices are subject to foreign government regulations, which may vary substantially from country to country.

In order to maintain the right to affix the CE Mark to sell medical devices in the European Union, periodic surveillance audits of the company premises and, if needed, at major subcontractors' premises must to be carried out by a Notified Body. In addition, all manufacturers placing medical devices into the market in the EU must comply with the EU medical device vigilance system. Under this system, serious incidents must be reported to the relevant authorities of the EU member states, and manufacturers are required to take Field Safety Corrective Actions, (FSCAs), to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. A serious incident is defined as any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect that directly or indirectly led, might have led or might lead to death, temporary or permanent serious deterioration of health state, or a serious public health threat. An FSCA can include the withdrawal of the device from the market, or a recall thereof. FSCAs must be communicated by the manufacturer or its legal representative to the users of the device through Field Safety Notices.

The advertising and promotion of medical devices is subject to some general principles set forth by EU directives. Directive 2006/114/EC concerning misleading and comparative advertising and Directive 2005/29/EC on unfair commercial practices. While the aforementioned directives are not specific to the advertising of medical devices, the provisions of national law transposing them must also be complied with and contain general rules, for example requiring that advertisements are evidenced, balanced and not misleading. Specific requirements are defined at national level. EU member states laws related to the advertising and promotion of medical devices, which vary between jurisdictions, may limit or restrict the advertising and promotion of products to the general public and may impose limitations on promotional activities with healthcare professionals.

Many EU member states have adopted specific anti-gift statutes that further limit commercial practices for medical devices, in particular vis-à-vis healthcare professionals and organizations. Additionally, there has been a recent trend of increased regulation of payments and transfers of value provided to healthcare professionals or entities. In addition, many EU member states have adopted national "Sunshine Acts" which impose reporting and transparency requirements (often on an annual basis), similar to the requirements in the United States, on medical device manufacturers. Certain countries also mandate implementation of commercial compliance programs.

Failure to comply with applicable regulatory requirements can result in enforcement action by the applicable regulatory authorities, which may include any of the following sanctions: fines, injunctions, civil or criminal penalties, recall or seizure of our current or future products, operating restrictions, partial suspension or total shutdown of production, refusing our request for renewing marketing authorization of our products or for granting marketing authorization for new products.

Federal Trade Commission Regulatory Oversight

Our advertising for our products in the United States is subject to federal truth-in-advertising laws enforced by the Federal Trade Commission (FTC), as well as comparable state consumer protection laws. Under the Federal Trade Commission Act, or FTC Act, the FTC is empowered, among other things, to (a) prevent unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce; (b) seek monetary redress and other relief for conduct injurious to consumers; and (c) gather and compile information and conduct investigations relating to the organization, business, practices, and management of entities engaged in commerce. The FTC has very broad enforcement authority, and failure to abide by the substantive requirements of the FTC Act and other consumer protection laws can result in administrative or judicial penalties, including civil penalties, injunctions affecting the manner in which we would be able to market services or products in the future, or criminal prosecution.

Federal Communications Commission Regulation

The Dario Blood Glucose Monitoring System includes a wireless radio frequency transmitter and receiver and, therefore, is subject to equipment authorization requirements in the United States. The Federal Communications Commission (FCC) requires advance clearance of all radio frequency devices before they can be imported into, sold or marketed in the United States. These clearances ensure that the proposed products comply with FCC radio frequency emission and power level standards and will not cause interference.

State Licensure Requirements

Several U.S. states require that Durable Medical Equipment ("DME") providers be licensed in order to sell products to patients in that state. Certain of these states require that DME providers maintain an in-state location. Some states also require a device manufacturer or distributor to obtain a license in order to distribute prescription medical devices to customers in such states. If these rules are determined to be applicable to us and if we were found to be noncompliant, we could lose our licensure in that state, which could prohibit us from selling our current or future products to patients in that state.

Other U.S. Healthcare Laws and Regulations

We must comply with various U.S. federal and state laws, rules and regulations pertaining to healthcare fraud and abuse, including anti-kickback laws and physician self-referral laws, rules and regulations. Violations of the fraud and abuse laws are punishable by criminal and civil sanctions, including, in some instances, exclusion from participation in federal and state healthcare programs, including Medicare and Medicaid. These laws include the following:

- the federal Anti-Kickback Statute (AKS) prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal health care program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the AKS or specific intent to violate it to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the FCA or federal civil money penalties statute;

- the federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act (FCA), which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by Medicare, Medicaid, or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payers if they are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;

- the Civil Monetary Penalties Law, which prohibits, among other things, the offering or giving of remuneration, which includes, without limitation, any transfer of items or services for free or for less than fair market value (with limited exceptions), to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of items or services reimbursable by a federal or state governmental program;

- the Health Insurance Portability and Accountability Act of 1996 (HIPAA) imposes criminal and civil liability for executing a scheme to defraud any health care benefit program or making false statements relating to health care matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health (HITECH) Act, and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- The federal transparency requirements under the Physician Payments Sunshine Act require manufacturers of FDA-approved drugs, devices, biologics and medical supplies covered by Medicare or Medicaid to report, on an annual basis, to the CMS information related to payments and other transfers of value to physicians, certain advanced non-physician healthcare practitioners, and teaching hospitals or to entities or individuals at the request of, or designated on behalf of, such physicians, non-physician healthcare practitioners, and teaching hospitals as well as certain ownership and investment interests held by physicians and their immediate family members; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by nongovernmental third-party payors, including private insurers.

Certain states also have adopted marketing and/or transparency laws relevant to device manufacturers, some of which are broader in scope in comparison to applicable federal laws. Some state laws require medical device companies to comply with the relevant industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring device manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures. In addition, state and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Violation of any of the federal and state healthcare laws may result in penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of operations. Our actual or perceived failure to comply with healthcare and data privacy laws could result in liability or reputational harm and could harm our business. Ensuring compliance with such laws could also impair our efforts to maintain and expand our customer base and thereby decrease our future revenues.

U.S. and European Data Security and Data Privacy Laws

HIPAA's administrative simplification provisions established comprehensive U.S. federal standards for the privacy and security of health information. In 2009, Congress enacted Subtitle D of the HITECH provisions of the American Recovery and Reinvestment Act of 2009, which expanded and strengthened HIPAA, created new targets for enforcement, imposed new penalties for noncompliance and established new breach notification requirements. HIPAA applies to health plans, healthcare clearing houses, and healthcare providers that conduct certain healthcare transactions electronically, which are referred to collectively as Covered Entities, as well as individuals or entities that perform services for Covered Entities involving the use, or disclosure of, individually identifiable health information or protected health information (PHI) under HIPAA. Such service providers are called "Business Associates." Under HIPAA, as amended by the HITECH Act, HHS has issued regulations to protect the privacy and security of PHI used or disclosed by Covered Entities and Business Associates. HIPAA also regulates and standardizes the codes, formats and identifiers used in certain

healthcare transactions and standardization of identifiers for health plans and providers, for example insurance billing. Any non-compliance with HIPAA and HITECH and related penalties, could adversely impact our business.

The HIPAA security standards require the adoption of administrative, physical, and technical safeguards and the adoption of written security policies and procedures to maintain the security of protected health information.

The HIPAA privacy regulations address the privacy of PHI by limiting the use and release of such information. They also set forth certain rights that an individual has with respect to his or her PHI maintained by a covered entity, including the right to access or amend certain records containing PHI, request an accounting of disclosures of PHI or to request restrictions on the use or disclosure of PHI. The HIPAA breach notification regulations impose certain reporting requirements on Covered Entities and their Business Associates in the event of a breach of PHI.

Significant civil and criminal fines and other penalties may be imposed for violating HIPAA directly, and in connection with acts or omissions of any agents, including a downstream Business associate, as determined according to the federal common law of agency. Civil penalties are adjusted for inflation on an annual basis and can exceed one million dollars per year for failure to comply with a HIPAA requirement. A single breach incident can violate multiple requirements. Additionally, a person who knowingly obtains or discloses PHI in violation of HIPAA may face a criminal penalties (including fines and imprisonment), which increase if the wrongful conduct involves false pretenses or the intent to sell, transfer or use PHI for commercial advantage, personal gain or malicious harm. Covered Entities are also subject to enforcement by state Attorneys General who were given authority to enforce HIPAA.

Additionally, while HIPAA does not create a private right of action allowing individuals to file suit against us in civil court for violations of HIPAA, its standards have been used as the basis for duty of care cases in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI.

Even when HIPAA does not apply, according to the FTC, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. The FTC and states' Attorneys General have also brought enforcement actions and prosecuted some data breach cases as unfair and/or deceptive acts or practices under the FTC Act and comparable state laws.

The HIPAA privacy and security regulations establish a uniform federal "floor" and do not preempt state laws that are more stringent or provide individuals with greater rights with respect to the privacy or security of, and access to, their records containing PHI. These laws overlap with HIPAA and may 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. The State of California, for example, has implemented comprehensive laws and regulations. The California Confidentiality of Medical Information Act (CMIA), imposes restrictive requirements regulating the use and disclosure of health information and other personally identifiable information. The California Consumer Privacy Act of 2018 (the CCPA) went into effect January 1, 2020. The CCPA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. It also creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches which has led to an increase data breach litigation. Although the law includes limited exceptions, including for PHI maintained by a covered entity or business associate under HIPAA and medical information maintained by healthcare providers under the CMIA, it may regulate or impact our processing of personal information depending on the context. Further, the California Privacy Rights Act (CPRA) went into effect January 1, 2023, amending the CCPA. The CPRA imposes additional data protection obligations 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 and expands the application of the CCPA to all human resources personal information of California-based employees. It also created a new regulatory entity, the California Privacy Protection Agency data protection agency, which is authorized to issue substantive regulations under the CPRA and is expected to result in increased privacy and information security

enforcement. Other states have implemented similar laws protecting identifiable health and personal information, and most such laws differ from each other in significant ways and may not be preempted by HIPAA, thus complicating compliance efforts.

In dealing with health information for the development of our technology or for commercial purposes, we will be indirectly affected by HIPAA and state-imposed health information privacy and security laws because these laws regulate the ability of our customers and research collaborators to share health information with us. Additionally, we must identify and comply with all applicable state laws for the protection of personal information with respect to employee information or other personal information that we collect.

In the European Union, increasingly stringent data protection and privacy rules that have and will continue to have substantial impact on the use of personal and patient data across the healthcare industry became stronger in May 2018. The EU General Data Protection Regulation (GDPR) applies across the European Union and includes, among other things, a requirement for prompt notice of data breaches to data subjects and supervisory authorities in certain circumstances and significant fines for non-compliance. The GDPR fine framework can be up to 20 million euros, or up to 4% of our total global turnover of the preceding fiscal year, whichever is higher. The GDPR sets out a number of requirements that must be complied with when handling the personal data of such European Union-based data subjects including: providing expanded disclosures about how their personal data will be used; higher standards for organizations to demonstrate that they have obtained valid consent or have another legal basis in place to justify their data processing activities; the obligation to appoint data protection officers in certain circumstances; new rights for individuals to be "forgotten" and rights to data portability, as well as enhanced current rights (e.g. access requests); the principal of accountability and demonstrating compliance through policies, procedures, training and audit; and the new mandatory data breach regime. In particular, medical or health data, genetic data and biometric data where the latter is used to uniquely identify an individual are all classified as "special category" data under the GDPR and are afforded greater protection and require additional compliance measures. Noncompliance could result in the imposition of fines, penalties, data lockup or orders to stop noncompliant activities.

We could also be subject to evolving European Union laws on data export, for transfers of data outside the European Union to themselves, group companies or third parties. The GDPR only permits exports of data outside the European Union to jurisdictions that ensure an adequate level of data protection. The United States has not been deemed to offer an adequate level of protection, so in order for us to transfer personal data from the EU to the United States, we must identify a legal basis for data transfer (e.g., the European Union Commission approved Standard Contractual Clauses). On July 16, 2020, the Court of Justice of the European Union or the CJEU, issued a landmark opinion in the case Maximilian Schrems vs. Facebook (Case C-311/18), called Schrems II. This decision (a) called into question commonly relied upon data transfer mechanisms as between the European Union member states and the United States (such as the Standard Contractual Clauses) and (b) invalidateds the EU-U.S. Privacy Shield on which many companies had relied as an acceptable mechanism for transferring such data from the EU to the United States. However, on July 10, 2023, the European Commission adopted an adequacy decision for a new mechanism for transferring data from the EU to the United States – the EU-U.S. Data Privacy Framework, which provides EU individuals with several new rights, including the right to obtain access to their data, or obtain correction or deletion of incorrect or unlawfully handled data. The adequacy decision followed the signing of an executive order introducing new binding safeguards to address the points raised in the Schrems II decision by the CJEU. The European Commission will continually review developments in the United States along with its adequacy decision. Adequacy decisions can be adapted or even withdrawn in the event of developments affecting the level of protection in the applicable jurisdiction. Future actions of EU data protection authorities are difficult to predict. Some customers or other service providers may respond to these evolving laws and regulations by asking us to make certain privacy or data-related contractual commitments that we are unable or unwilling to make. This could lead to the loss of current or prospective customers or other business relationships.

Intellectual Property

Patent applications

On May 8, 2011, certain of our founders filed a Patent Cooperation Treaty (PCT) Application No. PCT/IL2011/000369, titled "Fluids Testing Apparatus and Methods of Use." This PCT claimed priority from two

preceding U.S. provisional applications filed by our founders, with the earliest priority date being May 9, 2010. The PCT application was transferred to us by our founders on October 27, 2011.

This application covers the novel blood glucose measurement device, comprising the glucose meter; and an adaptor that connects the glucose meter to a smart-phone to receive power supply and data display, storage, and analysis. A PCT search report and written opinion on patentability that we received from World Intellectual Property Organization (known as WIPO) that included only two "Y" citations and one additional non-relevant reference. Corresponding national applications of our PCT were filed in the U.S., Europe, Japan, China, Australia and Israel.

On May 1, 2014, we announced the receipt of a U.S. Notice of Allowance for a key patent relating to how the Dario Blood Glucose Monitoring System draws power from and transmits data to a smartphone via the audio jack port. This patent was issued as U.S. Patent No. 8,797,180 in August 2014, and in August2015, we received U.S. patent (No. 9,125,549) that broadened our registered patent No. 8,797,180 to include testing of other bodily fluids through an audio jack connection. We believe these early patents represent critical intellectual property recognition and a significant initial validation of our intellectual property efforts. Further, a corresponding European patent was granted to us in May 2016, as European patent No. 2569622 for testing of fluids through an audio jack connection. An additional corresponding patent was granted in Israel in April 2016.

On November 11, 2017, U.S. patent No. 9,832,301 titled "Systems and methods for adjusting power levels on a monitoring device" was granted. This patent enhances the way the Dario Blood Glucose Monitoring System communicates with users' smartphone devices. This family includes a corresponding pending application in China.

Additionally, we recently received U.S. patent No. 10,445,072 that enables optical communication between the Dario Blood Glucose Monitoring System and the end user's smartphone devices.

Additional patent applications are in the process, of being discussed and developed, and we believe that we have a rich potential pipeline of future technologies that we intend to develop.

For example, we are further seeking to develop and protect new intellectual property around future generations of our hardware and software with the goal of achieving enhanced functionality, user interface, data usability, cyber protection, and artificial intelligence enhancement.

In early 2022, we acquired Physimax and acquired the following patent – US 10,709,374 B2 titled "System and Method for Assessment of Musculoskeletal Profile of a Target Individual."

This patent was also submitted as EP application #19767795.8 on the 05/03/2019 and is currently pending.

Design patents and patent applications on the Dario Blood Glucose Monitoring System

To further protect our market distinction and branding for the Dario Blood Glucose Monitoring System, three U.S. Design Applications have been filed and granted covering the glucose meter, the cartridge, and connection dongle. At least some of these applications were granted and registered in the United States, as well as, Canada, Europe, and Hong Kong.

Trademark applications

We have also filed several families of trademark applications covering the "Dario" name (wordmark), the Dario name and logo (logo), the Dario logo alone (logo), the DARIO-LITE wordmark, the LABSTYLE INNOVATIONS wordmark, the DARIOHEALTH wordmark, and the DARIOHEALTH logo. In particular, the "Dario" wordmark is registered as a trademark in Australia, Canada, China, Costa Rica, United States, Israel, Hong Kong, South Africa, Japan, Costa Rica, Europe, Israel, Korea, Mexico, New Zealand, Panama and Russia. The "DARIOHEALTH" wordmark is registered as a trademark in the United States, Canada, China and India.

Upright also added the following trademarks to our list: UPRIGHT, UPRIGHT GO – registered in the US, AU and EM, and UPRIGHT DASHBOARD, UPRIGHT DESKTOP, UPRIGHT GO 2, UPRIGHT POSTURE IS WITHING REACH – registered in the U.S.

Utility Models

We have been granted Utility Models for our core invention in Japan.

Other intangible assets

As the number of Dario users grows, an ever-growing amount of data is being collected from diabetic patients, including their blood sugar levels, meal compositions, routines, physical exercise (intensity and duration) as well as many other factors, and lately also blood pressure data, which are all useful for creating meaningful correlations between these factors and insulin use. We expect that this database will be highly valuable and may be capitalized in many ways. The accumulation of this type of know-how and related algorithms are protected as trade secrets using specialized confidentiality protocols.

Twill Intellectual Property

Granted Patents

On October 27, 2020, the United States Patent Office issued Patent No. US 10,813,584 B2 titled "ASSESSING ADHERENCE FIDELITY TO BEHAVIORAL INTERVENTIONS USING INTERACTIVITY AND NATURAL LANGUAGE PROCESSING". The abstract contained in the patent award describes this patent as "A computer system apparatus and a method carried out by such apparatus for interacting with a user via a behavior intervention designed to cause an increase in emotional well-being of the user. The behavior intervention has a plurality of conditions to be satisfied. The process includes receiving input data from the user during the behavior intervention, performing, on at least a portion of the received input data having text, semantic analysis to identify terms that satisfy the plurality of conditions and assessing, based on an amount of completeness of satisfying the plurality of conditions, a level of adherence to the behavior intervention. When one or more of the plurality of conditions are determined not as satisfied, the process includes generating a prompt designed to elicit, from the user, a response specific to satisfying the missing conditions."

There are also pending associated patent applications filed in the European Patent Office (Application 18835438.5), Canada (Application 3070229), and Hong Kong (Application 620200109481).

On February 7, 2023, the United States Patent Office issued Patent No. US 11,575,737 B2 titled "DYNAMIC INTERACTIVE NETWORK SYSTEM FOR PROVIDING ONLINE SERVICE AND SOCIAL COMMUNITY FOR ENGAGING, LEARNING, AND TRAINING SKILLS FOR MENTAL HEALTH". The abstract contained in the patent award describes this patent as "A dynamic interactive network system provides an online service and social community for engaging, learning, and training skills for happiness. The system includes a processor and memory storing instructions which when executed by the processor configure the processor to provide the online service. The instructions further configure the processor to provide tracks including activities, provide an initial happiness level and a track to a user based on a self-assessment completed by the user upon signing up, monitor progress of the user based on self-assessments periodically completed by the user, modify the track based on the self-assessments, suggest followers to the user from the users whose profiles match the profile of the user in terms of demographics, psychographics, and rating of the users on the online service, and generate a happiness graph for the user that correlates the activities and the followers with their impact on happiness level of the user."

On February 20, 2024, the United States Patent Office issued Patent No. US 11,909,811 B2 titled "DYNAMIC INTERACTIVE NETWORK SYSTEM FOR PROVIDING ONLINE SERVICE AND SOCIAL COMMUNITY FOR ENGAGING, LEARNING, AND TRAINING SKILLS FOR MENTAL HEALTH". This patent is a continuation of Patent No. 11,575,737 with additional claims.

On August 10, 2023, the United States Patent Office issued Patent No. US 11,727,217 B2 titled "SYSTEMS AND METHODS FOR DYNAMIC USER INTERACTION FOR IMPROVING MENTAL HEALTH". The abstract contained in the patent award describes this patent as "A computing system for interacting with a user comprises a processor and a memory storing executable software which, when executed by the processor, causes the processor to

commence an interactive session with a user, receive input data from the user during the interactive session, analyze the received input data and output a response to the user to continue the interactive session with the user. The processor, prior to outputting the response, identifies one or more topics from the received input data, ascertains a tone of the received input data, generates a mirroring prompt based on the ascertained tone of the received input data, and output to the user the generated mirroring prompt. The processor outputs the mirroring prompt to the user during the interactive session to cause an increase in a level of engagement of the user with the interactive session".

On October 10, 2023, the United States Patent Office issued Patent No. US 11,779,270 B2 titled "SYSTEMS AND METHODS FOR TRAINING ARTIFICIALLY-INTELLIGENT CLASSIFIER". The abstract contained in the patent award describes the patent as "A computing system/method for enabling a user to improve, via training, a system designed to increase the emotional and/or physical well-being of persons or designed for other purposes. The system/method includes retrieving a user response from a dialogue database, the user response having already labeled thereto an assigned class having a highest confidence score, the confidence score indicating degree of confidence that context of the retrieved user response is of the assigned class, displaying, the assigned class, along with other classes each having a respective lower confidence score, and receiving an indication of validity of the assigned class. The system/method further includes retrieving of a pair of sequential user response and follow-up prompt from the database, displaying user-selectable ratings, each rating designating a respectively different quality to the follow-up prompt, receiving selection of a rating and a related comment, and associating the selection and the comment to the follow-up prompt."

There are also pending associated patent applications filed in the European Patent Office (Application 19847959.4), Canada (Application 3109113).

Patent Applications

On October 25, 2021, patent application 17/510,341 was filed in the United States Patent office. Titled "DYNAMIC INTERACTION SYSTEM AND METHOD", the abstract for this application describes as "A method and system are provided for dynamic user interaction. The method includes assessing input data, received from a user, that is used to determine a psychological state of the user. The method further includes determining a current psychological state of the user, using an application stored in non-transitory storage media, based on the input data, and determining possible courses of action for the user based on the determined current psychological state of the user. The method additionally includes presenting the current psychological state and the possible courses of action to the user through a physical interface.".

On December 8, 2021, patent application 17/546,020 was filed in the United States Patent office. Titled "CUSTOMIZABLE THERAPY SYSTEM AND PROCESS", the abstract for this application describes as "The present invention is directed to a computing system and a process carried out by such system for providing a therapy session personalized to the circumstances of the user. The therapy session includes an audio component that is automatically generated by an algorithm that makes a voice seem to be that of an actual person. In a similar way, a video component to the therapy session may also be presented."

On January 26, 2022, patent application 17/585,003 was filed in the United States Patent office. Titled "SENSOR TRACKING BASED PATIENT SOCIAL CONTENT SYSTEM", the abstract for this application describes as "A computing system that includes a server, the system functions as a patient social content system (PSCS) which, among other functions, provides content to a patient/user. A device with a network connection to the computing system permits the patient to provide information to the computing system. In addition, one or more sensors are configured to detect changes in various physical parameters relevant to the patient. Electrical signals from the sensors are conveyed to the computing system so that the computing system is aware of changes in physical parameters of the patient. Based on the changed physical parameters of the patient, the computing system provides different content to the user that is relevant to the changes. Overall, processes carried out by the system establish and maintain a patient social content system that utilizes tracking data received from one or more sensors.".

On August 1, 2022, patent application 17/878,901 was filed in the United States Patent office. Titled "APPARATUS FOR COMPUTER GENERATED DIALOGUE AND TASK-SPECIFIC NESTED FILE ARCHITECTURE THEREOF", the abstract for this application describes as "The present disclosure relates to digital devices adapted to increase the efficacy of a computerimplemented migraine treatment plan. In some embodiments, an apparatus generates an interactive session comprising a plurality of tracks and sets a need set according to a baseline level. The need set may comprise a selection of one or more tracks, wherein the selection is a function of the baseline level and/or a variable level. The interactive session may utilize a threetiered architecture interactive dialogue module comprising a master file, a plurality of skeleton files, and a plurality of skin sets, wherein each of the plurality of skin sets is nested within one of the plurality of skeleton files and the plurality of skeleton files are nested within the master file. Accordingly, the tracks, the activities, and the tasks, may each utilize the master file, the skeleton files, and the skin sets, respectively.".

Associated applications have been filed in the WIPO (Application No.PCT/US 2022/046487 and EPO (Application No. 22881741.7)

On October 12, 2022, patent application 17/878,901 was filed in the United States Patent office. Titled "MODIFIABLE PHARMACEUTICAL PROTOCOL FOR MIGRAINE TREATMENT AND ASSESSMENT OF DRUG EFFICACY THEREOF", the abstract for this application describes as "The present disclosure relates to a treatment protocol for treatment of migraine comprising an abortive drug adapted to bind with a plurality of calcitonin gene-related peptides (CGRP) receptors. The abortive drug may be adapted to mitigate vasodilation in a user. The treatment protocol may comprise evaluating medication-relevant information from a user input to determine positive and/or negative effects of the abortive drug regimen. The treatment protocol may include a preventative drug regimen and a corresponding preventative drug. The treatment protocol may be configured to evaluate the efficacy of the abortive and/or preventive drug regimens based on the determined positive and/or negative effects. In a further embodiment, the drug protocol may be configured to generate suggested alterations to either regimen based on the efficacy evaluation."

On October 12, 2022, patent application 17/964,871 was filed in the United States Patent office. Titled "PHARMACEUTICAL ADMINISTRATION TRACKING AND TREATMENT COMPLIANCE SYSTEM', the abstract for this application describes as "The present disclosure relates to a medication tracking and compliance system. In an embodiment, the system receives an initial drug regimen comprising one or more drugs configured to inhibit a calcitonin superfamily of peptides. The system, via a client device, may receive user input and extract the medication-relevant information from said user input. In a further embodiment, the medication-relevant information may be analyzed in view of drug-specific information to evaluate potential positive and/or negative effects. The system may generate an activity within the interactive session, where the activity may be replaced with a succeeding activity based on the activity content efficacy and activity type efficacy of the previously generated activity."

On October 12, 2022, patent application 17/964,874 was filed in the United States Patent office. Titled "DISTRIBUTED NETWORK FOR MODIFIABLE INTERACTIVE SESSIONS AND ADHERENCE ENHANCEMENT THEREOF", the abstract for this application describes as "The present disclosure relates to a system of networked devices configured to increase the efficacy of a migraine treatment plan and adherence to said treatment plan. The system may comprise a client device and a server, wherein the client device is adapted to generate an interactive session including one or more tracks. In a further embodiment, the client device receives user input and alters the track based on an instant instruction. The instant instruction may be generated by the server based on at least the received input data and the need set. Thus, the server may transmit the instant instruction to the client device, enabling the client device to alter the track such as to improve at least one need from the need set."

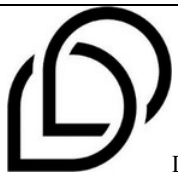
On April 19, 2023, patent application 18/136,787 was filed in the United States Patent office. Titled "SYSTEMS AND METHODS FOR MANAGING DYNAMIC USER INTERACTIONS WITH ONLINE SERVICES FOR ENHANCING MENTAL HEALTH OF USERS", the abstract for this application describes as "A system for conducting dialogues with users of an online service recommending N activities comprises a processor to generate a first file including M portions for conducting the dialogues. The processor generates N second files for the N activities, respectively. The processor includes in each of the N second files references to a plurality of the M portions of the first file. The processor generates a plurality of third files, each corresponding to a task for performing one of the N activities. The processor conducts a dialogue with one of the users about one of the N activities using one of the N second files corresponding to

the one of the N activities, a plurality of the M portions of the first file referenced by the one of the N second files, and one of the third files corresponding to a task for performing the one of the N activities.

On August 15, 2023, patent application 18/234,319, a Continuation of application No. 17/671,251, filed on Feb. 14, 2022, now Pat. No. 11,727,217, was filed in the United States Patent office. Titled "SYSTEM S AND METH ODS FOR DYNAMIC USER INTERACTION FOR IMPROVING MENTAL HEALTH", the abstract for this application describes as " A computing system for interacting with a user comprises a processor and a memory storing executable software which, when executed by the processor, causes the processor to commence an interactive session with a user, receive input data from the user during the interactive session, analyze the received input data and output a response to the user to continue the interactive session with the user. The processor, prior to outputting the response, identifies one or more topics from the received input data, ascertains a tone of the received input data, generates a mirroring prompt based on the ascertained tone of the received input data, and output to the user the generated mirroring prompt. The processor outputs the mirroring prompt to the user during the interactive session to cause an increase in a level of engagement of the user with the interactive session."

Associated applications have been filed in EP (Application No. 21194661.1)

Granted Trademarks

Country	Mark	Registration No.	Regitrsation Date
USA	Therapeutic Media	7281217	01/16/2024
USA	Duet	7270430	01/09/2024
USA	KOPA	6531581	10/19/2021
USA	 Circular Design (Talk Bubble Design)	6108363	07/21/2020
USA	ANNA	6024641	03/31/2020
USA	happify HEALTH	5546023	08/21/2018
USA	HAPPIFY HEALTH	5565951	09/18/2018
Madrid Protocol	HAPPIFY	1216735	Renewal: 10/15/2023
USA	HAPPIFY	4475643	01/28/2014
Madrid Protocol	SEQUENCE	1697868	08/23/2022
USA	SEQUENCE	7231798	11/28/2023
Madrid Protocol	TWILL	1712124 (BR,UK)	08/25/2022
Madrid Protocol	ASPIRO	1738488 (AU,UK)	04/28/2023
USA	 DD Stylized	7310387	02/20/2024

Competition

In recent years, a number of digitally supported solutions have emerged to manage diabetes and other chronic conditions. Competitors are developing new technologies rapidly and, in some cases, are also expanding to manage other chronic conditions. In this crowded field, our success is predicated on our flexibility to adapt to evolving customer requirements in digital health and superior execution in engagement, retention and clinical outcomes in a manner that delivers clear return on investment in required time-horizons and in complex, highly regulated business environments. We expect new entrants in the field and the emergence of novel technologies, as well as competition from larger technology platform players such as Amazon, Apple and Google. Dario's competitors vary by intervention (devices, applications, coaching and analytics), by channel (health plan, pharma, provider, employer) and by condition (including, for example, diabetes, MSK, HTN, behavioral health and others). Certain of our competitors offer this integrated approach in varying degrees, including, among others, Hinge Health, Inc., Livongo Health Inc. (acquired by Teladoc Health Inc.), Omada Health, Inc., Vida Health, Inc. and Virta Health Corp. We believe that our competitors are comparatively disadvantaged along several axes:

- Our competitors offer point solutions for a single condition (which model is unattractive to enterprise customers needing to manage multiple vendor relationships and who recognize that conditions frequently overlap in the same individual);
- Our competitors fail to share member-level data or granular reporting with partners, which prevents these partners from leveraging their own assets to support care;
- Competitor applications have limited or minimal levels of personalization, where communications (or "nudge") from the application may be somewhat personalized, but actual user experiences are heavily templated, and not personalized or dynamic;
- Competitor applications are supported only by short term outcome data, as compared to our studies which cover a 2-year period and offer 8 years of direct-to-consumer data;
- Failure of any one of our competitors to successfully engage and retain a substantial portion of the base population, as few have the direct-to-consumer experience or data required, resulting in frustrated customers who cannot realize promised cost savings;
- Customers of our competitors suffer an inadequate user experience, as evidenced by few app store reviews and low scores in Apple, Google and Amazon stores;
- Our competitors offer medical device-oriented approaches with delayed product update cadences, rather than our more agile, software-driven approaches that push out new products every few weeks;
- Our competitors have slowed their improvements in the area of clinical metrics (including, for example, blood pressure, HbA1c, and pain), which decreases the solution's return on investment;
- Our competitors often utilize cumbersome form factors and alternative connected devices, which are not easily portable or that otherwise require significant user effort for connectivity. By contrast, our diabetes solution, for example, utilizes lancets, strips and a dongle held in a lipstick-sized device that physically connects to a user's phone and doesn't require independent charging. As another example, our MSK device is small and easily attaches to body parts for convenient and easy use;
- Our competitors' applications experience limited interoperability and connectivity, such that they are unable to integrate with third party devices, electronic health records or partnered solutions; and
- Our competitors have higher costs; our solutions are priced 30-50% lower than current comparable in-market solutions.

Employees

As of March 22, 2024, and following the acquisition of Twill Inc., we had 276 full-time employees and 18 part-time employees. We have employment agreements with our four executive officers. See “Management – Employment Agreements.”

Item 1A. Risk Factors

Investing in our securities is highly speculative and involves a high degree of risk. You should carefully consider the following factors and other information in this Annual Report and our other SEC filings before making a decision to invest in our securities. Additional risks and uncertainties that we are unaware of may become important factors that affect us. If any of the following events occur, our business, financial conditions and operating results may be materially and adversely affected. In that event, the trading price of our common stock and warrants may decline, and you could lose all or part of your investment.

Risks Related to Our Financial Position and Capital Requirements

We were formed in August 2011 and are thus subject to the risks associated with new businesses.

We were formed in August 2011 as a new business and, commencing from 2015, we entered the commercialization stage of our technology. As such, this limited operating history may not be adequate to enable you to fully assess our ability to develop and commercialize the Dario Smart Diabetes Management Solution, achieve market acceptance of the Dario Smart Diabetes Management Solution, develop other products and respond to competition. We commenced a commercial launch of the free Dario Smart Diabetes Management application in the United Kingdom in late 2013 and commenced an initial soft launch of the full Dario Smart Diabetes Management Solution (including the app and the Dario Blood Glucose Monitoring System) in selected jurisdictions in March 2014 with the goal of collecting customer feedback to refine our longer-term roll-out strategy and continued to scale up launch during 2014 in the United Kingdom, the Netherlands and New Zealand, in 2015 in Australia, Israel and Canada and in 2016 in the United States. These efforts have not generated sufficient revenues, and we will need to generate additional revenues over the next years. Therefore, we are, and expect for the foreseeable future to be, subject to all the risks and uncertainties, inherent in a new business and the development and sale of new medical devices and related software applications. As a result, we may be unable to fully develop, obtain regulatory approval for, commercialize, manufacture, market, sell and derive material revenues in the timeframes we project, if at all, and our inability to do so would materially and adversely impact our viability as a company. In addition, we still must establish many functions necessary to operate a business, including finalizing our managerial and administrative structure, continuing product and technology development, assessing and commencing our marketing activities, implementing financial systems and controls and personnel recruitment.

Accordingly, you should consider our prospects in light of the costs, uncertainties, delays and difficulties frequently encountered by companies in their initial revenue generating stages, particularly those in the medical device and mobile health fields. In particular, potential investors should consider that there is a significant risk that we will not be able to:

- implement or execute our current business plan, or that our business plan is sound;
- maintain our management team and the Company's board of directors (the "Board of Directors");
- raise sufficient funds in the capital markets or otherwise to effectuate our business plan;
- determine that our technologies that we have developed are commercially viable; and/or
- attract, enter into or maintain contracts with, and retain customers.

In the event that we do not successfully address these risks, our business, prospects, financial condition, and results of operations could be materially and adversely affected.

Given our limited revenue and lack of positive cash flow, we will need to raise additional capital, which may be unavailable to us or, even if consummated, may cause dilution or place significant restrictions on our ability to operate.

According to our management's estimates, based on our current cash on hand and further based on our budget and the assumption that initial commercial sales will commence during our anticipated timeframes, we believe that we will have sufficient resources to continue our activities through 2025.

Since we might be unable to generate sufficient revenue or cash flow to fund our operations for the foreseeable future, we will need to seek additional equity or debt financing to provide the capital required to maintain or expand our operations. We may also need additional funding for developing products and services, increasing our sales and marketing capabilities, and promoting brand identity, as well as for working capital requirements and other operating and general corporate purposes. Moreover, the regulatory compliance arising out of being a publicly registered company has dramatically increased our costs.

We currently have a credit facility in place with Avenue Venture Opportunities Fund L.P. and Avenue Venture Opportunities Fund II, L.P., of which $30 million was made available in May 2023. However, there can be no assurance that we will be able to raise sufficient additional capital on acceptable terms, or at all. If such financing is not available on satisfactory terms, or is not available at all, we may be required to delay, scale back or eliminate the development of business opportunities and our operations and financial condition may be materially adversely affected.

If we raise additional capital by issuing equity securities, the percentage ownership of our existing stockholders may be reduced, and accordingly these stockholders may experience substantial dilution. We may also issue equity securities that provide for rights, preferences and privileges senior to those of our common stock. Given our need for cash and that equity raising is the most common type of fundraising for companies like ours, the risk of dilution is particularly significant for stockholders of our company.

Debt financing, if obtained, may involve agreements that include liens on our assets, covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, could increase our expenses and require that our assets be provided as a security for such debt. Debt financing would also be required to be repaid regardless of our operating results.

If we raise additional funds through collaborations and licensing arrangements, we may be required to relinquish some rights to our technologies or candidate products, or to grant licenses on terms that are not favorable to us.

Funding from any source may be unavailable to us on acceptable terms, or at all. If we do not have sufficient capital to fund our operations and expenses, we may not be able to achieve or maintain competitiveness, which could lead to the failure of our business and the loss of your investment.

We have incurred significant losses since inception. As such, you cannot rely upon our historical operating performance to make an investment decision regarding our company.

Since our inception, we have engaged primarily in research and development activities and in 2015 entered the commercialization stage. We have financed our operations primarily through private placements and public offerings of common stock and have incurred losses in each year since inception including net losses of $59,427,000 and $62,193,000 in 2023 and 2022, respectively. Our accumulated deficit at December 31, 2023 was approximately $349,361,000. We do not know whether or when we will become profitable. Our ability to generate revenue and achieve profitability depends upon our ability, alone or with others, to launch Dario in additional European countries, and elsewhere and manufacture, market and sell Dario where approved. We may be unable to achieve any or all of these goals.

We may be subject to claims for rescission or damages in connection with certain sales of shares of our securities.

In March 2016, the Securities and Exchange Commission declared effective a registration statement that we filed to cover 66,667 shares 76,667 warrants to purchase common stock, 76,667 shares of common stock underlying such warrants, and underwriters' warrants to purchase up to 7,172 shares of common stock. Sales of approximately 2,778 shares of common stock, approximately 12,778 shares of common stock underlying warrants and approximately 1,278 shares of common stock underlying underwriters' warrants may not have been made in accordance with Section 5 of the Securities Act of 1933, as amended. Accordingly, the purchasers of those securities may have rescission rights or be entitled to damages. The amount of such liability, if any, is uncertain. In the event that we are required to make payments to investors as a result of these unregistered sales of securities, our liquidity could be negatively impacted.

Risks Related to Our Business

There is no assurance that our DarioEngage software platform will succeed or be adopted by healthcare providers.

Our product offering consists of our DarioEngage software platform, where we digitally engage with Dario users, assist them in monitoring their chronic illnesses and provide them with coaching, support, digital communications, and real-time alerts, trends and pattern analysis. We expect that the DarioEngage software platform may be leveraged by our potential partners, such as clinics, health care service providers, employers, and payers for scalable monitoring of people with diabetes in a cost-effective manner, which we expect will open for us additional revenue streams. While we have begun to execute agreements with employers and health plans in the United States, we have not yet seen wide adoption of our platform. Therefore, the success of our DarioEngage software platform will depend entirely on our potential partners' adoption of the platform and we cannot assure you that our potential partners will do so, or, if adopted, that they will continue to use the platform continually and for an extended period of time. If we cannot encourage potential partners to utilize our DarioEngage software platform we may not succeed in marketing the product to our potential partners, the failure of which may materially and adversely affect our business and operating results.

We only recently began commercializing Dario, and our success will depend on the acceptance of Dario in the healthcare market.

Dario has been CE marked since 2013, enabling us to commercialize in 32 countries across Europe as well as in certain other countries worldwide. It was also approved by the regulatory authorities in Australia, New Zealand, Canada, Israel and South Africa, and most recently in December 2015, we received FDA clearance. As a result, we have a limited history of commercializing Dario and commenced selling Dario in the United States in 2016. We have limited experience engaging in commercial activities and limited established relationships with physicians and hospitals as well as third-party suppliers on whom we depend for the manufacture of our product. We are faced with the risk that the marketplace will not be receptive to Dario over competing products and that we will be unable to compete effectively. Factors that could affect our ability to establish Dario or any potential future product include:

- the development of products or devices which could result in a shift of customer preferences away from our device and services and significantly decrease revenue;
- the increased use of improved diabetes drugs that could encourage certain diabetics to test less often, resulting in less usage of a self-monitoring test device for certain types of diabetics;
- the challenges of developing (or acquiring externally-developed) technology solutions that are adequate and competitive in meeting the requirements of next-generation design challenges, including interoperability with various electronic health records;
- the significant number of current competitors in the BGMS market who have significantly greater brand recognition and more recognizable trademarks and who have established relationships with healthcare providers and payors; and
- intense competition to attract acquisition targets, which may make it more difficult for us to acquire companies or technologies at an acceptable price or at all.

We cannot assure you that Dario or any future product will gain broad market acceptance. If the market for Dario or any future product fails to develop or develops more slowly than expected, or if any of the technology and standards supported by us do not achieve or sustain market acceptance, our business and operating results would be materially and adversely affected.

We cannot accurately predict the volume or timing of any future sales, making the timing of any revenues difficult to predict.

We may be faced with lengthy customer evaluation and approval processes associated with Dario. Consequently, we may incur substantial expenses and devote significant management effort and expense in developing customer adoption of Dario which may not result in revenue generation. We must also obtain regulatory approvals of Dario in certain

jurisdictions as well as approval for insurance reimbursement in order to initiate sales of Dario, each of which is subject to risk and potential delays, and neither of which may actually occur. As such, we cannot accurately predict the volume or timing of any future sales.

If Dario fails to satisfy current or future customer requirements, we may be required to make significant expenditures to redesign the product, and we may have insufficient resources to do so.

Dario is being designed to address an evolving marketplace and must comply with current and evolving customer requirements in order to gain market acceptance. There is a risk that Dario will not meet anticipated customer requirements or desires. If we are required to redesign our products to address customer demands or otherwise modify our business model, we may incur significant unanticipated expenses and losses, and we may be left with insufficient resources to engage in such activities. If we are unable to redesign our products, develop new products or modify our business model to meet customer desires or any other customer requirements that may emerge, our operating results would be materially adversely affected, and our business might fail.

We expect to derive substantially all of our revenues from our principal technology, which leaves us subject to the risk of reliance on such technology.

We expect to derive substantially all of our revenues from sales of products derived from our principal technology. Our initial product utilizing this technology is Dario. As such, any factor adversely affecting sales of Dario, including the product release cycles, regulatory issues, market acceptance, product competition, performance and reliability, reputation, price competition and economic and market conditions, would likely harm our operating results. We may be unable to develop other products utilizing our technology, which would likely lead to the failure of our business. Moreover, in spite of our efforts related to the registration of our technology, if patent protection is not available for our principal technology, the viability of Dario and any other products that may be derived from such technology would likely be adversely impacted to a significant degree, which would materially impair our prospects.

We are dependent upon third-party manufacturers and suppliers making us vulnerable to supply shortages and problems and price fluctuations, which could harm our business.

We do not own or operate manufacturing facilities for clinical or commercial production of the Dario Blood Glucose Monitoring System, and we lack the resources and the capability to manufacture the Dario Blood Glucose Monitoring System on a commercial scale. Therefore, we rely on a limited number of suppliers who manufacture and assemble certain components of the Dario Blood Glucose Monitoring System. Our suppliers may encounter problems during manufacturing for a variety of reasons, including, for example, failure to follow specific protocols and procedures, failure to comply with applicable legal and regulatory requirements, equipment malfunction and environmental factors, failure to properly conduct their own business affairs, and infringement of third-party intellectual property rights, any of which could delay or impede their ability to meet our requirements. Our reliance on these third-party suppliers also subjects us to other risks that could harm our business, including:

- we are not a major customer of many of our suppliers, and these suppliers may therefore give other customers' needs higher priority than ours;
- third parties may threaten or enforce their intellectual property rights against our suppliers, which may cause disruptions or delays in shipment, or may force our suppliers to cease conducting business with us;
- we may not be able to obtain an adequate supply in a timely manner or on commercially reasonable terms;
- our suppliers, especially new suppliers, may make errors in manufacturing that could negatively affect the efficacy or safety of the Dario Blood Glucose Monitoring System or cause delays in shipment;
- we may have difficulty locating and qualifying alternative suppliers;

- switching components or suppliers may require product redesign and possibly submission to FDA, European Economic Area Notified Bodies, or other foreign regulatory bodies, which could significantly impede or delay our commercial activities;
- one or more of our sole- or single-source suppliers may be unwilling or unable to supply components of the Dario Blood Glucose Monitoring System;
- other customers may use fair or unfair negotiation tactics and/or pressures to impede our use of the supplier;
- the occurrence of a fire, natural disaster or other catastrophe impacting one or more of our suppliers may affect their ability to deliver products to us in a timely manner; and
- our suppliers may encounter financial or other business hardships unrelated to our demand, which could inhibit their ability to fulfill our orders and meet our requirements.

We may not be able to quickly establish additional or alternative suppliers if necessary, in part because we may need to undertake additional activities to establish such suppliers as required by the regulatory approval process. Any interruption or delay in obtaining products from our third-party suppliers, or our inability to obtain products from qualified alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to switch to competing products. Given our reliance on certain single-source suppliers, we are especially susceptible to supply shortages because we do not have alternate suppliers currently available.

We rely in part on a small group of third-party distributors to effectively distribute our products.

We depend in part on medical device distributors for the marketing and selling of our products in certain territories in which we have launched product sales. We depend on these distributors' efforts to market our products, yet we are unable to control their efforts completely. These distributors typically sell a variety of other, non-competing products that may limit the resources they dedicate to selling Dario. In addition, we are unable to ensure that our distributors comply with all applicable laws regarding the sale of our products. If our distributors fail to effectively market and sell Dario, in full compliance with applicable laws, our operating results and business may suffer. Recruiting and retaining qualified third-party distributors and training them in our technology and product offering requires significant time and resources. To develop and expand our distribution, we must continue to scale and improve our processes and procedures that support our distributors. Further, if our relationship with a successful distributor terminates, we may be unable to replace that distributor without disruption to our business. If we fail to maintain positive relationships with our distributors, fail to develop new relationships with other distributors, including in new markets, fail to manage, train or incentivize existing distributors effectively, or fail to provide distributors with competitive products on attractive terms, or if these distributors are not successful in their sales efforts, our revenue may decrease and our operating results, reputation and business may be harmed.

Failure in our online and digital marketing efforts could significantly impact our ability to generate sales.

In several of our principal target markets, we utilize online and digital marketing in order to create awareness to Dario. Our management believes that using online advertisement through affiliate networks and a variety of other pay-for-performance methods will be superior for marketing and generating sales of Dario rather than utilizing traditional, expensive retail channels. However, there is a risk that our marketing strategy could fail. Because we plan to use non-traditional retail sales tools and to rely on healthcare providers to educate our customers about Dario, we cannot predict the level of success, if any, that we may achieve by marketing Dario via the internet. The failure of our online marketing efforts would significantly and negatively impact our ability to generate sales.

Our Dario application, which is a key to our business model, is available via Apple's App Store and via Google's Android platforms and maybe in the future via additional platforms. If we are unable to achieve or maintain a good relationship with each of Apple and Google or similar platforms, or if the Apple App Store or the Google Play Store or any other applicable platform were unavailable for any prolonged period of time, our business will suffer.

A key component of the Dario Solution is an iPhone or Android application which includes tools to help diabetic patients manage their disease. This application is compatible with Apple's iOS and with Google's Android platforms and may in the future become compatible via additional platforms. If we are unable to make our Dario Smart Diabetes Management application compatible with these platforms, or if there is any deterioration in our relationship with either Apple or Google or others after our application is available, our business would be materially harmed.

We are subject to each of Apple's and Google's standard terms and conditions for application developers, which govern the promotion, distribution, and operation of games and other applications on their respective storefronts. Each of Apple and Google has broad discretion to change its standard terms and conditions, including changes which could require us to pay to have our Dario application available for downloading. In addition, these standard terms and conditions can be vague and subject to changing interpretations by Apple or Google. We may not receive any advance warning of such changes. In addition, each of Apple and Google has the right to prohibit a developer from distributing its applications on its storefront if the developer violates its standard terms and conditions. In the event that either Apple or Google ever determines that we are in violation of its standard terms and conditions, including by a new interpretation, and prohibits us from distributing our Dario Management application on its storefront, it would materially harm our business.

Additionally, we will rely on the continued function of the Apple App Store and the Google Play Store as digital storefronts where our Dario application may be obtained. There have been occasions in the past when these digital storefronts were unavailable for short periods of time or where there have been issues with the in-app purchasing functionality within the storefront. In the event that either the Apple App Store or the Google Play Store is unavailable or if in-app purchasing functionality within the storefront is non-operational for a prolonged period of time, it would have a material adverse effect on the ability of our customers to secure the Dario Smart Diabetes Management application, which would materially harm our business.

We rely upon Software-as-a-Services, or SAAS, technologies from third parties to operate our business, and interruptions or performance problems with these technologies may adversely affect our business, financial condition and results of operations.

We rely on hosted SaaS applications from third parties in order to operate critical functions of our business, including platform delivery, enterprise resource planning, customer relationship management, billing, project management and accounting and financial reporting. If these services become unavailable due to extended outages, interruptions or because they are no longer available on commercially reasonable terms, our expenses could increase, our ability to manage finances could be interrupted and our processes for managing sales of our platform and products and supporting our customers could be impaired until equivalent services, if available, are identified, obtained and implemented, all of which could adversely affect our business, financial condition and results of operations.

The SaaS pricing model is evolving and our failure to manage its evolution and demand could lead to lower than expected revenue and profit.

We derive most of our revenue growth from subscription offerings and, specifically, SaaS offerings. This business model depends heavily on achieving economies of scale because the initial upfront investment is costly and the associated revenue is recognized on a ratable basis. If we fail to achieve appropriate economies of scale or if we fail to manage or anticipate the evolution and demand of the SaaS pricing model, then our business and operating results could be adversely affected.

Our results of operations may fluctuate significantly due to the timing of our recognition of SaaS revenues.

We may experience volatility in our reported revenues and operating results due to the differences in timing of revenue recognition between our SaaS offerings and our traditional on-premise software and hardware sales. SaaS revenues are generally recognized ratably over the life of the subscriptions. In contrast, revenue from our on-premise

software and hardware sales is generally recognized in full at the time of delivery. Accordingly, the SaaS delivery model creates risks related to the timing of revenue recognition not associated with our traditional on-premise software delivery model and hardware sales. A portion of our SaaS revenue results from the recognition of deferred revenue relating to subscription agreements entered into during prior reporting periods. A decline in new or renewed subscriptions in any period may not be immediately reflected in our reported financial results for that period, but may result in a decline in our revenue in future reporting periods. If any of our assumptions about revenue from our SaaS delivery model prove incorrect, our actual results may vary materially from those anticipated, estimated, or projected.

Any damage, failure or disruption of our SaaS network infrastructure or data centers could impair our ability to effectively provide our solution, harm our reputation and adversely affect our business.

Our SaaS network infrastructure is a critical part of our business operations. Our clients access our solution through standard web browsers, smart phones, tablets and other web-enabled devices and depend on us for fast and reliable access to our solution. We serve all of our clients from our data centers located in the United-States. Our SaaS network infrastructure and data centers are vulnerable to damage, failure and disruption.

In the future, we may experience issues with our computing and communications infrastructure, or data centers caused by the following factors:

•human error;

•telecommunications failures or outages from third-party providers;

• computer viruses or cyber-attacks;

•break-ins or other security breaches;

•acts of terrorism, sabotage, intentional acts of vandalism or other misconduct;

•tornadoes, fires, earthquakes, hurricanes, floods and other natural disasters;

•power loss; and

•other unforeseen interruptions or damages.

If our SaaS network infrastructure or our clients' ability to access our solution is interrupted, client and employee data from recent transactions may be permanently lost, and we could be exposed to significant claims by clients, particularly if the access interruption is associated with problems in the timely delivery of funds payable to employees or tax authorities. Further, any adverse changes in service levels at our data centers resulting from damage to or failure of our data centers could result in disruptions in our services. Any significant instances of system downtime or performance problems at our data centers could negatively affect our reputation and ability to attract new clients, prevent us from gaining new or additional business from our current clients, or cause our current clients to terminate their use of our solution, any of which would adversely impact our revenues. In addition, if our network infrastructure and data centers fail to support increased capacity due to growth in our business, our clients may experience interruptions in the availability of our solution. Such interruptions may reduce our revenues, cause us to issue refunds to clients or adversely affect our retention of existing clients, any of which could have a negative impact on our business, operating results or financial condition.

Our products are subject to technological changes which may impact their use.

Our Dario Blood Glucose Monitoring System is currently designed to be plugged into the Lighting jack for Apple devices or the USB-C jack for other mobile devices. As a result, our products are subject to future technological changes to mobile devices that may occur in the future. If we are unable to modify our products to keep pace with such technological changes, it would have a material adverse effect the ability of our customers to use our products, which would materially harm our business.

As we conduct business internationally, we are susceptible to risks associated with international relationships.

Outside of the United States, we operate our business internationally, presently in Europe, Australia and Canada. The international operation of our business requires significant management attention, which could negatively affect our business if it diverts their attention from their other responsibilities. In the event that we are unable to manage the complications associated with international operations, our business prospects could be materially and adversely affected. In addition, as a result of the crisis in Ukraine, both the United States and the EU have implemented sanctions against certain Russian individuals and entities, as well with respect to Belarus, and may impact the economic and political stability in the EU. If the EU experiences economic and political instability as a result of these current tensions, our business, including revenue, profitability and cash flows, and operations could be adversely affected. In addition, doing business with foreign customers subjects us to additional risks that we do not generally face in the United States. These risks and uncertainties include:

- management, communication and integration problems resulting from cultural differences and geographic dispersion;
- localization of products and services, including translation of foreign languages;
- delivery, logistics and storage costs;
- longer accounts receivable payment cycles and difficulties in collecting accounts receivable;
- difficulties supporting international operations;
- difficulties supporting customer services;
- changes in economic and political conditions;
- impact of trade protection measures;
- complying with import or export licensing requirements;
- exchange rate fluctuations;
- competition from companies with international operations, including large international competitors and entrenched local companies;
- potentially adverse tax consequences, including foreign tax systems and restrictions on the repatriation of earnings;
- maintaining and servicing computer hardware in distant locations;
- keeping current and complying with a wide variety of foreign laws and legal standards, including local labor laws;
- securing or maintaining protection for our intellectual property; and
- reduced or varied protection for intellectual property rights, including the ability to transfer such rights to third parties, in some countries.

The occurrence of any or all of these risks could adversely affect our international business and, consequently, our results of operations and financial condition.

We expect to be exposed to fluctuations in currency exchange rates, which could adversely affect our results of operations.

Because we expect to conduct a material portion of our business outside of the United States but report our financial results in U.S. Dollars, we face exposure to adverse movements in currency exchange rates. Our foreign operations will be exposed to foreign exchange rate fluctuations as the financial results are translated from the local currency into U.S. Dollars upon consolidation. Specifically, the U.S. Dollar cost of our operations in Israel is influenced by any movements in the currency exchange rate of the New Israeli Shekel (NIS). Such movements in the currency exchange rate may have a negative effect on our financial results. If the U.S. Dollar weakens against foreign currencies, the translation of these foreign currencies denominated transactions will result in increased revenue, operating expenses and net income. Similarly, if the U.S. Dollar strengthens against foreign currencies, the translation of these foreign currencies denominated transactions will result in decreased revenue, operating expenses and net income. As exchange rates vary, sales and other operating results, when translated, may differ materially from our or the capital market's expectations.

Non-U.S. governments often impose strict price controls, which may adversely affect our future profitability.

We intend to seek approval to market Dario and any future product in both the U.S. and in non-U.S. jurisdictions. If we obtain approval in one or more non-U.S. jurisdictions, we will be subject to rules and regulations in those jurisdictions relating to our products. In some countries, particularly countries of the European Union, each of which has developed its own rules and regulations, pricing may be subject to governmental control under certain circumstances. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a medical device candidate. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product to other available products. If reimbursement of our product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

Our Dario Solution and associated business processes may contain undetected errors, which could limit our ability to provide our services and diminish the attractiveness of our service offerings.

The Dario Management Solution may contain undetected errors, defects or bugs. As a result, our customers or end users may discover errors or defects in our products, software or the systems we design, or the products or systems incorporating our designs and intellectual property may not operate as expected. We may discover significant errors or defects in the future that we may not be able to fix. Our inability to fix any of those errors could limit our ability to provide our products, impair the reputation of our brand and diminish the attractiveness of our product offerings to our customers.

In addition, we may utilize third-party technology or components in our products, and we rely on those third parties to provide support services to us. Failure of those third parties to provide necessary support services could materially adversely impact our business.

Our future performance will depend on the continued engagement of key members of our management team.

Our future performance depends to a large extent on the continued services of members of our current management including, in particular, Erez Raphael, our Chief Executive Officer and a member of our Board of Directors and Zvi Ben David, our Chief Financial Officer, Treasurer and Secretary, and Richard Anderson, our President and General Manager for North America. In the event that we lose the continued services of such key personnel for any reason, this could have a material adverse effect on our business, operations, and prospects.

If we are not able to attract and retain highly skilled managerial, scientific and technical personnel, we may not be able to implement our business model successfully.

We believe that our management team must be able to act decisively to apply and adapt our business model in the rapidly changing markets in which we will compete. In addition, we will rely upon technical and scientific employees or third-party contractors to effectively establish, manage and grow our business. Consequently, we believe that our future viability will depend largely on our ability to attract and retain highly skilled managerial, sales, scientific and technical personnel. In order to do so, we may need to pay higher compensation or fees to our employees or consultants than we

currently expect, and such higher compensation payments would have a negative effect on our operating results. Competition for experienced, high-quality personnel is intense and we cannot assure that we will be able to recruit and retain such personnel. We may not be able to hire or retain the necessary personnel to implement our business strategy. Our failure to hire and retain such personnel could impair our ability to develop new products and manage our business effectively.

We may not generate the expected benefits of our acquisition of Twill, and the integration of this business could disrupt our ongoing business, distract our management and increase our expenses.

Through our acquisitions of Twill, we expanded our product offering to include digital-first solutions with a mission to improve users mental and physical health. We believe that the successful integration of Twill's business into our operations is important for our future financial performance. This will require that we integrate more closely the companies' product offerings and research and development capabilities, retain key employees, assimilate diverse corporate cultures, further integrate management information systems and consolidate the acquired operations, each of which could pose significant challenges. The difficulty of combining Twill with our company may be increased by the need to integrate personnel, and changes effected in the combination may cause key employees to leave.

It is possible that the integration process could take longer than anticipated and could result in the loss of valuable employees, additional and unforeseen expenses, the disruption of our ongoing business, processes and systems, or inconsistencies in standards, controls, procedures, practices, policies and compensation arrangements, any of which could adversely affect our ability to achieve the anticipated benefits of the acquisitions. The diversion of the attention of management created by the integration process, any disruptions or other difficulties encountered in the integration process, and unforeseen liabilities or unanticipated problems with the acquired businesses could have a material adverse effect on our business, operating results and financial condition. There can be no assurance that these acquisitions will provide the benefits we expect or that we will be able to integrate and develop the operations of Twill successfully. Any failure to do so could have a material adverse effect on our business, operating results and financial condition.

Risks Related to Product Development and Regulatory Approval

The regulatory clearance process which we must navigate is expensive, time-consuming, and uncertain and may prevent us from obtaining clearance for the commercialization of Dario or our any future product.

We are not permitted to market Dario in any jurisdiction until we receive marketing authorization from the applicable regulatory authority. To date, we have received regulatory authorization in Australia, Canada, Israel, Italy, the Netherlands, New Zealand, the United Kingdom, and the United States.

The research, design, testing, manufacturing, labeling, selling, marketing and distribution of medical devices are subject to extensive regulation by the FDA and non-U.S. regulatory authorities, which regulations differ from country to country. In particular, marketing authorization requirements vary between countries and can involve additional product testing and additional administrative review periods. The time required to obtain marketing authorization in other countries might differ from that required to obtain FDA clearance or other marketing authorization. Obtaining authorization for a device in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory authorization in one country may negatively impact the regulatory process in others. There can be no assurance that even after such time and expenditures, we will be able to obtain necessary regulatory approvals for clinical testing or for the manufacturing or marketing of any products. In addition, during the regulatory process, other companies may develop other technologies with the same intended use as our products. Significant delays in receiving, or the failure to receive, marketing authorization for our new products would have an adverse effect on our ability to expand our business.

We are also subject to numerous post-marketing regulatory requirements, which include quality management system regulations, labeling regulations and medical device reporting regulations. Specifically, the medical device reporting regulations require us to report to different regulatory agencies if our device causes or contributes to a death or serious injury, or malfunctions in a way that would likely cause or contribute to a death or serious injury. In addition, these regulatory requirements may change in the future in a way that adversely affects us, or various regulatory authorities may take other actions that could prevent or delay authorization of our products under development or impact our ability to gain authorization for modifications to our currently approved or cleared products in a timely manner. If we fail to comply

with present or future regulatory requirements that are applicable to us, we may be subject to enforcement action by regulatory agencies, which may include, among others, any of the following sanctions:

- untitled letters, warning letters, fines, injunctions, consent decrees, and civil penalties;
- customer notification, or orders for repair, replacement or refunds;
- voluntary or mandatory recall or seizure of our current or future products;
- imposing operating restrictions, suspension or shutdown of production;
- refusing our requests for marketing authorization of new products, new intended uses or modifications to Dario or future products;
- suspending or withdrawing marketing authorizations that have already been granted; and
- criminal prosecution.

The occurrence of any of these events may have a material adverse effect on our business, financial condition and results of operations.

We have conducted limited clinical trials of Dario. Clinical and nonclinical data is susceptible to varying interpretations, which could delay, limit or prevent additional regulatory clearances.

To date, we have conducted limited clinical trials on Dario. There can be no assurance that we will successfully complete additional clinical trials necessary to receive additional regulatory approvals in certain jurisdictions. While studies conducted by us have produced results we believe to be encouraging and indicative of the potential efficacy of Dario, data already obtained, or in the future obtained, from nonclinical studies and clinical trials do not necessarily predict the results that will be obtained from later nonclinical studies or clinical trials. Moreover, nonclinical and clinical data are susceptible to varying interpretations, which could delay, limit or prevent additional regulatory approvals. A number of companies in the medical device and pharmaceutical industries have suffered significant setbacks in advanced clinical trials, even after promising results in earlier studies. If we fail to adequately demonstrate the safety and effectiveness of a product candidate under development, it could delay or prevent regulatory authorization of the device, resulting in delays to commercialization, and could materially harm our business. Even though we have received CE mark and FDA clearance of Dario, there can be no assurance that we will be able to receive authorization for other potential applications of our principal technology, or that we will receive regulatory authorizations from other targeted regions or countries.

We may be unable to complete required clinical trials, or we may experience significant delays in completing such clinical trials, which could significantly delay our targeted product launch timeframe and impair our viability and business plan.

The completion of any future clinical trials for Dario or other trials that we may be required to undertake in the future could be delayed, suspended or terminated for several reasons, including:

- delay or failure in reaching agreement with regulatory authorities on a trial design that we are able to execute;
- delay or failure in obtaining authorization to commence a trial, including approval from the appropriate IRB to conduct testing of a product candidate on human subjects, or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical trial;
- delay in reaching, or failure to reach, agreement on acceptable terms with prospective contract research organizations and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- failure or inability to conduct the clinical trial in accordance with regulatory requirements;

- sites participating in the trial may drop out of the trial, which may require us to engage new sites for an expansion of the number of sites that are permitted to be involved in the trial;
- failure to initiate or delay of or inability to complete a clinical trial as a result of a clinical hold imposed by a regulatory authority due to observed safety findings or other reasons;
- delays that we may experience in patient enrollment or completion of certain trials;
- patients may not enroll in, remain in or complete, the clinical trial at the rates we expect; and
- clinical investigators may not perform our clinical trial on our anticipated schedule or consistent with the clinical trial protocol and good clinical practices.

In addition, the U.S. Congress recently amended the FDCA to require sponsors of any pivotal study to support marketing authorization of a medical device to design and submit a diversity action plan for such clinical trial. The action plan must describe appropriate diversity goals for enrollment, as well as a rationale for the goals and a description of how the sponsor will meet them. For any future pivotal studies involving our device products or product candidates, we must submit a diversity action plan to the FDA by the time a pivotal study protocol is submitted to the agency for review, as applicable, unless we are able to obtain a waiver for some or all of the requirements for a diversity action plan. It is unknown at this time how the diversity action plan may affect the planning and timing of any future pivotal study for our products or product candidates or what specific information FDA will expect in such plan. However, initiation of such studies may be delayed if the FDA objects to a proposed diversity action plans for any future pivotal study of our product candidates, and we may experience difficulties recruiting a diverse population of patients in attempting to fulfill the requirements of any approved diversity action plan.

If our ongoing or future clinical trials are delayed it will take us longer to further commercialize Dario and generate additional revenues. Moreover, our development costs will increase if we have material delays in our clinical trial or if we need to perform more or larger clinical trials than planned. We may be faced with similar risks in connection with future trials we conduct. See “Business - Clinical Trials” for a description of our clinical trials performed to date.

If we or our manufacturers fail to comply with the FDA’s Quality System Regulation or any applicable state equivalent, our operations could be interrupted, and our operating results could suffer.

We, our manufacturers and suppliers must, unless specifically exempt by regulation, follow the FDA’s QSR, as well as similar regulations of foreign jurisdictions regarding the manufacturing process. In addition, we and certain of our manufacturers and suppliers are subject to inspection by regulatory authorities to assess regulatory compliance from time to time and may not be able to demonstrate adequate compliance with applicable regulations. If we, our affiliates, our manufacturers or suppliers are found to be in significant non-compliance or fail to take satisfactory corrective action in response to adverse inspectional findings, the FDA or other applicable regulatory authority could take enforcement actions against us and our manufacturers which could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers’ demands. Accordingly, our operating results could suffer.

We are subject to the risk of reliance on third parties to conduct our clinical trial work.

We depend on independent clinical investigators to conduct our clinical trials. Contract research organizations may also assist us in the collection and analysis of data. These investigators and contract research organizations will not be our employees and we will not be able to control, other than by contract, the number of resources, including the time that they devote to products that we develop. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the investigators or contract research organizations does not relieve us of our regulatory responsibilities. If the independent investigators or contract research organizations fail to devote sufficient resources to our clinical trials, or if their performance is substandard, it will delay the approval or clearance and commercialization of any products that we develop. Further, the FDA and other regulatory bodies around the world require that we comply with GCP standards for conducting, recording and reporting clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial subjects are protected. If our independent clinical investigators and contract research

organizations fail to comply with GCP, the results of our clinical trials could be called into question and the clinical development of our product candidates could be delayed. Failure of clinical investigators or contract research organizations to meet their obligations to us or comply with federal regulations could adversely affect the clinical development of our product candidates and harm our business. Moreover, we intend to conduct several clinical trials in order to support our marketing efforts and business development purposes. Such clinical trials will be conducted by third parties as well. Failure of such clinical trials to meet their primary endpoints could adversely affect our marketing efforts.

If any of our relationships with the investigators or contract research organizations conducting our ongoing or future trials terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms, or at all. Entering into arrangements with alternative contract research organizations, trial investigators or other third parties involves additional cost and requires management focus and time, in addition to requiring a transition period when a new contract research organization, trial investigator or other third party begins work. If third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain are compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any clinical trials such third parties are associated with may be extended, delayed or terminated, and we may not be able to obtain marketing authorization for or successfully commercialize our product candidates.

Because we have relied on third parties to conduct our clinical trials, our internal capacity to perform these functions is limited. Outsourcing these functions involves risk that third parties may not perform to our standards, may not produce results in a timely manner or may fail to perform at all. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. To the extent we are unable to identify and successfully manage the performance of third-party service providers in the future, our business may be adversely affected. Though we carefully manage our relationships with our contract research organizations and investigators, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

Recent initiatives by the FDA to enhance and modernize various regulatory pathways for device products and its overall approach to safety and innovation in the medical technology industry creates the possibility of changing product development costs, requirements, and other factors and additional uncertainty for our future products and business.

Regulatory requirements may change in the future in a way that adversely affects us. Any change in the laws or regulations that govern the clearance and approval processes or the post-market compliance requirements relating to our current and future products could make it more difficult and costly to obtain clearance or approval for new products, or to produce, market and distribute existing products. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing authorization that we otherwise may have obtained, and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

In recent years, the U.S. government, including the FDA and other government agencies, have been focusing on the cybersecurity risks associated with certain medical devices and encouraging device manufacturers to take a more proactive approach to assessing the cybersecurity risks of their devices both during development and on a periodic basis after the devices are in commercial distribution. For example, in December 2022, the Congress enacted the Consolidated Appropriations Act for 2023, an omnibus appropriations bill, which included amendments to the FDCA under the Food and Drug Omnibus Reform Act of 2022 ("FDORA"). In addition to the requirement that sponsors of pivotal trials submit diversity action plans for pivotal trials (see "*Government Regulation—Clinical Trials*"), FDORA included new requirements for cyber devices, defined as any medical device that is or includes software that is validated, installed, or authorized by the manufacturer; can connect to the internet; and may be vulnerable to cybersecurity threats. Under the FDORA amendments to the FDCA, any application for marketing authorization of the cyber device must include a software bill of materials and a cybersecurity plan describing the methods by which the manufacturer will monitor, identify and address cybersecurity vulnerabilities. Any failure by a cyber device manufacturer to comply with applicable cybersecurity requirements is considered a violation of the FDCA and will subject the manufacturer to enforcement actions and possibly legal sanctions. Further regulatory efforts by the FDA or other federal or state regulatory authorities could

lead to new, onerous cybersecurity requirements in the future as well as additional product liability or other litigation risks if any of our products is considered to be susceptible to third-party tampering.

In addition, Congress passed the 21st Century Cures Act in December 2016, which made multiple changes to the FDA's rules for medical devices as well as for clinical trials, and the Medical Device User Fee reauthorization package in September 2022, which affects medical device regulation both pre- and post-approval and could have certain impacts on our business. In recent years, the FDA has also considered a series of efforts to modernize and streamline the 510(k) notification and regulatory review process and monitoring post-market safety. For example, as of October 2023, all 510(k) applications (unless specifically exempted) must be submitted to the FDA electronically using the electronic submission template and resource, or eSTAR, and the Center for Devices and Radiological Health (CDRH) Portal. Further changes in the FDA 510(k) process could make clearance more difficult to obtain, increase delay, add uncertainty and have other significant adverse effects on our ability to obtain and maintain clearance for our products.

Furthermore, the FDA issued a Final Rule on February 2, 2024 describing amendments to harmonize the QSR with ISO 13485:2016, which will become effective on February 2, 2026. The harmonization process is not expected to have a significant impact on the quality system compliance operations of device manufacturers because most requirements described in the QSR correspond to requirements set forth in ISO 13485:2016. However, device manufacturers will likely need to revise certain quality system procedures to ensure compliance with the harmonized regulations and any failure by us or our third-party manufacturers to make such revisions or adapt to the harmonized regulations, once they become effective, may result in observations of noncompliance during facility inspections by the FDA or comparable regulatory authorities.

Broad-based domestic and international government initiatives to reduce spending, particularly those related to healthcare costs, may reduce reimbursement rates for medical procedures, or make it more difficult for customers to purchase our products and services, all of which could adversely affect our business.

Healthcare reforms, changes in healthcare policies and changes to third-party coverage and reimbursements, including legislation enacted reforming the U.S. healthcare system and both domestic and foreign healthcare cost containment legislation, and any future changes to such legislation, may affect demand for our products and services and may have a material adverse effect on our financial condition and results of operations. Reforms implemented under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, (the "ACA") in the United States, as well as state-level healthcare reform proposals, could reduce medical procedure volumes and impact the demand for medical device products or the prices at which we can sell products. The impact of healthcare reform legislation, and practices including price regulation, competitive pricing, comparative effectiveness of therapies, technology assessments, and managed care arrangements are uncertain. There can be no assurance that current levels of reimbursement will not be decreased in the future, or that future legislation, regulation, or reimbursement policies of third parties will not adversely affect the demand for our products and services or our ability to sell products and provide services on a profitable basis. The adoption of significant changes to the healthcare system in the United States, the EEA or other jurisdictions in which we may market our products and services, could limit the prices we are able to charge for our products and services or the amounts of reimbursement available for our products and services, could limit the acceptance and availability of our products and services, reduce medical procedure volumes and increase operational and other costs.

Legislative and regulatory changes under the ACA remain possible, but it is unknown what form any such changes or any law would take, and how or whether it may affect the medical device industry as a whole or our business in the future. In addition to the ACA, there have been and will likely continue to be other federal and state changes that affect the provision of healthcare goods and services in the United States. While we are unable to predict what changes may ultimately be enacted, to the extent that future changes affect how our products and services are paid for and reimbursed by government and private payers, our business could be adversely impacted. Moreover, complying with any new legislation or reversing changes implemented under the ACA could be time-intensive and expensive, resulting in a material adverse effect on the business.

In addition, there has been heightened governmental scrutiny, including increasing legislative and enforcement interest, in recent years over the manner in which manufacturers set prices for their marketed healthcare products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed, among other things, to bring

more transparency to healthcare product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for healthcare products. Individual states in the United States have also become increasingly active in implementing regulations designed to control healthcare product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures and, in some cases, mechanisms to encourage importation of healthcare products from other countries. Additionally, third-party payors and governmental authorities have become increasingly interested in reference pricing systems and publication of discounts and list prices.

We are subject to federal, state and foreign laws prohibiting "kickbacks" and false or fraudulent claims, and other fraud and abuse laws, transparency laws, and other healthcare laws and regulations, which, if violated, could subject us to substantial penalties. Additionally, any challenge to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.

Our relationships with customers and third-party payors are subject to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain our sales, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs and certain customer and product support programs, we may have with hospitals, physicians or other purchasers of medical devices. Other federal and state laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, or are for items or services that were not provided as claimed. These laws include, among others, the federal Anti-Kickback Statute, the federal civil False Claims Act, other federal healthcare false statement and fraud statutes, the Open Payments program under the Physician Payments Sunshine Act, the Civil Monetary Penalties Law, and analogous fraud and abuse and transparency laws in most states, as described in "*Government Regulation—Other U.S. Healthcare Laws and Regulations*." Although the federal laws generally apply only to products or services for which payment may be made by a government healthcare program, state laws often apply regardless of whether federal funds may be involved.

While we believe and strive to ensure that our business arrangements with third parties and other activities and programs comply with all applicable laws, these laws are complex, and our activities may be found not to be compliant with one or more of these laws, which may result in significant civil, criminal and/or administrative penalties, fines, damages and exclusion from participation in government healthcare programs. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity, and be costly to respond to, and thus could have a material adverse effect on our business, financial condition and results of operations. Our compliance with Medicare and Medicaid regulations may be reviewed by federal or state agencies, including the Office of Inspector General for the U.S. Department of Health and Human Services (HHS-OIG), CMS, and the Department of Justice, or may be subject to whistleblower lawsuits under federal and state false claims laws.

Product liability suits, whether or not meritorious, could be brought against us due to an alleged defective product or for the misuse of Dario or our potential future products. These suits could result in expensive and time-consuming litigation, payment of substantial damages, and an increase in our insurance rates.

If Dario or any of our future products are defectively designed or manufactured, contain defective components, or are misused, or if someone claims any of the foregoing, whether or not meritorious, we may become subject to substantial and costly litigation. Misusing our device or failing to adhere to the operating guidelines or the device producing inaccurate meter readings could cause significant harm to patients, including death. In addition, if our operating guidelines are found to be inadequate, we may be subject to liability. Product liability claims could divert management's attention from our core business, be expensive to defend and result in sizable damage awards against us. While we maintain product liability insurance, we may not have sufficient insurance coverage for all future claims. Any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, could harm our reputation in the industry and could reduce revenue. Product liability claims in excess of our insurance coverage would be paid out of cash reserves harming our financial condition and adversely affecting our results of operations.

If we are found to have violated laws protecting the confidentiality of patient health information, we could be subject to civil or criminal penalties, which could increase our liabilities and harm our reputation or our business.

Part of our business plan includes the storage and potential monetization of medical data of users of Dario. There are a number of federal and state laws protecting the confidentiality of certain patient health information, including patient records, and restricting the use and disclosure of that protected information. In particular, the U.S. Department of Health and Human Services promulgated patient privacy rules under the Health Insurance Portability and Accountability Act of 1996 (which we refer to as HIPAA). These privacy rules protect medical records and other personal health information by limiting their use and disclosure, giving individuals the right to access, amend and seek accounting of their own health information and limiting most use and disclosures of health information to the minimum amount reasonably necessary to accomplish the intended purpose. We may face difficulties in holding such information in compliance with applicable law. If we are found to be in violation of the privacy rules under HIPAA, we could be subject to civil or criminal penalties, which could increase our liabilities, harm our reputation and have a material adverse effect on our business, financial condition and results of operations.

In addition to data protection laws passed by the U.S. federal government, many U.S. states and foreign countries have implemented their own data protection laws, some of which may apply simultaneously and conflict with U.S. federal law. Many of these laws create consumer rights including the right to know what personal information is collected, the right to know whether the data is sold or disclosed and to whom, the right to request that a company delete personal information collected, the right to opt-out of the sale of personal information and the right to non-discrimination in terms of price or service when a consumer exercises a privacy right. If we fail to comply with these regulations, we could be subject to civil sanctions, including fines and penalties for noncompliance.

In particular, data protection, privacy, and other laws and regulations adopted in jurisdictions outside of the United States can be more restrictive than corresponding U.S. laws and regulations. Data localization laws in some countries generally mandate that certain types of data collected in a particular country be stored and/or processed within that country. We could be subject to audits in Europe and around the world, particularly in the areas of consumer and data protection, as we continue to grow and expand our operations. Legislators and regulators may make legal and regulatory changes, or interpret and apply existing laws, in ways that make our products less useful to customers, require us to incur substantial costs, expose us to unanticipated civil or criminal liability, or cause us to change our business practices. These changes or increased costs could negatively impact our business and results of operations in material ways. For example, the GDPR imposes requirements in the European Economic Area relating to, among other things, consent to process personal data of individuals, the information provided to individuals regarding the processing of their personal data, the security and confidentiality of personal data, notifications in the event of data breaches and use of third-party processors. The GDPR also imposes restrictions on the transfer of personal data from the European Economic Area to third countries like the United States, although the European Commission recently adopted an adequacy decision for the EU-U.S. Data Privacy Framework. If we fail to comply with these standards, we could be subject to criminal penalties and civil sanctions, including fines and penalties and amounts could be significant.

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

We are exposed to the risk that our employees, independent contractors, consultants, manufacturers and suppliers may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (i) the laws of the FDA and other similar foreign regulatory bodies, including those laws requiring the reporting of true, complete and accurate information to such regulators; (ii) manufacturing standards; (iii) healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or (iv) laws that require the true, complete and accurate reporting of financial information or data. These laws may impact, among other things, future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commissions, certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials.

Although we have a code of business conduct and ethics, it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent these activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, additional integrity reporting and oversight obligations, possible exclusion from participation in Medicare, Medicaid and other government healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment of operations, any of which could adversely affect our ability to operate our business and our results of operations. Whether or not we are successful in defending against any such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations, which could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Our Intellectual Property

The failure to obtain or maintain patents, licensing agreements and other intellectual property could materially impact our ability to compete effectively.

In order for our business to be viable and to compete effectively, we need to develop and maintain, and we will heavily rely on, our proprietary position with respect to our technologies and intellectual property. We filed a Patent Cooperation Treaty (or PCT) application for a "Fluids Testing Apparatus and Methods of Use" in May 2011 which incorporates two U.S. provisional applications submitted in the preceding year. The PCT covers the specific processes related to blood glucose level measurement as well as more general methods of rapid tests of body fluids and has subsequently been converted into several national phase patent applications. We have also filed patent applications for other aspects of the Dario Blood Glucose Monitoring Solution. We have also obtained numerous Web domains.

However, to date, we have only been issued four patents (three of which were issued in the United States) relating to how the Dario Blood Glucose Monitoring System draws power from and transmits data to a smartphone via the audio jack port. None of our other patents have been granted by a patent office. In addition, there are significant risks associated with our actual or proposed intellectual property. The risks and uncertainties that we face with respect to our pending patent and other proprietary rights principally include the following:

- pending patent applications we have filed or will file may not result in issued patents or may take longer than we expect to result in issued patents;
- we may be subject to interference proceedings;
- we may be subject to opposition proceedings in foreign countries;
- any patents that are issued to us may not provide meaningful protection;
- we may not be able to develop additional proprietary technologies that are patentable;
- other companies may challenge patents licensed or issued to us;
- other companies may have independently developed and/or patented (or may in the future independently develop and patent) similar or alternative technologies, or duplicate our technologies;
- other companies may design their technologies around technologies we have licensed or developed; and
- enforcement of patents is complex, uncertain and very expensive.

We cannot be certain that patents will be issued as a result of any of our pending or future applications, or that any of our patents, once issued, will provide us with adequate protection from competing products. For example, issued patents may be circumvented or challenged, declared invalid or unenforceable, or narrowed in scope. In addition, since

the publication of discoveries in scientific or patent literature often lags behind actual discoveries, we cannot be certain that we were the first to make our inventions or to file patent applications covering those inventions.

It is also possible that others may have or may obtain issued patents that could prevent us from commercializing our products or require us to obtain licenses requiring the payment of significant fees or royalties in order to enable us to conduct our business. As to those patents that we have licensed, our rights depend on maintaining our obligations to the licensor under the applicable license agreement, and we may be unable to do so.

Costly litigation may be necessary to protect our intellectual property rights and we may be subject to claims alleging the violation of the intellectual property rights of others.

We may face significant expense and liability as a result of litigation or other proceedings relating to patents and intellectual property rights of others. In the event that another party has also filed a patent application or been issued a patent relating to an invention or technology claimed by us in pending applications, we may be required to participate in an interference proceeding declared by the United States Patent and Trademark Office to determine priority of invention, which could result in substantial uncertainties and costs for us, even if the eventual outcome was favorable to us. We, or our licensors, also could be required to participate in interference proceedings involving issued patents and pending applications of another entity. An adverse outcome in an interference proceeding could require us to cease using the technology, substantially modify it or to license rights from prevailing third parties.

The cost to us of any patent litigation or other proceeding relating to our licensed patents or patent applications, even if resolved in our favor, could be substantial, especially given our early stage of development. Our ability to enforce our patent protection could be limited by our financial resources and may be subject to lengthy delays. A third party may claim that we are using inventions claimed by their patents and may go to court to stop us from engaging in our normal operations and activities, such as research, development and the sale of any future products. Such lawsuits are expensive and would consume significant time and other resources. There is a risk that a court will decide that we are infringing the third party's patents and will order us to stop the activities claimed by the patents. In addition, there is a risk that a court will order us to pay the other party damages for having infringed their patents.

Moreover, there is no guarantee that any prevailing patent owner would offer us a license so that we could continue to engage in activities claimed by the patent, or that such a license if made available to us, could be acquired on commercially acceptable terms. In addition, third parties may, in the future, assert other intellectual property infringement claims against us with respect to our services, technologies or other matters.

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

We have limited intellectual property rights outside the United States. Filing, prosecuting and defending patents on devices in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patents to develop their own products and further, may export otherwise infringing products to territories where we have patents, but enforcement is not as strong as that in the United States.

Many companies have encountered significant problems in protecting and defending intellectual property in foreign jurisdictions. The legal systems of certain countries, particularly China and certain other developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to medical devices and biopharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. To date, we have not sought to enforce any issued patents in these foreign jurisdictions. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third

parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. The requirements for patentability may differ in certain countries, particularly developing countries. Certain countries in Europe and developing countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. 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.

We rely on confidentiality agreements that could be breached and may be difficult to enforce, which could result in third parties using our intellectual property to compete against us.

Although we believe that we take reasonable steps to protect our intellectual property, including the use of agreements relating to the non-disclosure of confidential information to third parties, as well as agreements that purport to require the disclosure and assignment to us of the rights to the ideas, developments, discoveries and inventions of our employees and consultants while we employ them, the agreements can be difficult and costly to enforce. Although we seek to enter into these types of agreements with our contractors, consultants, advisors and research collaborators, to the extent that employees and consultants utilize or independently develop intellectual property in connection with any of our projects, disputes may arise as to the intellectual property rights associated with our technology. If a dispute arises, a court may determine that the right belongs to a third party. In addition, enforcement of our rights can be costly and unpredictable. We also rely on trade secrets and proprietary know-how that we seek to protect in part by confidentiality agreements with our employees, contractors, consultants, advisors or others. Despite the protective measures we employ, we still face the risk that:

- these agreements may be breached;
- these agreements may not provide adequate remedies for the applicable type of breach;
- our proprietary know-how will otherwise become known; or
- our competitors will independently develop similar technology or proprietary information.

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

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. In addition, the Israeli Supreme Court ruled in 2012 that an employee who receives a patent or contributes to an invention during his employment may be allowed to seek compensation for such contributions from his or her employer, even if the employee's contract of employment specifically states otherwise and the employee has transferred all intellectual property rights to the employer. The Israeli Supreme Court ruled that the fact that a contract revokes an employee's right for royalties and compensation, does not rule out the right of the employee to claim their right for royalties. As a result, it is unclear whether and, if so, to what extent our employees may be able to claim compensation with respect to our future revenue. We may receive less revenue from future products if any of our employees successfully claim for compensation for their work in developing our intellectual property, which in turn could impact our future profitability.

Risks Related to Our Industry

We face intense competition in the digital support solution and the self-monitoring of blood glucose market, and as a result we may be unable to effectively compete in our industry.

In recent years, a number of digitally supported solutions have emerged to manage diabetes and other chronic conditions. Competitors are developing new technologies rapidly and, in some cases, are also expanding to manage other chronic conditions. With our first product, Dario, we compete directly and primarily with large pharmaceutical and medical device companies such as Abbott Laboratories, Asensia (formerly Bayer Diabetes Care), Johnson & Johnson LifeScan, Roche Diagnostics and Sanofi. The first four of these companies has a combined majority market share of the BGMS business and strong research and development capacity for next-generation products. Their dominant market position since the late 1990s, and significant control over the market could significantly limit our ability to introduce Dario or effectively market and generate sales of the product. We will also compete with numerous second-tier and third-tier competitors.

In addition, we only recently transformed our business to primarily focus on the sale of our digital support solution, which joins a crowded field of competitors such as Amazon, Apple and Google. Our competitors vary by intervention (devices, applications, coaching and analytics), by channel (health plan, pharma, provider, employer) and by condition (including, for example, diabetes, MSK, blood hypertension, and others). Certain of our competitors offer this integrated approach in varying degrees, including, among others, Hinge Health, Inc., Livongo Health Inc. (acquired by Teladoc Health Inc.), Omada Health, Inc., Vida Health, Inc., Virta Health Corp., Informed Data Systems Inc. (OneDrop), Glooko, Inc., and OnDuo LLC.

Competition in the digitally supported solutions market and BGMS market is extremely intense, which can lead to, among other things, price reductions, longer selling cycles, lower product margins, loss of market share and additional working capital requirements. To succeed, we must, among other critical matters, gain consumer acceptance for Dario and potential future devices incorporating our principal technology and offer better strategic concepts, technical solutions, prices and response time, or a combination of these factors, than those of other competitors. If our competitors offer significant discounts on certain products, we may need to lower our prices or offer other favorable terms in order to compete successfully. Moreover, any broad-based changes to our prices and pricing policies could make it difficult to generate revenues or cause our revenues, if established, to decline. Some of our competitors may bundle certain software products offering competing applications for diabetes management at low prices for promotional purposes or as a long-term pricing strategy. These practices could significantly reduce demand for Dario or potential future products or constrain prices we can charge. Moreover, if our competitors develop and commercialize products that are more effective or desirable than Dario or the other products that we may develop, we may not convince our customers to use our products. Any such changes would likely reduce our commercial opportunity and revenue potential and could materially adversely impact our operating results.

If we fail to respond quickly to technological developments our products may become uncompetitive and obsolete.

The BGMS market and other markets in which we plan to compete experience rapid technological developments, changes in industry standards, changes in customer requirements and frequent new product introductions and improvements. If we are unable to respond quickly to these developments, we may lose competitive position, and Dario or any other device or technology may become uncompetitive or obsolete, causing revenues and operating results to suffer. In order to compete, we must develop or acquire new devices and improve our existing device on a schedule that keeps pace with technological developments and the requirements for products addressing a broad spectrum and designers and designer expertise in our industries. We must also be able to support a range of changing customer preferences. For instance, as non-invasive technologies become more readily available in the market, we may be required to adopt our platform to accommodate the use of non-invasive or continuous blood glucose sensors. We cannot guarantee that we will be successful in any manner in these efforts.

If third-party payors do not provide adequate coverage and reimbursement for the use of our products and services, our revenue will be negatively impacted.

In the United States and other jurisdictions such as Germany and England, we expect that our products and services should generally be available for full or partial patient reimbursement by third-party payers. Our success in

marketing our services depend and will depend in large part on whether U.S. and international government health administrative authorities, private health insurers and other organizations adequately cover and reimburse customers for the cost of our products and services.

In the United States, we expect to derive nearly all our sales from sales directly to consumers as well as retail pharmacy and DME distributors who typically bill various third-party payors, including Medicare, Medicaid, private commercial insurance companies, health maintenance organizations, health plans and other healthcare-related organizations, to cover all or a portion of the costs and fees associated with our products and services and bill patients for any applicable deductibles or co-payments. Access to adequate coverage and reimbursement for Center for Medicare and Medicaid Services (CMS) procedures using our products and services (and our other products and services in development) by third-party payors is essential to the acceptance of our products by our customers.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy of coverage and reimbursement for medical device products and services exists among third-party payors. Therefore, coverage and reimbursement for medical device products and services can differ significantly from payor to payor. In addition, payors continually review new technologies for possible coverage and can, without notice, deny coverage for these new products and procedures. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained, or maintained if obtained.

Reimbursement systems in international markets vary significantly by country and by region within some countries, and reimbursement approvals must be obtained on a country-by-country basis. In many international markets, a product must be approved for reimbursement before it can be approved for sale in that country. Further, many international markets have government-managed healthcare systems that control reimbursement for new devices and procedures. In most markets, there are private insurance systems as well as government-managed systems. If sufficient coverage and reimbursement are not available for our current or future products, in either the United States or internationally, the demand for our products and our revenues will be adversely affected.

Risks Related to Our Operations in Israel

Potential political, economic and military instability in the State of Israel, where our management team and our research and development facilities are located, may adversely affect our results of operations.

Our operating subsidiary, along with our management team and our research and development facilities, is located in Israel. Accordingly, political, economic and military conditions in Israel and the surrounding region may directly affect our business and operations. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its neighboring countries. Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its trading partners could adversely affect our operations and results of operations. The hostilities involved missile strikes against civilian targets in various parts of Israel, including areas in which our employees and some of our consultants are located, and negatively affected business conditions in Israel. Our offices, located in Caesarea, Israel, are within the range of the missiles and rockets that have been fired at Israeli cities and towns from Gaza sporadically since 2006, with escalations in violence (such as the recent escalation in July 2014) during which there were a substantially larger number of rocket and missile attacks aimed at Israel.

On October 7, 2023, Hamas terrorists infiltrated Israel's southern border from the Gaza Strip and conducted a series of attacks on civilian and military targets. Hamas also launched extensive rocket attacks on Israeli population and industrial centers located along Israel's border with the Gaza Strip and in other areas within the State of Israel. Following the attack, Israel's security cabinet declared war against Hamas and the Israeli military began to call-up reservists for active duty. Moreover, the clash between Israel and Hezbollah in Lebanon, may escalate in the future into a greater regional conflict. In the months since the initial attack by Hamas, clashes with Hezbollah on Israel's northern border with Lebanon and attacks on Israeli-controlled or owned ships in the Red Sea by members of the Houthi Movement in Yemen have taken place. It is possible that other terrorist organizations, including Palestinian military organizations in the West Bank, as well as other hostile countries, such as Iran, will join the hostilities and that such clashes may escalate in the future into a greater regional conflict.

Any hostilities involving Israel, terrorist activities, political instability or violence in the region, or the interruption or curtailment of trade or transport between Israel and its trading partners could make it more difficult for us to raise capital and adversely affect our operations and results of operations and the market price of our securities. At this time, it is not possible to predict the intensity or duration of the war, nor can we predict how this war will ultimately affect Israel's economy in general, which may involve additional credit rating agencies downgrading Israel's credit rating score after Moody's downgrading of Israel's credit rating from A1 to A2 and outlook rating from "stable" to "negative", and we continue to monitor the situation closely and examine the potential disruptions that could adversely affect our operations.

Our commercial insurance does not cover losses that may occur as a result of an event associated with the security situation in the Middle East. Although the Israeli government is currently committed to covering the reinstatement value of direct damages that are caused by terrorist attacks or acts of war, we cannot assure you that this government coverage will be maintained or, if maintained, will be sufficient to compensate us fully for damages incurred. Any losses or damages incurred by us could have a material adverse effect on our business, financial condition, and results of operations.

Further, majority of the members of our management and employees are located and reside in Israel. Shelter-in-place and work-from-home measures, government-imposed restrictions on movement and travel and other precautions taken to address the ongoing conflict may temporarily disrupt our management and employees' ability to effectively perform their daily tasks.

Further, many Israeli citizens are obligated to perform several days, and in some cases, more, of annual military reserve duty each year until they reach the age of 40 (or older for certain reservists) and, in the event of a military conflict, may be called to active duty. In response to the series of attacks on civilian and military targets in October 2023, there have been significant call-ups of military reservists. Although many such military reservists have been discharged, they may be called up again depending on how events unfold. Our operations could be disrupted by such call-ups.

It is currently not possible to predict the duration or severity of the ongoing conflict or its effects on our business, operations and financial condition. The ongoing conflict is rapidly evolving and developing, and could disrupt our business and operations, and adversely affect our ability to raise additional funds or sell our securities, among other impacts.

Political instability in Israel, originating before October 2023, could also disrupt our operations. Having held five general elections between 2019 and 2022, government policy is subject to regular disruptive changes. The current government of Israel has pursued extensive changes to Israel's judicial system. In response to the foregoing developments, individuals, organizations and institutions, both within and outside of Israel, have voiced concerns that the proposed changes may negatively impact the business environment in Israel including reluctance of foreign investors to invest or transact business in Israel as well as increased currency fluctuations, downgrades in credit rating, increased interest rates, increased volatility in securities markets, and other changes in macroeconomic conditions within Israel. Currently, the proposed judicial reforms been put on hold due to the ongoing focus on the war, while the Supreme Court of Israel ruled that the judicial reform passed into legislation relating to reasonability is unconstitutional. If such changes to the judicial system resume and take effect, however, there may be an adverse effect on our business, our results of operations and our ability to raise additional funds.

Our operations may be disrupted as a result of the obligation of Israeli citizens to perform military service.

Many Israeli citizens are obligated to perform several days, and in some cases more, of annual military reserve duty each year until they reach the age of 40 (or older, for reservists who are military officers or who have certain occupations) and, in the event of a military conflict, may be called to active duty. In response to increases in terrorist activity, there have been periods of significant call-ups of military reservists. It is possible that there will be military reserve duty call-ups in the future. Our operations could be disrupted by such call-ups, which may include the call-up of members of our management. Such disruption could materially adversely affect our business, financial condition and results of operations.

Investors may have difficulties enforcing a U.S. judgment, including judgments based upon the civil liability provisions of the U.S. federal securities laws, against us, or our executive officers and directors or asserting U.S. securities laws claims in Israel.

Certain of our directors and officers are not residents of the United States and whose assets may be located outside the United States. Service of process upon us or our non-U.S. resident directors and officers and enforcement of judgments obtained in the United States against us or our non-U.S. our directors and executive officers may be difficult to obtain within the United States. We have been informed by our legal counsel in Israel that it may be difficult to assert claims under U.S. securities laws in original actions instituted in Israel or obtain a judgment based on the civil liability provisions of U.S. federal securities laws. Israeli courts may refuse to hear a claim based on a violation of U.S. securities laws against us or our officers and directors because Israel may not be the most appropriate forum to bring such a claim. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not U.S. law is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be proved as a fact, which can be a time-consuming and costly process. Certain matters of procedure will also be governed by Israeli law. There is little binding case law in Israel addressing the matters described above. Israeli courts might not enforce judgments rendered outside Israel, which may make it difficult to collect on judgments rendered against us or our officers and directors.

Moreover, among other reasons, including but not limited to, fraud or absence of due process, or the existence of a judgment which is at variance with another judgment that was given in the same matter if a suit in the same matter between the same parties was pending before a court or tribunal in Israel, an Israeli court will not enforce a foreign judgment if it was given in a state whose laws do not provide for the enforcement of judgments of Israeli courts (subject to exceptional cases) or if its enforcement is likely to prejudice the sovereignty or security of the State of Israel.

Risks Related to the Ownership of Our Common Stock

Our officers and directors may exert significant influence over our affairs, including the outcome of matters requiring stockholder approval.

As of the date of this Annual Report, our officers and directors collectively have a beneficial ownership interest of approximately 15.7% of our Company. As a result, such individuals will have the ability, acting together, to control the election of our directors and the outcome of corporate actions requiring stockholder approval, such as: (i) a merger or a sale of our company, (ii) a sale of all or substantially all of our assets, and (iii) amendments to our certificate of incorporation and bylaws. This concentration of voting power and control could have a significant effect in delaying, deferring or preventing an action that might otherwise be beneficial to our other stockholders and be disadvantageous to our stockholders with interests different from those individuals. Certain of these individuals also have significant control over our business, policies and affairs as officers or directors of our company. Therefore, you should not invest in reliance on your ability to have any control over our company.

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

The trading market for our common stock may be influenced by the research and reports that securities or industry analysts may publish about us, our business, our market or our competitors. If any of the analysts who may cover us change their recommendation regarding our common stock adversely, or provide more favorable relative recommendations about our competitors, the price of our common stock would likely decline. If any analyst who may cover us were to cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause the price of our common stock or trading volume to decline.

The market price of our common stock may be significantly volatile.

The market price for our common stock may be significantly volatile and subject to wide fluctuations in response to factors including the following:

- actual or anticipated fluctuations in our quarterly or annual operating results;

- changes in financial or operational estimates or projections;
- conditions in markets generally;
- changes in the economic performance or market valuations of companies similar to ours; and
- general economic or political conditions in the United States or elsewhere.

In particular, the market prices for securities of mHealth and medical device have historically been particularly volatile. Some of the factors that may cause the market price of our common stock and warrants to fluctuate include:

- any delay in or the results of our clinical trials;
- any delay in manufacturing of our products;
- any delay with the approval for reimbursement for the patients from their insurance companies;
- our failure to comply with regulatory requirements;
- the announcements of clinical trial data, and the investment community's perception of and reaction to those data;
- the results of clinical trials conducted by others on products that would compete with ours;
- any delay or failure to receive clearance or approval from regulatory agencies or bodies;
- our inability to commercially launch products or market and generate sales of our products, including Dario;
- failure of Dario or any other products, even if approved for marketing, to achieve any level of commercial success;
- our failure to obtain patent protection for any of our technologies and products (including those related to Dario) or the issuance of third-party patents that cover our proposed technologies or products;
- developments or disputes concerning our product's intellectual property rights;
- our or our competitors' technological innovations;
- general and industry-specific economic conditions that may affect our expenditures;
- changes in market valuations of similar companies;
- announcements by us or our competitors of significant contracts, acquisitions, strategic partnerships, joint ventures, capital commitments, new technologies, or patents;
- future sales of our common stock or other securities, including shares issuable upon the exercise of outstanding warrants or otherwise issued pursuant to certain contractual rights;
- period-to-period fluctuations in our financial results; and
- low or high trading volume of our common stock due to many factors, including the terms of our financing arrangements.

In addition, if we fail to reach important research, development or commercialization milestone or result by a publicly expected deadline, even if by only a small margin, there could be a significant impact on the market price of our common stock and warrants. Additionally, as we approach the announcement of anticipated significant information and

as we announce such information, we expect the price of our common stock and warrants to be particularly volatile, and negative results would have a substantial negative impact on the price of our common stock and warrants.

In some cases, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our business operations and reputation.

Shares eligible for future sale may adversely affect the market for our common stock and warrants.

From time to time, certain of our stockholders may be eligible to sell all or some of their shares of common stock by means of ordinary brokerage transactions in the open market pursuant to Rule 144, promulgated under the Securities Act, subject to certain limitations. In general, pursuant to Rule 144, after satisfying a six month holding period: (i) affiliated stockholder (or stockholders whose shares are aggregated) may, under certain circumstances, sell within any three month period a number of securities which does not exceed the greater of 1% of the then outstanding shares of common stock or the average weekly trading volume of the class during the four calendar weeks prior to such sale and (ii) non-affiliated stockholders may sell without such limitations, provided we are current in our public reporting obligations. Rule 144 also permits the sale of securities by non-affiliates that have satisfied a one year holding period without any limitation or restriction. Any substantial sale of our common stock pursuant to Rule 144 or pursuant to any resale report may have a material adverse effect on the market price of our securities.

Our compliance with complicated U.S. regulations concerning corporate governance and public disclosure is expensive. Moreover, our ability to comply with all applicable laws, rules and regulations is uncertain given our management's relative inexperience with operating U.S. public companies.

As a publicly reporting company, we are faced with expensive and complicated and evolving disclosure, governance and compliance laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act and the Dodd-Frank Act, and, to the extent we complete our anticipated public offering, the rules of the Nasdaq Stock Market. New or changing 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, which could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. As a result, our efforts to comply with evolving laws, regulations and standards of a U.S. public company are likely to continue to result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities.

Moreover, our executive officers have little experience in operating a U.S. public company, which makes our ability to comply with applicable laws, rules and regulations uncertain. Our failure to company with all laws, rules and regulations applicable to U.S. public companies could subject us or our management to regulatory scrutiny or sanction, which could harm our reputation and stock price.

If we fail to maintain effective internal control over financial reporting, the price of our common stock may be adversely affected.

Our internal control over financial reporting may have weaknesses and conditions that could require correction or remediation, the disclosure of which may have an adverse impact on the price of our common stock. We are required to establish and maintain appropriate internal control over financial reporting. Failure to establish those controls, or any failure of those controls once established, could adversely affect our public disclosures regarding our business, prospects, financial condition or results of operations. In addition, management's assessment of internal control over financial reporting may identify weaknesses and conditions that need to be addressed in our internal control over financial reporting or other matters that may raise concerns for investors. Any actual or perceived weaknesses and conditions that need to be addressed in our internal control over financial reporting or disclosure of management's assessment of our internal control over financial reporting may have an adverse impact on the price of our common stock.

Anti-takeover provisions in our charter documents and Delaware law could discourage, delay or prevent a change in control of our company and may affect the trading price of our common stock and warrants.

We are 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 in control would be beneficial to our existing stockholders. In addition, our certificate of incorporation and bylaws may discourage, delay or prevent a change in our management or control over us that stockholders may consider favorable. Our certificate of incorporation and bylaws:

- authorize the issuance of "blank check" preferred stock that could be issued by our Board of Directors to thwart a takeover attempt;
- provide that vacancies on our Board of Directors, including newly created directorships, may be filled only by a majority vote of directors then in office;
- provide that special meetings of stockholders may only be called by our Chairman, Chief Executive Officer and/or President or other executive officer, our Board of Directors or a super-majority (66 2/3%) of our stockholders;
- place restrictive requirements (including advance notification of stockholder nominations and proposals) on how special meetings of stockholders may be called by our stockholders;
- do not provide stockholders with the ability to cumulate their votes; and
- provide that our Board of Directors or a super-majority of our stockholders (66 2/3%) may amend our bylaws.

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

We are a smaller reporting company ("SRC") and a non-accelerated filer, which allows us to take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not SRCs or non-accelerated filers, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, reduced disclosure obligations regarding executive compensation in our Annual Report and our periodic reports and proxy statements and providing only two years of audited financial statements in our Annual Report and our periodic reports. We will remain an SRC until (a) the aggregate market value of our outstanding common stock held by non-affiliates as of the last business day our most recently completed second fiscal quarter exceeds $250 million or (b) (1) we have over $100 million in annual revenues and (2) the aggregate market value of our outstanding common stock held by non-affiliates as of the last business day our most recently completed second fiscal quarter exceeds $700 million. We cannot predict whether investors will find our common stock less attractive if we rely on certain or all of 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 and may decline.

We do not currently intend to pay dividends on our common stock in the foreseeable future, and consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.

We have never declared or paid cash dividends on our common stock and do not anticipate paying any cash dividends to holders of our common stock in the foreseeable future. Consequently, 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. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which our stockholders have purchased their shares.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 1C. Cybersecurity

We maintain a comprehensive process for identifying, assessing, and managing material risks from cybersecurity threats as part of our broader risk management system and processes. We obtain input, as appropriate, for our cybersecurity risk management program on the security industry and threat trends from external experts and internal threat intelligence team. A team of dedicated privacy, safety, and security professionals oversees cybersecurity risk management and mitigation, incident prevention, detection, and remediation. Leadership of this team includes professionals with deep cybersecurity expertise, including our Chief Information Security Officer. Our executive leadership team, along with input from the above team, are responsible for our overall enterprise risk management system and processes and regularly consider cybersecurity risks in the context of other material risks to the company.

As part of our cybersecurity risk management system, our incident management team tracks and logs privacy and security incidents across the Company, our vendors, and other third-party service providers to remediate and resolve any such incidents. Significant incidents are reviewed regularly by a cross-functional working group to determine whether further escalation is appropriate. Any incident assessed as potentially being or potentially becoming material is immediately escalated for further assessment, and then reported to designated members of our senior management. We consult with outside counsel as appropriate, including on materiality analysis and disclosure matters, and our senior management makes the final materiality determinations and disclosure and other compliance decisions.

The Audit Committee has oversight responsibility for risks and incidents relating to cybersecurity threats, including compliance with disclosure requirements, cooperation with law enforcement, and related effects on financial and other risks, and it reports any findings and recommendations, as appropriate, to the full Board for consideration. Senior management regularly discusses cyber risks and trends and, should they arise, any material incidents with the Audit Committee.

Our business strategy, results of operations and financial condition have not been materially affected by risks from cybersecurity threats, including as a result of previously identified cybersecurity incidents, but we cannot provide assurance that they will not be materially affected in the future by such risks or any future material incidents. For more information on our cybersecurity related risks, see Item 1A Risk Factors of this Annual Report on Form 10-K.

Item 2. Properties

We do not own any real property. Currently, we maintain offices at 5 Tarshish St., Caesarea Industrial Park, 3088900, Israel. On June 6, 2023, we signed a lease agreement for these facilities for a period of 5 years commencing upon the completion of adjustments of the office space. We moved into these offices during August 2023. The rental agreement will be extended automatically for an additional 60 months following expiration of the initial term. The monthly rent and management services under this lease are approximately $22,400.

Item 3. Legal Proceedings

We are currently not a party to any pending legal proceeding, nor is our property the subject of a pending legal proceeding, that we believe is not ordinary routine litigation incidental to our business or otherwise material to the financial condition of our business.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market Information

Our common stock is quoted on the Nasdaq Capital Market under the symbol "DRIO".

Record Holders

As of March 22, 2024, we had 342 stockholders of record of our common stock.

Dividends

We have never paid any cash dividends on our common stock. We anticipate that we will retain funds and future earnings to support operations and to finance the growth and development of our business. Therefore, we do not expect to pay cash dividends in the foreseeable future. Any future determination to pay dividends will be at the discretion of our Board of Directors and will depend on our financial condition, results of operations, capital requirements and other factors that our Board of Directors deems relevant. In addition, the terms of any future debt or credit financings may preclude us from paying dividends.

Securities Authorized for Issuance Under Equity Compensation Plans as of December 31, 2023:

The following table provides information as of December 31, 2023, with respect to options outstanding under the Company's Amended and Restated 2012 Equity Incentive Plan (the "2012 Equity Incentive Plan"), the Company's 2020 Equity Incentive Plan (the "2020 Equity Incentive Plan"), and the Company's other equity compensation arrangements.

Plan category	Forfeited shares (7)	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance
Equity compensation plans approved by security holders	143,946	1,987,896	$ 9.59	1,650,197
Equity compensation plans not approved by security holders (1)		433	$ 2,502.00	—
Equity compensation plans not approved by security holders (2)		112,500	$ 8.41	—
Equity compensation plans not approved by security holders (3)		50,000	$ 5.75	—
Equity compensation plans not approved by security holders (4)		20,000	$ 18.62	—
Equity compensation plans not approved by security holders (5)		200,000	$ 5.97	—
Equity compensation plans not approved by security holders (6)		180,000	3.93	—
Total	143,946	2,550,829		1,650,197

In March 2013, our Board adopted a non-employee director's remuneration policy.

(1) On May 2014, our Board approved the grant of non-plan options to the Company's Scientific Advisory Board ("SAB"). These options have an exercise price of $2,502.00 vest in 4 quarterly installments in arrears, have a cashless exercise feature and a ten-year term.

(2) In January 2020, our Board approved the grant of non-plan options as a material inducement for employment, in accordance with Nasdaq Listing Rule 5635(c)(4), to our newly hired President and General Manager for North America. The options have an exercise price of $8.41 per share. 90,000 options are time based and vest over a three-year period. One third vests after one year and the balance vests over eight quarterly installments after the first anniversary; these options have a cashless exercise feature and a six-year term. An additional 90,000 options are performance based, and vest over a three-year period. One third vest after one year and the balance vest over eight quarterly installments after the first anniversary; these options have a cashless exercise feature and a six-year term. 22,500 options will commence vesting every calendar year for the next four years, commencing in 2021, and only if certain performance milestones were met in the immediately preceding year. 22,500 of these options have expired on each of January 1, 2021, January 1, 2022, January 1, 2023 and January 1, 2024 as the performance milestones were not met.

(3) In March 2020, our Board approved the grant of certain non-plan options as a material inducement for employment, in accordance with Nasdaq Listing Rule 5635(c)(4), to our newly hired Chief Medical Officer. The options have an exercise price of $5.75 per share, and vest over a three-year period with one third vesting after one year and the balance vesting over eight quarterly installments after the first anniversary; these options have a cashless exercise feature and a six-year term.

(4) In July 2021, our Board approved the grant of certain non-plan options as a material inducement for employment, in accordance with Nasdaq Listing Rule 5635(c)(4), to our newly hired Special Vice President of Market Access. The options have an exercise price of $18.62 per share, and vest over a three-year period with one third vesting after one year and the balance vesting over eight quarterly installments after the first anniversary; these options have a cashless exercise feature and a ten-year term.

(5) In January 2023, our Board approved the grant of certain non-plan options as a material inducement for employment, in accordance with Nasdaq Listing Rule 5635(c)(4), to our newly hired Senior Vice President of Growth. The options have an exercise price of $5.97 per share, 100,000 options are time based and vest over a three-year period. One third vests after one year and the balance vests over eight quarterly installments after the first anniversary; these options have a cashless exercise feature and a ten-year term. An additional 100,000 options are performance based, and vest over a three-year period. 50,000 performance options will vest upon achieving 2023 or 2024 revenue targets upon the release by the corporation of its annual consolidated financial statements according to GAAP, and 50,000 additional performance options will vest upon achieving 2024 revenue targets. The entire 100,000 performance options will vest upon achieving 2024 revenue targets if the 2023 revenue target was not achieved.

(6) In April 2023, our Board approved the grant of certain non-plan options as a material inducement for employment, in accordance with Nasdaq Listing Rule 5635(c)(4), to our newly hired Chief Product Officer. The options have an exercise price of $3.93 per share, 100,000 options are time based and vest over a three-ear period. One third vests after one year and the balance vests over eight quarterly installments after the first anniversary; these options have a cashless exercise feature and a ten-year term. An additional 80,000 options are performance based, and vest upon achieving personal objective that were set up within sixty days from commencement of employment. The performance-based options expired on January 1, 2024 as the performance milestones were not met.

(7) 143,946 restricted shares of common stock issued to certain of our employees were forfeited, as they were not vested upon certain employee departures.

On January 23, 2012, our Board of Directors and a majority of the holders of our then outstanding shares of our common stock adopted our 2012 Equity Incentive Plan (which includes both U.S. and Israeli sub-plans). On January 23, 2012, an Israeli sub-plan was adopted under our 2012 Equity Incentive Plan, which sets forth the terms for the grant of stock awards to Israeli employees or Israeli non-employees. The sub-plan was adopted in accordance with the amended sections 102 and 3(i) of Israel's Income Tax Ordinance. The sub-plan is part of the 2012 Equity Incentive Plan and subject to the same terms and conditions. On September 26, 2016 and November 30, 2016, respectively, our Board of Directors and stockholders approved an amendment to the 2012 Equity Incentive Plan increasing the number of shares of common stock available under the plan to 1,873,000 as well as amended the 2012 Equity Incentive Plan to permit grants of shares of common stock. On February 2, 2017 and March 9, 2017, respectively, our Board of Directors and stockholders approved

an amendment to the 2012 Equity Incentive Plan increasing the number of shares of common stock available under the plan to 2,373,000. On October 9, 2017 and December 4, 2017, respectively, our Board of Directors and stockholders approved an amendment to the 2012 Equity Incentive Plan increasing the number of shares of common stock available under the plan to 3,873,000. On March 26, 2018 and May 18, 2018, respectively, our Board of Directors and stockholders approved an amendment to the 2012 Equity Incentive Plan increasing the number of shares of common stock available under the plan to 5,373,000. On October 7, 2018 and November 29, 2018, respectively, our Board of Directors and stockholders approved an amendment to the 2012 Equity Incentive Plan increasing the number of shares of common stock available under the plan to 7,873,000. On September 3, 2019 and November 6, 2019, respectively, our Board of Directors and stockholders approved an amendment to the 2012 Equity Incentive Plan increasing the number of shares of common stock available under the plan to 618,650 on a post reverse stock split basis. On December 26, 2019 and February 5, 2020, respectively, our Board of Directors and stockholders approved an amendment to the 2012 Equity Incentive Plan increasing the number of shares of common stock available under the plan to 1,968,650. The 2012 Equity Incentive Plan expired on January 23, 2022. On September 2, 2020 and October 14, 2020, respectively, our Board of Directors and stockholders approved and adopted the Company's 2020 Equity Incentive Plan (the "2020 Equity Incentive Plan"), reserving for issuance a pool of 900,000 shares of the Company's common stock under the plan. On January 1, 2021, the number of shares of common stock available under the plan increased to 1,828,890 according to the terms thereof. On June 7, 2021, the number of shares of common stock available under the plan increased to 2,528,890 according to the terms thereof. On January 1, 2022, the number of shares of common stock available under the plan increased to 3,868,514 according to the terms thereof. On January 1, 2023, the number of shares of common stock available under the plan increased to 5,862,860 according to the terms thereof. On January 1, 2024, the number of shares of common stock available under the plan increased to 8,356,624 according to the terms thereof. As of March 22, 2024, there were 1,004,832 shares of Common Stock reserved for issuance thereunder. The Company's officers and directors are among the persons eligible to receive awards under the 2020 Equity Incentive Plan in accordance with the terms and conditions thereunder.

The purpose of our 2020 Equity Incentive Plan is to attract and retain directors, officers, consultants, advisors and employees whose services are considered valuable, to encourage a sense of proprietorship and to stimulate an active interest of such persons in our development and financial achievements The 2020 Equity Incentive Plan will be administered by the Compensation Committee of our Board of Directors or by the full board, which may determine, among other things, the (a) terms and conditions of any option or stock purchase right granted, including the exercise price and the vesting schedule, (b) persons who are to receive options and stock purchase rights and (c) the number of shares to be subject to each option and stock purchase right. The 2020 Equity Incentive Plan will each provide for the grant of (i) "incentive" options (qualified under section 422 of the Internal Revenue Code of 1986, as amended) to employees of our company and (ii) non-qualified options to directors and consultants of our company. In addition, our Board of Directors has authorized the appointment of IBI Capital Compensation and Trusts (2004) Ltd. to act as a trustee for grants of options under the Israeli sub-plan to Israeli residents.

In connection with the administration of our 2020 Equity Incentive Plan, our Compensation Committee will:

- determine which employees and other persons will be granted awards under our 2020 Equity Incentive Plan;
- grant the awards to those selected to participate;
- determine the exercise price for options; and
- prescribe any limitations, restrictions and conditions upon any awards, including the vesting conditions of awards.

Our Compensation Committee will: (i) interpret our 2020 Equity Incentive Plan; and (ii) make all other determinations and take all other action that may be necessary or advisable to implement and administer our 2020 Equity Incentive Plan.

The 2020 Equity Incentive Plan provides that in the event of a change of control event, the Compensation Committee or our Board of Directors shall have the discretion to determine whether and to what extent to accelerate the vesting, exercise or payment of an award.

In addition, our Board of Directors may amend our 2020 Equity Incentive Plan at any time. However, without stockholder approval, our 2020 Equity Incentive Plan may not be amended in a manner that would:

- increase the number of shares that may be issued under such Equity Incentive Plan;
- materially modify the requirements for eligibility for participation in such Equity Incentive Plan;
- materially increase the benefits to participants provided by such Equity Incentive Plan; or
- otherwise disqualify such Equity Incentive Plan for coverage under Rule 16b-3 promulgated under the Exchange Act.

Awards previously granted under our 2020 Equity Incentive Plan may not be impaired or affected by any amendment of such without the consent of the affected grantees.

Option Exercises

To date, no options have been exercised by our directors or officers.

Unregistered Sales of Equity Securities and Use of Proceeds

During the fourth quarter of 2023, we issued an aggregate 30,167 shares of our common stock to certain of our service providers as compensation to them for services rendered.

We claimed exemption from registration under the Securities Act of 1933, as amended, or the Securities Act, for the foregoing transactions under Section 4(a)(2) of the Securities Act.

Item 6. [Reserved]

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

Readers are advised to review the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes and other financial information included elsewhere in this Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. See "Cautionary Note Regarding Forward-Looking Statements". You should review the "Risk Factors" section of this Annual Report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a leading global DTx company revolutionizing the way people manage their health across the chronic condition spectrum to live a better and healthier life. Our mission is to transform how affected individuals manage their health and chronic conditions by empowering our customers to easily manage their conditions and take steps to improve their overall health. Most chronic conditions are driven by personal behaviors and the actions that are or are not taken. We believe that changing these behaviors can dramatically improve our customers' overall health and substantially reduce unnecessary health spending. However, behavioral change and habit formation are difficult, especially in managing chronic disease and related conditions. Our digital therapeutics endeavor to produce lasting behavior changes in our customers by applying a novel combination of AI-driven dynamic personalization and behavioral science at scale. This allows us to engage and support our customers, and offer them a complete virtual care solution, ideally resulting in improved health outcomes and reduced total cost of care.

Our principal operating subsidiary, LabStyle Innovation Ltd., is an Israeli company ("LabStyle") with its headquarters in Caesarea, Israel. We were formed on August 11, 2011, as a Delaware corporation with the name LabStyle Innovations Corp. On July 28, 2016, we changed our name to DarioHealth Corp. We began our sales in the direct-to-

consumer space, solving first for what we deemed the most difficult problems: how to engage users and support behavior change to improve clinical outcomes in diabetes. Our most developed AI tools leverage the direct-to-consumer experience from over 150,000 members to drive superior engagement and outcomes. In early 2020, we broadened our solutions to include other medical conditions in addition to diabetes, and to serve business customers who seek to improve the health of their stakeholders. We also subsequently acquired Upright, PsyInnovations, Physimax Technology, and most recently Twill, to further our platform. Presently, we have deployed solutions for diabetes, hypertension, pre-diabetes, MSK and behavioral health, which conditions will also be powered by our AI-driven behavior change platform. We are currently delivering our solutions to providers, employers, health plans and pharmaceutical companies. We continue to achieve key benchmarks as we rapidly scale our B2B2C model, including more than 100 total signed contracts as of today. We believe we have a unique and defensible position in the market thanks to our unique solution origin in consumer markets.

On January 26, 2021, Dario, Labstyle, Upright Technologies Ltd., an Israeli limited company, Vertex C (C.I.) Fund L.P. (in its capacity as the representative of the Selling Shareholders), and all holders of Upright's outstanding securities (the "Selling Shareholders"), entered into a share purchase agreement (the "Upright Agreement") pursuant to which Dario, through Labstyle, acquired all of the outstanding securities of Upright. The agreement was consummated on February 1, 2021, and Upright now operates as our wholly owned subsidiary. As part of the acquisition, we issued the Selling Shareholders 1,687,612 shares of our common stock and agreed to assume options to purchase up to 100,193 shares of our common stock, subject to certain escrow and indemnity provisions contained in the Upright Agreement (in the aggregate, the "Consideration Shares"). In addition, the shares issued are subject to the terms of a lock-up agreement, pursuant to which the Selling Shareholders (subject to certain exceptions) have agreed to restrict their ability to transfer their shares as follows: (i) shares representing 20% of their respective Consideration Shares will be restricted from transfer for a period of one hundred and eighty (180) days from the date of the closing of the acquisition (the "Closing Date"), (ii) shares representing 30% of their respective Consideration Shares will be restricted from transfer for a period of two hundred and seventy (270) days from the Closing Date, (iii) shares representing 30% of their respective Consideration Shares will be restricted from transfer for a period of three hundred and sixty (360) days from the Closing Date and (iv) shares representing 20% of their respective Consideration Shares will be restricted from transfer for a period of four hundred and fifty (450) days from the Closing Date.

We, along with TWILL Merger Sub, Inc. ("Merger Sub"), Twill and Bilal Khan, solely in his capacity as the representatives of Twill's stockholders and other equity holders, entered into an Agreement and Plan of Merger (the "Merger Agreement"), dated February 15, 2024 (the "Closing Date"). Pursuant to the provisions of the Merger Agreement, on the Closing Date, (i) Merger Sub was merged with and into Twill (the "Merger"), the separate corporate existence of Merger Sub ceased and Twill continued as the surviving company and a wholly owned subsidiary of the Company, (ii) we paid to Twill's debt holders and equity holders aggregate consideration ("Merger Consideration") of (A) $10.0 million in cash, (B) pre-funded warrants (the "Pre-Funded Warrants") to purchase up to 10,000,400 shares (the "Warrant Shares") of our common stock issuable to a trust (the "Trust") formed for the benefit of certain equity and debt holders of Twill, issuable in 4 equal tranches, (C) stock options to purchase up to 2,963,459 shares of common stock issued to employees of Twill as an inducement to their employment with us, issued outside of our equity compensation plans, pursuant to Nasdaq Rule 5635(c)(4), with an exercise price of $2.55 per share, and (D) a combination of warrants and restricted stock units ("RSUs") to acquire up to 1,766,508 shares of common stock issued to certain outgoing board members, consultants and outgoing officers of Twill (all of such RSUs and warrants being subject to the approval of the Company's stockholders, pursuant to Nasdaq Rule 5635), and (iii) the parties to the Merger Agreement consummated the transactions contemplated thereby. The Merger Agreement contains various customary representations, warranties and covenants. As a result of the Merger, Twill will operate as our wholly owned subsidiary.

The Pre-Funded Warrants are subject to a non-waivable 19.99% ownership blocker and the issuance of any shares of common stock underlying such warrants that are in excess of such amount shall be subject to the approval of our stockholders. In addition, the Company, the Trust and WhiteHawk Capital Partner LP (the "Beneficiary"), have executed a Lock Up/Leak Out Agreement (the "Leak Out Agreement"), pursuant to which until such time as the Trust receives $10,600,000 in aggregate net proceeds (the "Leak Out Period"), (i) the Trust shall only be allowed to sell such Warrant Shares at a rate of up to 10% of the average daily trading volume of the common stock in a manner which will not negatively affect the share price, (ii) all such sales shall be conducted pursuant to Rule 144 and (iii) that the Beneficiary shall not cause the Trust to engage in any short selling of such Warrant Shares during the Leak-Out Period. The Company has agreed to seek stockholder approval within 135 days following the closing of the Merger to permit the full exercise of the Pre-Funded Warrants (the "Warrant Vote"). In addition, we entered into voting agreements with certain existing

stockholders to vote in favor of the Warrant Vote. We have agreed to call a stockholder meeting each fiscal quarter thereafter to the extent the Warrant Vote is not approved by the Company's stockholders.

Pursuant to the terms of the Merger Agreement, we also agreed to appoint a new member to our board of directors, nominated by Twill equity holders and subject to such nominee being acceptable to us, within 90 days following the closing of the Merger. Such appointment right shall continue until the earlier of 540 days following the closing of the Merger, or the date which the Trust exercises its third tranche of Pre-Funded Warrants.

In addition, we executed certain consulting agreements (the "Consulting Agreements") with Ofer Leidner and Bilal Khan, each former officers of Twill. Pursuant to the terms of the Consulting Agreements, we agreed to retain the services of Messrs. Leidner and Khan for a period of at least 14 months and 6 months respectively, in exchange for monthly consulting fees of $35,416 and $35,417, respectively. In addition, the Company agreed to issue to Mr. Leidner warrants to purchase up to 1,032,946 shares of common stock, of which 717,946 are subject to time vesting and 315,000 are subject to certain performance-based metrics, and to issue to Mr. Khan 350,000 fully vested RSUs which shall be vest subject to stockholder approval.

Readers are cautioned that, according to our management's estimates, based on our budget and the initial launch of our commercial sales, we believe that we will have sufficient resources to continue our activity through 2025 without raising additional capital. This includes an amount of anticipated inflows from sales of Dario through direct sales in the United States and through distribution partners. If we are unable to scale up our commercial launch of Dario or meet our commercial sales targets (or if we are unable to ramp up revenues), and if we are unable to obtain additional capital resources in the near term, we may be unable to continue activities, absent material alterations in our business plans, and our business might fail.

Critical Accounting Policies

Our consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP"). Our fiscal year ends December 31.

This Management's Discussion and Analysis of Financial Condition and Results of Operations discuss our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these consolidated financial statements requires making estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported revenues and expenses for the reporting periods. On an ongoing basis, we evaluate such estimates and judgments. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ (perhaps significantly) from these estimates under different assumptions or conditions.

While all the accounting policies impact the consolidated financial statements, certain policies may be viewed to be critical. Our management believes that the accounting policies which involve more significant judgments and estimates used in the preparation of our consolidated financial statements, include revenue recognition, inventories, liability related to certain warrants, and accounting for production lines and its related useful life and impairment.

Revenue Recognition

Revenue is recognized under the five-step methodology in accordance with Accounting Standards Codification ("ASC") - ASC 606, which requires us to identify the contract with the customer, identify the performance obligations in the contract, determine the transaction price, allocate the transaction price to the performance obligations identified, and recognize revenue when (or as) each performance obligation is satisfied.

We derive our revenue principally from:

Consumers revenue

We consider customer and distributers purchase orders to be the contracts with a customer. For each contract, we consider the promise to transfer tangible products and/or services, each of which are distinct, to be the identified performance obligations. In determining the transaction price, we evaluate whether the price is subject to rebates and adjustments to determine the net consideration to which we expect to receive. As our standard payment terms are less than one year, the contracts have no significant financing component. We allocate the transaction price to each distinct performance obligation based on their relative standalone selling price. Revenue from tangible products is recognized when control of the product is transferred to the customer (i.e., when our performance obligation is satisfied), which typically occurs at shipment. The revenues from fixed-price services are recognized ratably over the contract period and the costs associated with these contracts are recognized as incurred.

Commercial revenue - B2B2C

We provide mobile and web-based digital therapeutics health management programs to employers and health plans for their employees or covered individuals including live clinical coaching, content, automated journeys, hardware, and life-style coaching, currently supporting diabetes, prediabetes and obesity, hypertension, behavioral health (BH) and musculoskeletal health (MSK). At contract inception, we assess the type of services being provided and assess the performance obligations in the contract. Revenue is recognized either on a per engaged member per month (PEMPM) or a per employee per month (PEPM) basis. Our contracts consist of a fixed price that is based on the monthly number of members and clinical programs consumed by each member. The price is determined during contract negotiations with customers.

Certain of our contracts include client performance guarantees and a portion of the fees in those contracts are subject to performance-based metrics such as clinical outcomes or minimum member utilization rate. We include in the transaction price some or all of an amount of variable consideration only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Refund to a customer that results from performance levels that were not met by the end of the measurement period are adjusted to the transaction price, and therefore estimated at the outset of the arrangement.

Commercial revenue - Strategic partnerships

The Company has also entered into contracts with a preferred partner and a health plan provider in which the Company provides data license, development and implementation services.

Inventories

Inventory write-down is measured as the difference between the cost of the inventory and net realized value based upon assumptions about future demand, and is charged to the cost of sales. At the point of the loss recognition, a new, lower-cost basis for that inventory is established, and subsequent changes in facts and circumstances do not result in the restoration or increase in that newly established cost basis.

If there were to be a sudden and significant decrease in demand for our products or if there were a higher incidence of inventory obsolescence because of rapidly changing technology and customer requirements, we could be required to increase our inventory write-downs and our gross margin could be adversely affected. Inventory and supply chain management remain areas of focus as we balance the need to maintain supply chain flexibility, to help ensure competitive lead times with the risk of inventory obsolescence.

During the year ended December 31, 2023, total inventory write-downs expenses amounted to $121,000.

Production Lines

Capitalization of Costs. We capitalize direct incremental costs of third-party manufacturers related to the equipment in our production lines. We cease construction cost capitalization relating to our production lines once they are ready for its intended use and held available for occupancy. All renovations and betterments that extend the economic useful lives of assets and/or improve the performance of the production lines are capitalized.

Useful Lives of Assets. We are required to make subjective assessments as to the useful lives of our production lines for purposes of determining the amount of depreciation to record on an annual basis with respect to our construction of the production lines. These assessments have a direct impact on our net income (loss). Production lines are usually depreciated on a straight-line basis over a period of up to seven years, except any renovations and betterments which are depreciated over the remaining life of the production lines.

Impairment of production lines. We are required to review our production lines for impairment in accordance with ASC 360, "Property, Plant and Equipment," whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted cash flows expected to be generated by the assets. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets.

Results of Operations

Comparison of the Year Ended December 31, 2023 to Year Ended December 31, 2022

Revenues

Revenues for the year ended December 31, 2023, amounted to $20,352,000 compared to $27,656,000 during the year ended December 31, 2022. The decrease in revenues for the year ended December 31, 2023, compared to the year ended December 31, 2022, is due to a decrease in revenues from sales to consumers and our strategic partnerships.

Revenues generated during the year ended December 31, 2023, were derived from the sale of services to our strategic partners, commercial customers and consumers located mainly in the United States.

Cost of Revenues

During the years ended December 31, 2023 and 2022, we recorded costs related to revenues in the amount of $14,368,000 and $18,001,000, respectively. The decrease in cost of revenues was due to the decrease in revenues. Cost of revenues excluding amortization of acquired technology during the year ended December 31, 2023 and 2022, was $10,370,000 and $14,012,000, respectively.

Cost of revenues consist mainly of cost of device production, employees' salaries and related overhead costs, depreciation of production line and related cost of equipment used in production, amortization of technologies, hosting costs, shipping and handling costs and inventory write-downs.

Gross Profit

Gross profit for the year ended December 31, 2023, amounted to $5,984,000 (29.4% of revenues) compared to $9,655,000 (34.9% of revenues) for the year ended December 31, 2022. The decrease in gross profit as a percentage of revenue for the year ended December 31, 2023, compared to the year ended December 31, 2022, is due to the decrease in revenues derived from sales through our strategic partnerships. Gross profit for the year ended December 31, 2023, excluding amortization of acquired technology were $10,370,000 (51.0% of revenues) compared to $14,012,000 (50.7% of revenues) during the year ended December 31, 2022.

Research and Development Expenses

Our research and development expenses increased by $599,000 to $20,248,000 for the year ended December 31, 2023, compared to $19,649,000 for the year ended December 31, 2022. This increase was mainly due to the increase in our payroll expenses during the year ended December 31, 2023. Our research and development expenses, excluding stock-based compensation and depreciation, for the year ended December 31, 2023, were $16,367,000 compared to $15,995,000 for the year ended December 31, 2022, an increase of $372,000. This increase is mainly as a result of an increase in salaries and software development expenses.

Research and development expenses consist mainly of payroll expenses to employees involved in research and development activities, expenses related to: (i) our solutions including our Dario Smart Diabetes Management Solution,

DarioEngage platform, Dario Move solution and our digital behavioral health solution, (ii) labor contractors and engineering expenses, (iii) depreciation and maintenance fees related to equipment and software tools used in research and development, (iv) clinical trials performed in the United States to satisfy the FDA product approval requirements and (v) facilities expenses associated with and allocated to research and development activities.

Sales and Marketing

Our sales and marketing expenses decreased by $6,538,000 to $23,785,000 for the year ended December 31, 2023, compared to $30,323,000 for the year ended December 31, 2022. This decrease was mainly due to the decreases in our digital marketing and payroll related expenses during the year ended December 31, 2023. Our sales and marketing expenses, excluding stock-based compensation, depreciation and amortization, for the year ended December 31, 2023, were $17,146,000 compared to $23,880,000 for the year ended December 31, 2022, a decrease of $6,734,000. This decrease was due to a decrease in our digital marketing, and payroll related expenses.

Sales and marketing expenses consist mainly of payroll expenses, online marketing campaigns of our service offering, trade show expenses, customer support expenses and marketing consultants, marketing expenses and subcontractors.

General and Administrative Expenses

Our general and administrative expenses increased by $1,647,000 to $18,140,000 for the year ended December 31, 2023, compared to $16,493,000 for the year ended December 31, 2022. The increase was mainly due to an increase in our stock-based compensation, during the year ended December 31, 2023. Our general and administrative expenses, excluding stock-based compensation, acquisition costs and depreciation, for the year ended December 31, 2023, were $8,663,000 compared to $9,803,000 for the year ended December 31, 2022, a decrease of $1,140,000. This decrease was due to a decrease in, insurance, consulting services, and investor relations expenses.

Our general and administrative expenses consist mainly of payroll and stock-based compensation expenses for management, employees, directors and consultants, legal and accounting fees, patent registration, expenses related to investor relations, as well as our office rent and related expenses.

Finance expenses, net

Our finance expenses, net, decreased by $2,205,000 to $3,174,000 for the year ended December 31, 2023, compared to $5,379,000 financing expenses for the year ended December 31, 2022. The changes in our financial expenses were mainly due to the remeasurement of our long term loan and interest income received.

Financial expenses, net mainly include bank charges, interest expenses, interest income, and foreign currency translation differences.

Income tax

Income tax expenses were $64,000 for the year ended December 31, 2023, as compared to $4,000 for the year ended December 31, 2022.

Net loss

Net loss for the year ended December 31, 2023 was $59,427,000. Net loss for the year ended December 31, 2022, was $62,193,000. The decrease from 2022 was mainly due to the decrease in our operating and financing expenses.

Net operating loss carryforwards

As of December 31, 2023, we and WayForward had a U.S. federal net operating loss carryforward of approximately $44,870, of which $7,491 were generated from tax years 2011-2017 and can be carried forward and offset against taxable income, which expires during the years 2031 to 2037.

On December 22, 2017, the U.S. Tax Cuts and Jobs Act of 2017 (the "TCJA") modified the rules regarding utilization of net operating loss and net operating losses generated subsequent to the TCJA can only be used to offset 80% of taxable income with an indefinite carryforward period for unused carryforwards (i.e., they should not expire). During 2018 - 2023, we generated additional $37,379,000 of net operating losses carryforwards which are not subject to the annual limitation described above.

Our Israeli subsidiary, Labstyle, accumulated net operating losses for Israeli income tax purposes as of December 31, 2023, in the amount of approximately $189,653,000. The net operating losses may be carried forward and offset against taxable income in the future for an indefinite period.

In accordance with U.S. GAAP, it is required that a deferred tax asset be reduced by a valuation allowance if, based on the weight of available evidence it is more likely than not (a likelihood of more than 50 percent) that some portion or all of the deferred tax assets will not be realized. The valuation allowance should be sufficient to reduce the deferred tax asset to the amount which is more likely than not to be realized. As a result, we recorded a valuation allowance with respect to our deferred tax asset. Under Sections 382 and 383 of the Internal Revenue Code, if an ownership change occurs with respect to a "loss corporation" (as defined in the Internal Revenue Code), there are annual limitations on the amount of the net operating loss and other deductions which are available to us.

The factors described above resulted in net loss attributable to common stockholders of $63,511,000 and $63,836,000 for the year ended December 31, 2023 and 2022, respectively.

Non-GAAP Financial Measures

To supplement our consolidated financial statements presented in accordance with U.S. GAAP within this Annual Report on Form 10-K, management provides certain non-GAAP financial measures ("NGFM") of the Company's financial results, including such amounts captioned: "net loss before interest, taxes, depreciation, and amortization" or "EBITDA," and "Non-GAAP Adjusted Loss," as presented herein below. Importantly, we note the NGFM measures captioned "EBITDA" and "Non-GAAP Adjusted Loss" are not recognized terms under U.S. GAAP, and as such, they are not a substitute for, considered superior to, considered separately from, nor as an alternative to, U.S. GAAP and /or the most directly comparable U.S. GAAP financial measures.

Such NGFM are presented with the intent of providing greater transparency of information used by us in our financial performance analysis and operational decision-making. Additionally, we believe these NGFM provide meaningful information to assist investors, shareholders, and other readers of our consolidated financial statements, in making comparisons to our historical financial results, and analyzing the underlying financial results of our operations. The NGFM are provided to enhance readers' overall understanding of our current financial results and to provide further information to enhance the comparability of results between the current year period and the prior year period.

We believe the NGFM provide useful information by isolating certain expenses, gains, and losses, which are not necessarily indicative of our operating financial results and business outlook. In this regard, the presentation of the NGFM herein below, is to help the reader of our consolidated financial statements to understand the effects of the non-cash impact on our (U.S. GAAP) audited statement of operations of the revaluation of the warrants and the expense related to stock-based compensation, each as discussed herein above.

A reconciliation to the most directly comparable U.S. GAAP measure to NGFM, as discussed above, is as follows:

	Year Ended December 31, (in thousands)		
	2023	2022	$ Change
Net Loss Reconciliation			
Net loss - as reported	$ (59,427)	$ (62,193)	$ 2,766
Adjustments			
Depreciation expense	473	356	117
Amortization of acquired technology and brand	4,512	4,481	31
Other financial expenses, net	3,174	5,379	(2,205)
Income tax	64	4	60
EBITDA	(51,204)	(51,973)	769
Acquisition costs	128	—	128
Earn-out remeasurement	—	(497)	497
Stock-based compensation expenses	19,701	16,975	2,726
Non-GAAP adjusted loss	$ (31,375)	$ (35,495)	$ 4,120

Liquidity and Capital Resources

The Company has incurred net losses since its inception. As of December 31, 2023, The Company has incurred recurring losses and negative cash flows since inception and has an accumulated deficit of $349,361 as of December 31, 2023. For the year ended December 31, 2023, the Company used approximately $30,379 of cash in operations. Management believes the Company has sufficient funds to support its operation for at least a period of twelve months from the date of the issuance of these consolidated financial statements. The Company expect to incur future net losses and our transition to profitability is dependent upon, among other things, the successful development and commercialization of the Company's products and the achievement of a level of revenues adequate to support the cost structure. Until the Company achieves profitability or generates positive cash flows, it will continue to be dependent on raising additional funds. The Company intends to fund its future operations through cash on hand, additional private and/or public offerings of debt or equity securities or a combination of the foregoing. There are no assurances, however, that the Company will be able to obtain an adequate level of financial resources that are required for the long-term development and commercialization of its product offerings.

As of December 31, 2023, we had approximately $36,797,000 in cash and cash equivalents compared to $49,357,000 at December 31, 2022.

We have experienced cumulative losses of $349,361,000 from inception (August 11, 2011) through December 31, 2023 and have a stockholders' equity of $96,389,000 at December 31, 2023. In addition, we have not completed our efforts to establish a stable recurring source of revenues sufficient to cover our operating costs and expect to continue to generate losses for the foreseeable future.

Since inception, we have financed our operations primarily through private placements and public offerings of our common stock and warrants to purchase shares of our common stock, receiving aggregate net proceeds totaling $244,392,000 and a credit facility of $25,564,000 as of December 31, 2023.

On January 26, 2021, we entered into securities purchase agreements with institutional accredited investors relating to an offering with respect to the sale of an aggregate of 3,278,688 shares of the Company's common stock at a purchase price of $21.35 per share, for aggregate gross proceeds of $70,000,000. The closing of the offering was consummated on February 1, 2021. The purchase price per share represents the "Minimum Price" of the Company's Common Stock pursuant to Nasdaq Rule 5635(d) as of the date of execution of each respective securities purchase

agreement. The Company and the investors participating in the offering also executed a registration rights agreement pursuant to which the Company agreed to file a registration statement covering the resale of the shares within sixty (60) days following the final closing of the offering.

On October 22, 2021, we entered into a Sales Agreement ("Sales Agreement") with Cowen and Company, LLC ("Cowen"), pursuant to which we may issue and sell shares of our common stock having an aggregate offering price of up to $50,000,000 from time to time through Cowen. Upon entering into the Sales Agreement, we filed a new shelf registration statement on Form S-3, which was declared effective by the SEC on November 12, 2021. During the year ended December 31, 2023, we sold 408,043 shares of our common stock under the Sales Agreement for aggregate net proceeds of approximately $1,614,000.

On February 28, 2022, we entered into securities purchase agreements with institutional accredited investors relating to a registered direct offering with respect to the sale of an aggregate of 4,674,454 shares of our common stock and pre-funded warrants to purchase an aggregate of 667,559 shares of our common stock, at a purchase price of $7.49 per share. The aggregate gross proceeds were approximately $40,000,000.

On June 9, 2022, we entered into a Credit Agreement (the "Credit Agreement"), with OrbiMed Royalty and Credit Opportunities III, LP ("Orbimed"), as the lender for a five-year senior secured credit facility in an aggregate principal amount of up to $50 million (the "Loan Facility"), of which $25 million was made available on the closing date and up to $25 million was to be made available on or prior to June 30, 2023, subject to certain revenue requirements.

On May 1, 2023, we entered into a Loan and Security Agreement, and Supplement thereto (the "LSA"), with our subsidiary, PsyInnovations, collectively as the borrowers (the "Borrowers") and Avenue Venture Opportunities Fund II, L.P. and Avenue Venture Opportunities Fund, L.P., collectively as the lenders (the "Avenue Lenders"). The LSA provides for a four-year secured credit facility in an aggregate principal amount of up to $40 million (the "Loan Facility"), of which $30 million was made available on the closing date (the "Initial Tranche") and up to $10 million (the "Discretionary Tranche") may be made available on the later of July 1, 2023, or the date the Lender approves the issuance of the Discretionary Tranche. On May 1, 2023, the Borrowers closed on the Initial Tranche, less certain fees and expenses payable to or on behalf of the Avenue Lenders. As a result of the execution of the LSA and the funding of the Initial Tranche, we satisfied our prior Credit Agreement we previously executed with OrbiMed, on June 9, 2022, and terminated the Credit Agreement with Orbimed.

All obligations under the LSA are guaranteed by our wholly owned subsidiary, Labstyle. All obligations under the LSA, and the guarantees of those obligations, are secured by substantially all of our, PsyInnovations' and the guarantor's assets. Subject to certain milestones set forth in the LSA, the Borrowers shall make monthly payments to the Avenue Lenders of the interest at the then effective rate. If the Borrowers fail to meet the milestones set forth in the LSA, the Borrowers shall make monthly principal installments in advance in an amount sufficient to fully amortize the Loan. The Borrowers shall repay amounts outstanding under the Loan Facility in full immediately upon an acceleration as a result of an event of default as set forth in the LSA.

During the term of the Loan Facility, interest payable in cash by the Borrowers shall accrue on any outstanding balance due under the Loan Facility at a rate per annum equal to the higher of (x) the sum of four one-half percent (4.50%) plus the prime rate as published in the Wall Street Journal and (y) twelve and one-half percent (12.50%). During an event of default, any outstanding amount under the Loan Facility will bear interest at a rate of 5.00% in excess of the otherwise applicable rate of interest. The Borrowers will pay certain fees with respect to the Loan Facility, including an upfront commitment fee, an administration fee and a prepayment premium, as well as certain other fees and expenses of the Avenue Lenders.

On February 15, 2024, we entered into the First Amendment to Loan and Security Agreement and Supplement (the "Avenue Amendment") with the Avenue Lenders. Pursuant to the Avenue Amendment, the parties agreed to include the Merger Sub and Twill as parties to our existing loan facility with the Avenue Lenders. In addition, the Avenue Amendment provides (i) that we will seek stockholder approval to reprice the warrants issued to the lenders on May 1, 2023 to permit an amendment to the exercise price of such warrants to the "minimum price" as defined by Nasdaq rules as of the closing of the Twill Agreement and (ii) permit the Avenue Lenders, subject to Nasdaq rules, to convert up to two million of the principal amount of its loan to us at a conversion price of $4.0001 per share.

On May 1, 2023, we entered into securities purchase agreements (each, a "Series B Purchase Agreement") with accredited investors relating to an offering and the sale of an aggregate of 6,200 shares of newly designated Series B Preferred Stock (the "Series B Preferred Stock"), an aggregate of 7,946 shares of Series B-1 Preferred Stock (the "Series B-1 Preferred Stock"), and an aggregate of 150 shares of Series B-2 Preferred Stock (the "Series B-2 Preferred Stock") at a purchase price of $1,000 for each share of Preferred Stock. Certain of our executive officers and directors purchased shares of Series B-2 Preferred Stock in the Offering. On May 5, 2023, we entered into purchase agreements (the "Series B-3 Purchase Agreement" and together with the Series B Purchase Agreement, the "Purchase Agreement") with accredited investors, relating to the Offering, to an offering and the sale of an aggregate of 1,106 shares of newly designated Series B-3 Preferred Stock (the "Series B-3 Preferred Stock" and, collectively with the Series B Preferred Stock, the Series B-1 Preferred Stock and the Series B-2 Preferred Stock, the "Preferred Stock"), at a purchase price of $1,000 for each share of Preferred Stock. As a result of the sale of the Preferred Stock, the aggregate gross proceeds to the Company from the Offering are approximately $15.4 million. The closing of the Series B Preferred Stock, Series B-1 Preferred Stock and Series B-2 Preferred Stock occurred on May 4, 2023, and the closing of the Series B-3 Preferred Stock occurred on May 9, 2023.

On May 1, 2023, we executed an agreement (the "Preferred Agreement") with existing holders of our Series A-1 Convertible Preferred Stock. Pursuant to the Preferred Agreement, we agreed to issue such holders of Series A-1 Convertible Preferred Stock up to an aggregate of an additional 382,050 shares of common stock, in addition to the 1,273,499 shares of common stock issuable upon conversion of the Series A-1 Preferred Stock, in consideration for such holders agreeing not to convert their shares of Series A-1 Convertible Preferred Stock. Such shares of common stock are issuable on the following dates, assuming the Series A-1 Convertible Preferred Stock has not yet been converted: (i) up to an aggregate of 63,675 shares of Common Stock before July 1, 2023, if not converted for at least one quarter, (ii) up to an aggregate of 127,350 shares of Common Stock before October 1, 2023, if not converted for at least two quarters, (iii) up to an aggregate of 191,026 shares of Common Stock before January 1, 2024, if not converted for at least three quarters, (iv) up to an aggregate of 254,700 shares of Common Stock before April 1, 2024, if not converted for at least four quarters, and (v) up to an aggregate of 382,050 shares of Common Stock before July 1, 2024, if not converted for at least five quarters. The holders of Series A-1 Convertible Preferred Stock will not be entitled to receive any such shares if the issuance of such shares will exceed a non-waivable 19.99% ownership blocker.

On February 15, 2024, we entered into securities purchase agreements (each, a "Series C Purchase Agreement") with accredited investors relating to an offering (the "Offering") and the sale of an aggregate of (i) 17,307 shares of newly designated Series C Preferred Stock (the "Series C Preferred Stock"), and (ii) 4,000 shares of Series C-1 Preferred Stock (the "Series C-1 Preferred Stock"), at a purchase price of $1,000 for each share of Preferred Stock. In addition, on February 16, 2024, the Company entered into Series C Purchase Agreements with accredited investors relating to the Offering and the sale of an aggregate of 1,115 shares of Series C-2 Preferred Stock (the "Series C-2 Preferred Stock" and together with the Series C Preferred Stock and the Series C-1 Preferred Stock, the "Series C Preferred Stock"), at a purchase price of $1,000 for each share of Preferred Stock. As a result of the sale of the Series C Preferred Stock, the aggregate gross proceeds to the Company from the Offering were approximately $22,422,000. The closing of the Series C Preferred Stock, Series C-1 Preferred Stock and Series C-2 Preferred Stock occurred on or before February 21, 2024.

Readers are advised that available resources may be consumed more rapidly than currently anticipated, resulting in the need for additional funding sooner than expected. Should this occur, we will need to seek additional capital earlier than anticipated in order to fund (1) further development and, if needed (2) expenses which will be required in order to expand manufacturing of our products, (3) sales and marketing efforts and (4) general working capital. Such funding may be unavailable to us on acceptable terms, or at all. Our failure to obtain such funding when needed could create a negative impact on our stock price or could potentially lead to the failure of our company. This would particularly be the case if we are unable to commercially distribute our products and services in the jurisdictions and in the timeframes we expect.

Cash Flows

The following tables sets forth selected cash flow information for the periods indicated:

	December 31,	
	2023	2022
	$	$
Cash used in operating activities:	(30,379,000)	(47,845,000)
Cash used in investing activities:	(547,000)	(573,000)
Cash provided by financing activities:	18,253,000	61,940,000
	(12,673,000)	13,522,000

Net cash used in operating activities

Net cash used in operating activities was $30,379,000 for the year ended December 31, 2023, compared to $47,845,000 used in operations for the same period in 2022. Cash used in operations decreased mainly due to the decrease in our receivables and inventories, and the decrease in operating and financing expenses.

Net cash used in investing activities

Net cash used for investing activities was $547,000 for the year ended December 31, 2023, compared to cash used in investing activities of $573,000 for the year ended December 31, 2022. Cash used in investing activities increased mainly due to purchase of property and equipment and investment in short-term bank deposits in 2023 compared to 2022.

Net cash provided by financing activities

Net cash provided by financing activities was $18,253,000 for the year ended December 31, 2023, compared to $61,940,000 for the year ended December 31, 2022. During the year ended December 31, 2023, we raised net proceeds in an amount of approximately $16,482,000 through our May 2023 offering and net proceeds in an amount of approximately $1,771,000 through the LSA with the Avenue Lenders.

Contractual Obligations

Set forth below is a summary of our current obligations as of December 31, 2023, to make future payments due by the period indicated below, excluding payables and accruals. We expect to be able to meet our obligations in the ordinary course. Operating lease obligations are for motor vehicle and real property leases which we use in our business. Purchasing obligations consists of outstanding purchase orders for materials and services from our vendors.

	Payments due by period (In U.S. dollars thousands)			
Contractual Obligations	Total	Less than 1 year	1-3 years	Over 4 years
Operating Lease Obligations	$ 1,271	$ 124	$ 863	$ 284
Purchasing Obligations	4,511	4,511	—	—
Total contractual cash obligations	$ 5,782	$ 4,635	$ 863	$ 284

Contingencies

We account for our contingent liabilities in accordance with ASC 450 “Contingencies”. A provision is recorded when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated.

With respect to legal matters, provisions are reviewed and adjusted to reflect the impact of negotiations, estimated settlements, legal rulings, advice of legal counsel and other information and events pertaining to a particular matter. Currently, we are not a party to any ligation that we believe could have a material adverse effect on our business, financial position, results of operations or cash flows.

Recently Issued and Adopted Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-13, Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments ("ASU 2016-13"). ASU 2016-13 amends the impairment model to utilize an expected loss methodology in place of the currently used incurred loss methodology, which will result in the timelier recognition of losses, with an effective date for the first quarter of fiscal year 2020. In November 2019, the FASB issued ASU No. 2019-10 which delayed the effective date of ASU 2016-13 for smaller reporting companies (as defined by the SEC) and other non- Securities and Exchange Commission ("SEC") reporting entities to fiscal years beginning after December 15, 2022, including interim periods within those fiscal periods. The Company adopted the standard effective as of January 1, 2023, and the adoption of this standard did not have material impact on the Company's consolidated financial statements.

In August 2020, the FASB issued 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)" ("ASC470-20"). The new standard reduces the number of accounting models in ASC 470-20 that require separate accounting for non-bifurcated embedded conversion features. As a result, convertible instruments will no longer be subject to the cash conversion features model or to the beneficial conversion features model and be accounted for as a single unit of account as long as no other features require bifurcation and recognition as derivatives, The Company adopted ASU 2020-06, effective January 1, 2023, using the modified retrospective method. The prior period consolidated financial statements have not been retrospectively adjusted and continue to be reported under the accounting standards in effect for those periods. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

In October 2021, the FASB issued ASU 2021-08, which requires companies to apply ASC 606 to recognize and measure contract assets and contract liabilities from contracts with customers acquired in a business combination. This creates an exception to the general recognition and measurement principle in ASC 805. requires companies to apply ASC 606 to recognize and measure contract assets and contract liabilities from contracts with customers acquired in a business combination. For the Company, the guidance is effective for fiscal years beginning after 15 December 2022 and interim periods within those fiscal years. The Company completed its evaluation of ASU 2021-08, which we adopted on January 1, 2023. The adoption of ASU 2021-08 did not have a material impact on the Company's consolidated financial statements and related disclosures.

Recently issued accounting pronouncements, not yet adopted:

In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280), Improvements to Reportable Segment Disclosures, which expands annual and interim disclosure requirements for reportable segments, primarily through enhanced disclosures about significant segment expenses. In addition, it provides new segment disclosure requirements for entities with a single reportable segment. The guidance will be effective for the Company for annual periods beginning January 1, 2024, and for interim periods beginning January 1, 2025. Early adoption is permitted. The Company is currently evaluating the impact on its financial statement disclosures.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740), Improvements to Income Tax Disclosures, which requires disaggregated information about the effective tax rate reconciliation as well as information on income taxes paid. The guidance will be effective for the Company for annual periods beginning January 1, 2025, with early adoption permitted. The Company is currently evaluating the impact on its financial statement disclosures

Item 7A. Quantitative and Qualitative Disclosure About Market Risk

Not applicable.

Item 8. Financial Statements and Supplementary Data

Our consolidated financial statements and notes thereto and the report of Kost Forer Gabbay & Kasierer, a member of Ernst & Young Global, our independent registered public accounting firm, are set forth on pages F-1 through F-31 of this Annual Report.

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

Not applicable.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, at December 31, 2023, such disclosure controls and procedures were effective.

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, or persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure.

Limitations on the Effectiveness of Internal Controls

Readers are cautioned that our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will necessarily prevent all fraud and material error. An internal control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our control have been detected. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any control design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2023, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Report on Internal Control Over Financial Reporting

As required by the SEC rules and regulations, our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our consolidated financial statements for external reporting purposes in accordance with U.S. GAAP. Our 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 our company;

(2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with accounting principles generally accepted in the United States of America, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and

(3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect errors or misstatements in our consolidated financial statements. 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 or compliance with the policies or procedures may deteriorate. Management assessed the effectiveness of our internal control over financial reporting at December 31, 2023. In making these assessments, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework). Based on our assessments and those criteria, management determined that we maintained effective internal control over financial reporting at December 31, 2023.

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The following sets forth information regarding our executive officers and the members of our Board of Directors as of the date of this Annual Report. All directors hold office for one-year terms until the election and qualification of their successors. Officers are appointed by our Board of Directors and serve at the discretion of our Board of Directors, subject to applicable employment agreements.

Name	Age	Position(s)
Erez Raphael	50	Chief Executive Officer and Director
Zvi Ben David	63	Chief Financial Officer, Treasurer and Secretary
Richard Anderson	54	President
Tomer Ben-Kiki	53	Chief Operating Officer
Yoav Shaked	52	Chairman of the Board of Directors
Dennis Matheis	63	Director
Hila Karah	55	Director
Dennis M. McGrath	67	Director
Jon Kaplan	56	Director
Adam Stern	59	Director

Erez Raphael has served as our Chief Executive Officer since August 9, 2013 and as a director of our company since December 2013. Mr. Raphael served as Chairman of the Board of Directors from November 2014 to July 2018, and as a director from November 2014 to the present. He previously and until October 2012 served as our Vice President of Research and Development. Mr. Raphael has over 17 years of industry experience, having been responsible in his career for product delivery, technology and business development. Prior to joining us, from 2010 to 2012, Mr. Raphael served as Head of Business Operations for Nokia Siemens Networks, where he was responsible for establishing and implementing

a new portfolio business unit directed towards marketing and sales of complimentary products. Prior to that, from 1998 to 2010, he held increasingly senior positions at Amdocs Limited (Nasdaq:DOX) where he was ultimately responsible for advising the Chief Technology Officer and implementing matters of overall business strategy. Mr. Raphael holds a B.A. in economics and business management from Haifa University. We believe Mr. Raphael is qualified to serve on our Board of Directors because of his extensive experience with technology companies and in sales and marketing.

Zvi Ben David has served as our Chief Financial Officer, Treasurer and Secretary since January 7, 2015. Mr. Ben David has over 25 years of experience in corporate and international financial management, including at both publicly-listed and private companies. Since 2012, he has acted as an independent entrepreneur with, and investor in, various medical device ventures. From 2005 to 2012, Mr. Ben David served as the Chief Financial Officer of UltraShape Medical Ltd., a developer, manufacturer and marketer of innovative non-invasive technologies for fat cell destruction and body sculpting. While with UltraShape, he helped lead the company through $35 million in private financing, followed by the company's merger with a Tel Aviv Stock Exchange company and ultimately the company's sale to Syneron Medical Ltd. From 2000 to 2005, he served as Vice President and Chief Financial Officer of Given Imaging Ltd., where he was part of the management team that led that company's 2001 initial public offering and 2004 follow-on offering, and served as a director of that company from its establishment in 1998 to 2000. From 1995 to June 2000, Mr. Ben David served as Vice President and Chief Financial Officer of RDC Rafael Development Corporation, one of Given Imaging Ltd.'s principal shareholders. From 1994 to 1995, Mr. Ben David served as manager of the finance division of Electrochemical Industries (Frutarom) Ltd., an Israeli company traded on the Tel-Aviv Stock Exchange and the American Stock Exchange, and from 1989 to 1993, Mr. Ben David served as the manager of that company's economy and control department. From 1984 to 1988, Mr. Ben David worked at Avigosh & Kerbs, an accounting firm in Haifa, Israel. Mr. Ben David is a certified public accountant in Israel and holds a B.A. in economics and accounting from Haifa University.

Richard Anderson has served as our President since August 10 2022, and was previously our President and General Manager of North America from January 7, 2020 until August 10, 2022. From November 2003 to December 2019, Mr. Anderson worked for Catasys, Inc. (Nasdaq: CATS), where he served as President and Chief Operating Officer from July 2008 to December 2019, and as a member of its board of directors from November 2003 to July 2019. Prior to Catasys, Inc., Mr. Anderson served as Senior Executive Vice President of Hythiam, Inc., a predecessor company of Catasys, Inc., from 2005 to 2008. From 1999 to 2005, he also served as Chief Financial Officer and Secretary of Clearant, Inc., a biotechnology company. Prior to Clearant, from 1999 to 2001, he served as the Chief Financial Officer and Managing Director of Intellect Capital Group, a venture consulting firm. Earlier in his career, Mr. Anderson was a Senior Manager/Director for PricewaterhouseCoopers. Mr. Anderson holds a B.A. in Business Economics from the University of California at Santa Barbara.

Tomer Ben-Kiki has served as our Chief Operating Officer since February 15, 2024. Since October 2011, Mr. Ben-Kiki served as Co-Founder and Chief Executive Officer of Twill. From January 2003 through October 2010, he served as owner of Oberon Media, Inc. Mr. Ben-Kiki holds a Bachelor of Science from Tel-Aviv University.

Yoav Shaked has served as the Chairman of our Board of Directors since July 5, 2018. Since 2011, Mr. Shaked has served as a partner at Sequoia Capital, a leading global venture capital firm. In 2005, he co-founded Medpoint Ltd., a private medical device distribution company offering a wide range of medical products. Previously, he founded and served as Chief Executive Officer of Y-Med Inc. from May 2004 through November 2009, until its sale to C.R. Bard, Inc. After the sale of Y-Med Inc., Mr. Shaked served as the director of research at ThermopeutiX, a developer of innovative products for strokes and peripheral artery disease. Mr. Shaked currently serves on the board of directors of several biotechnology companies, including Endospan, Vibrant Gastro, B-Lite (G&G Biotechnology) and Orasis Pharmaceuticals, the latter of which he serves as Chairman of the Board. Mr. Shaked has a B.A. in biology from The Hebrew University of Jerusalem. We believe that Mr. Shaked is qualified to serve as Chairman of the Board because of his extensive experience both in biotechnology companies and in the venture capital realm.

Dennis Matheis has been a director of our company since July 2, 2020. Mr. Matheis spent nearly 30 years in various senior leadership roles in health insurance and healthcare. Since September 2022 he serves as the President and Chief Executive Officer of Sentara Healthcare, Inc. Prior to that, he served for 5 years as the President of Optima Health, Inc. and spent 13 years in leadership roles at Anthem, Inc., serving as President of Central Region and Exchanges encompassing six states and representing $12 billion in annual revenue. Mr. Matheis also served in senior leadership roles at Anthem Blue Cross and Blue Shield of Missouri, CIGNA Healthcare and Humana Health Plan, as well as Advocate

Health Care in Chicago. Mr. Matheis has a B.S. in Accounting from the University of Kentucky and practiced as a Certified Public Accountant before entering the healthcare industry. We believe that Mr. Matheis is qualified to serve on our Board of Directors because of his experience in the healthcare business.

Hila Karah has been a director of our company since November 23, 2014. Ms. Karah is an independent business consultant and an investor in several high-tech, biotech and internet companies. From 2006 to 2013, she served as a partner and Chief Investment Officer of Eurotrust Ltd., a family office. From 2002 to 2005, she served as a research analyst at Perceptive Life Sciences Ltd., a New York-based hedge fund. Prior to that, Ms. Karah served as research analyst at Oracle Partners Ltd., a health care-focused hedge fund. Ms. Karah has served as a director in several private and public companies including Intec Pharma, since 2009 and Cyren Ltd since 2008. Ms. Karah holds a B.A. in Molecular and Cell Biology from the University of California, Berkeley, and studied at the University of California, Berkeley-University of California, San Francisco Joint Medical Program. We believe Ms. Karah is qualified to serve on our Board of Directors because of her experience as an investor in and advisor to high-tech, biotech and internet companies.

Dennis M. McGrath has been a director of our company since November 12, 2013. Mr. McGrath is a seasoned medical device industry executive with extensive public company leadership experience possessing a broad range of skills in corporate finance, business development, corporate strategy, operations, and administration. After an 18 year career at PhotoMedex, Inc. (Nasdaq: PHMD), he recently joined PAVmed, Inc (Nasdaq: PAVM, PAVMW) as its Executive Vice President and Chief Financial Officer. Previously, from 2000 to 2017 Mr. McGrath served in several senior level positions of PhotoMedex, Inc. (Nasdaq: PHMD), a global manufacturer and distributor of medical device equipment and services, including from 2011 to 2017 as director, President, and Chief Financial Officer. Prior to PhotoMedex's reverse merger with Radiancy, Inc. in December 2011, he also served as Chief Executive Officer from 2009 to 2011 and served as Vice President of Finance and Chief Financial Officer from 2000 to 2009. He received honors as a P.A.C.T. (Philadelphia Alliance for Capital and Technology) finalist for the 2011 Investment Deal of the Year, award winner for the SmartCEO Magazine 2012 CEO of the Year for Turnaround Company, and finalist for the Ernst & Young 2013 Entrepreneur of the Year. He has extensive experience in mergers and acquisitions, both domestically and internationally, and particularly involving public company acquisitions, including Surgical Laser Technologies, Inc, (formerly, Nasdaq: SLTI), ProCyte Corporation (formerly, Nasdaq: PRCY), LCA Vision, Inc. (formerly, Nasdaq: LCAV) and Think New Ideas, Inc. (formerly, Nasdaq: THNK). Prior to PhotoMedex, he served in several senior level positions of AnswerThink Consulting Group, Inc. (then, Nasdaq: ANSR, now, The Hackett Group, Nasdaq: HCKT), a business consulting and technology integration company, including from 1999 to 2000 as Chief Operating Officer of the Internet Practice, the largest division of AnswerThink Consulting Group, Inc., while concurrently during the merger of the companies, serving as the acting Chief Financial Officer of Think New Ideas, Inc. (then, Nasdaq: THNK, now, Nasdaq: HCKT), an interactive marketing services and business solutions company. Mr. McGrath also served from 1996 until 1999 as Chief Financial Officer, Executive Vice President and director of TriSpan, Inc., an internet commerce solutions and technology consulting company, which was acquired by AnswerThink Consulting Group, Inc. in 1999. During his tenure at Arthur Andersen & Co., where he began his career, he became a Certified Public Accountant in 1981 and he holds a B.S., maxima cum laude, in accounting from LaSalle University. In addition to serving as a director of PhotoMedex, he serves as the audit chair and a director of several medical device companies, including Noninvasive Medical Technologies, Inc. and Cagent Vascular, LLC, and as an advisor to the board of an orphan drug company, Palvella Therapeutics, LLC. Formerly from 2007 to 2009, Mr. McGrath served as a director of Embrella Cardiovascular, Inc. (sold to Edwards Lifesciences Corporation, NYSE: EW). He also serves on the Board of Trustees for Manor College and the Board of Visitors for Taylor University. We believe Mr. McGrath is qualified to serve on our Board of Directors because of his accounting expertise and his experiences serving as an officer and director of public and private companies.

Jon Kaplan has been a director of our company since February 2023. Mr.

Kaplan, has extensive business experience consulting and advising healthcare companies. From September 2018 until July 2020, Mr. Kaplan served on the Board of Directors, and the audit committee, of Quorum Health Corporation. Since 2007, he has served as a Senior Partner and Managing Director of the Boston Consulting Group, Inc., or BCG, a privately-held company focused on providing management consulting services, where he recently served on BCG's global leadership council and as the practice leader of BCG's healthcare services. Mr. Kaplan, previously served in advisory board roles at digital health leaders Livongo, Transcarent, Circulation, and Picwell. Prior to BCG, Mr. Kaplan held senior roles at Accenture, Pricewaterhousecooper and Ernst & Young. Mr. Kaplan received a M.B.A. from the Kellogg Graduate School of Management at Northwestern University, a Masters of Public Health from the University of Pittsburgh and a B.A. in Economics from Cornell University. Mr. Kaplan is qualified to serve on our Board of Directors because of his experience in consulting and advising healthcare companies.

Adam Stern has been a director of our company since March 1, 2020. Mr. Stern, has been the head Private Equity Banking at Aegis Capital Corp. and CEO of SternAegis Ventures since 2012 and was a member of our board of directors between October 2011 and May 2014. Prior to Aegis, from 1997 to November 2012, he was with Spencer Trask Ventures, Inc., most recently as a Senior Managing Director, where he managed the structured finance group focusing primarily on the technology and life science sectors. Mr. Stern held increasingly responsible positions from 1989 to 1997 with Josephthal & Co., Inc., members of the New York Stock Exchange, where he served as Senior Vice President and Managing Director of Private Equity Marketing. He has been a FINRA licensed securities broker since 1987 and a General Securities Principal since 1991. Mr. Stern is a director of Aerami Therapeutics Holdings (formerly Dance Biopharm, Inc.), Matinas BioPharma Holdings, Inc. Adgero Biopharmaceuticals Holdings and Hydrofarm Holdings Group, Inc. Mr. Stern is a former director of InVivo Therapeutics Holdings Corp. (OTCQB: NVIV), Organovo Holdings, Inc. (NYSE MKT: ONVO) and PROLOR Biotech Ltd., which was sold to Opko Health, Inc. (NYSE: OPK) for approximately $600 million in 2013. Mr. Stern holds a Bachelor of Arts degree with honors from The University of South Florida in Tampa. We believe Mr. Stern is qualified to serve on our Board of Directors because of his experience in the capital markets, his experiences serving as a director of public and private companies and his experience with life sciences companies.

Scientific Advisory Board

We have established a Scientific Advisory Board (SAB), whose members will be available to us to advise on our scientific and business plans and operational strategies. Below is the biography of our current SAB member.

Dr. David Horwitz – Advisory Board Member, is presently a Senior Consultant with Numerof & Associates and also President of DLH Biomedical Consulting. He previously served as the Global Chief Medical Officer of the Johnson and Johnson Diabetes Institute. Prior to this, he was Vice President, Worldwide Clinical Affairs & Evidence-Based Medicine at LifeScan, Inc., a Johnson & Johnson company. During his time at LifeScan, Dr. Horwitz had, at various times, been responsible for Clinical Research, Medical Affairs, Regulatory Affairs, and Advocacy & Professional Affairs. Dr. Horwitz has previously held faculty positions in the medical schools at the University of Chicago and the University of Illinois, where he was a clinical professor of medicine. He is a Board-Certified internist and endocrinologist, and a Fellow of the American College of Physicians. He has published over 100 articles in scientific and clinical journals, primarily in the areas of diabetes and metabolism. He has completed a term as an industry representative on the Clinical Chemistry and Toxicology advisory panel of the U.S. Food and Drug Administration. He is presently serving as a volunteer physician for a charity-supported clinic.

Dr. Marilyn Ritholz –Advisory Board Member, is a Senior Psychologist at the Joslin Diabetes Center and treats both adults and adolescents with diabetes. In addition, she is on the faculty at Beth Israel Deaconess Medical Center (BIDMC) and is an Assistant Professor of Psychology at Harvard Medical School. Dr. Ritholz is an experienced qualitative researcher. In collaboration with colleagues, she has explored qualitative aspects of healthcare regarding the patient-provider relationship, provider communication about diabetes complications, and psychosocial factors associated with diabetes technology, including continuous glucose monitoring. She has published more than 20 qualitative articles on these topics.

Arnaud Robert – Advisory Board Member, is an accomplished international executive with 25 years of experience in creating new strategies, transforming companies, and driving business outcomes by leveraging digital, AI, and technology. His journey through the realms of Disney, Nike, Viking Cruises, Shaw Communications, and most recently at Sanofi as the EVP & Chief Digital Officer, has been marked by thoughtful leadership and deep digital transformations across business, operations, technology, people, and culture. He also launched several best-in-class experiences, including the Nike Apple watch running app and Disney Movies Anywhere (precursor to Disney+), both used by millions of consumers and widely profiled in the media. Currently, Arnaud is managing director of an advisory firm that helps CEOs, Private Equity Partners, and a large consultancy achieve their strategic objectives through M&A, operational excellence, and digital / AI / GenAI solutions. Arnaud was voted Business Transformation Top 150 (2022), Top 100 Global CDOs (2022 & 2023), and is a former member of the World Economic Forum Media Council. He holds a PhD in Computer Science from the Swiss Institute of Technology and has filed 50 patents.

Board Composition

Our business is managed under the direction of our Board of Directors. Our Board of Directors currently consists of seven members.

Pursuant to the terms of the placement agency agreement between us and Aegis Capital Corp., dated October 22, 2019, we granted Aegis the right to nominate an individual to the Board of Directors for a period of three years, which resulted in the appointment of Mr. Stern to serve on our Board of Directors.

There are no arrangements between our directors and any other person pursuant to which our directors were nominated or elected for their positions.

Board Committees

Our Board of Directors has three standing committees: An Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee.

Audit Committee

Our Audit Committee is comprised of Messrs. Shaked, McGrath and Matheis, each of whom is an independent director. Mr. McGrath is the Chairman of the Audit Committee. Mr. McGrath is an "audit committee financial expert" as defined in Item 407(d)(5)(ii) of Regulation S-K.

Our Audit Committee oversees our corporate accounting, financial reporting practices and the audits of financial statements. For this purpose, the Audit Committee has a charter (which is reviewed annually) and performs several functions. The Audit Committee charter is available on our website at dariohealth.investorroom.com under the "For Investors / Corporate Governance" section. The Audit Committee:

- evaluates the independence and performance of, and assesses the qualifications of, our independent auditor and engage such independent auditor;
- approves the plan and fees for the annual audit, quarterly reviews, tax and other audit-related services and approve in advance any non-audit service to be provided by our independent auditor;
- monitors the independence of our independent auditor and the rotation of partners of the independent auditor on our engagement team as required by law;
- reviews the financial statements to be included in our Annual Report on Form 10-K and Quarterly Reports on Form 10-Q and reviews with management and our independent auditor the results of the annual audit and reviews of our quarterly financial statements; and
- oversees all aspects our systems of internal accounting control and corporate governance functions on behalf of the Board of Directors.

Compensation Committee

Our Compensation Committee is comprised of Messrs. Shaked, McGrath and Ms. Karah. Mr. McGrath is the Chairman of the Compensation Committee.

The Compensation Committee reviews or recommends the compensation arrangements for our management and employees and also assists our Board of Directors in reviewing and approving matters such as company benefit and insurance plans, including monitoring the performance thereof. The Compensation Committee has a charter (which is reviewed annually) and performs several functions. The Compensation Committee charter is available on our website at dariohealth.investorroom.com under the "For Investors / Corporate Governance" section.

The Compensation Committee has the authority to directly engage, at our expense, any compensation to consultants, or other advisers as it deems necessary to carry out its responsibilities in determining the amount and form of employee, executive and director compensation.

Nominating and Corporate Governance Committee

Our Nominating and Corporate Governance Committee is currently comprised of Messers. Matheis and Shaked. Mr. Matheis is the Chairman of the Nominating and Corporate Governance Committee.

The Nominating and Corporate Governance Committee is charged with the responsibility of reviewing our corporate governance policies and with proposing potential director nominees to the Board of Directors for consideration. This committee also has the authority to oversee the hiring of potential executive positions in our company. The Nominating and Corporate Governance Committee operates under a written charter, which will be reviewed and evaluated at least annually.

Director Independence

Our Board of Directors has reviewed the materiality of any relationship that each of our directors has with us, either directly or indirectly. Based on this review, our Board of Directors has determined that, Messrs. Shaked, Matheis McGrath and Kaplan, and Ms. Karah are "independent directors" as defined in the Nasdaq Listing Rules and Rule 10A-3 promulgated under the Exchange Act.

Code of Ethics

On March 5, 2013, our Board of Directors adopted a Code of Business Conduct and Ethics and Insider Trading Policy which applies to all insiders including our principal executive officer, principal financial officer, and principal accounting officer. Our Code of Business Conduct and Ethics is available on our website at www.mydario.com under the Investors/Governance section. The information on our website is not incorporated by reference into this Report. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding amendment to, or waiver from, a provision of our Code of Ethics by posting such information on the website address specified above.

Limitation of Directors Liability and Indemnification

The Delaware General Corporation Law authorizes corporations to limit or eliminate, subject to certain conditions, the personal liability of directors to corporations and their stockholders for monetary damages for breach of their fiduciary duties. Our certificate of incorporation limits the liability of our directors to the fullest extent permitted by Delaware law.

We have director and officer liability insurance to cover liabilities our directors and officers may incur in connection with their services to us, including matters arising under the Securities Act. Our certificate of incorporation and bylaws also provide that we will indemnify our directors and officers who, by reason of the fact that he or she is one of our officers or directors, is involved in a legal proceeding of any nature.

We have entered into indemnification agreements with our directors and officers pursuant to which we agreed to indemnify each director and officer for any liability he or she may incur by reason of the fact that he or she serves as our director or officer, to the maximum extent permitted by law.

There is no pending litigation or proceeding involving any of our directors, officers, employees or agents in which indemnification will be required or permitted. We are not aware of any threatened litigation or proceeding that may result in a claim for such indemnification.

Item 11. Executive Compensation

The following table summarizes compensation of our named executive officers, as of December 31, 2023 and 2022.

Summary Compensation Table

Name and Principal Position	Year	Salary ($)*	Bonus ($)	Stock Awards	Option Awards ($)**	Non-equity incentive plan compensation	Non-qualified incentive plan compensation	All Other Compensation ($)	Total ($)
Erez Raphael	2023	$ 446,307 (1)	101,939 (2)	$ — (3)	$ —	—	—	$ 173,941 (4)	$ 722,187
(Chief Executive Officer)	2022	$ 489,848 (1)	$ 306,263 (2)	$ 1,977,250 (3)	$ —	—	—	$ 182,651 (4)	$ 2,956,012
Zvi Ben David	2023	$ 243,419 (5)	31,479 (6)	$ — (7)	$ —	—	—	$ 67,686 (8)	$ 342,584
(Chief Financial Officer)	2022	$ 268,022 (5)	87,504	$ 683,050 (7)	$ —	—	—	$ 73,522 (8)	$ 1,112,098
Richard Anderson	2023	$ 400,000 (9)	80,000 (10)	$ —	$ — (11)	—	—	$ 56,648 (12)	$ 536,648
(President)	2022	$ 689,955 (9)	250,000 (10)	$ —	$ 732,510 (11)	—	—	$ 58,467 (12)	$ 1,730,932

* Certain compensation paid by the company is denominated in New Israeli Shekel (or the NIS). Such compensation is calculated for purposes of this table based on the annual average currency exchange for such period.

** Amount shown does not reflect dollar amount actually received. Instead, this amount reflects the aggregate grant date fair value of each stock option granted in the fiscal years ended December 31, 2023, and December 31, 2022, computed in accordance with the provisions of ASC 718 "Compensation-Stock Compensation" ("ASC 718"). Assumptions used in accordance with ASC 718 are included in Note 9 to our consolidated financial statements included in this Annual Report.

(1) In accordance with his second amendment to the employment agreement with our company effective August 11, 2013, Mr. Raphael was entitled to a monthly salary of NIS 44,000, commencing April 1, 2016, his monthly salary was increased to NIS 80,000 (approximately $21,578 per month). On June 1, 2018, his monthly salary was increased to NIS 134,167 (approximately $36,188) and on April 1, 2021, his monthly salary was increased to NIS 137,466 (approximately $37,078 per month).

(2) In March 2022, Mr. Raphael was paid a bonus of $306,263 for his performance during 2021. On March 2023, Mr. Raphael was paid a bonus of $101,939 for his performance during 2022.

(3) On May 18, 2022, Mr. Raphael was granted 275,000 restricted shares of our common stock under our 2020 Equity Incentive Plan.

(4) In addition to his salary, Mr. Raphael is entitled to receive a leased automobile and mobile phone during his employment as well as reimbursements for expenses accrued. These benefits, as well as other social benefits under Israeli law, are included as part of his "All Other Compensation."

(5) In accordance with his employment agreement with our company effective January 8, 2015, Mr. Ben David was initially entitled to a monthly salary and additional compensation (excluding social benefits under applicable Israeli law) of NIS 31,200 (approximately $8,415) for providing eighty percent of his working time to our company. Beginning on March 1, 2015, Mr. Ben David began working for us on a full-time basis pursuant to the terms of his employment agreement at which point Mr. Ben David's salary was increased to NIS 39,000 (approximately $10,519 per month, commencing April 1, 2016, his monthly salary was updated to NIS 60,000 (approximately $16,183). Commencing June 1, 2018, his monthly salary was updated to NIS 67,200 (approximately $18,125), and commencing April 1, 2021, his monthly salary was updated to NIS 74,620 (approximately $20,127).

(6) In March 2022, Mr. Ben David was paid a bonus of $87,504 for his performance during 2021. In March 2023, Mr. Ben David was paid a bonus of $31,479 for his performance during 2022.

(7) On May 18, 2022, Mr. Ben David was granted 95,000 restricted shares of our common stock under our 2020 Equity Incentive Plan.

(8) In addition to his salary, Mr. Ben David is entitled to receive a mobile phone during his employment as well as reimbursements for expenses accrued. These benefits, as well as other social benefits under Israeli law, are included as part of his "All Other Compensation."

(9) In accordance with his employment agreement, effective in January 2020, Mr. Anderson was entitled to a monthly salary of $27,916.67. As of April 2022, Mr. Anderson is entitled to a monthly salary of $33,333.33.

(10) In April 2022, Mr. Anderson was paid a bonus of $250,000 for his performance during 2021. In April 2023, Mr. Anderson was paid a bonus of $80,000 for his performance during 2022.

(11) On May 18, 2022, Mr. Anderson was granted 135,000 options to purchase shares of our common stock under our 2020 Equity Incentive Plan, at an exercise price of $7.19 per share.

(12) In addition to his salary, Mr. Anderson is entitled to participate in any and other benefit plans and programs that the Company may offer to its employees from time to time according to the terms of such plans and the Company's practices and policies as well as reimbursements for expenses accrued. These benefits are included as part of his "All Other Compensation."

All compensation awarded to our executive officers was independently reviewed by our Compensation Committee.

Employment and Related Agreements

Except as set forth below, we currently have no other written employment agreements with any of our officers and directors. The following is a description of our current executive employment agreements:

Erez Raphael, *Chief Executive Officer and a Member of the Board of Directors* – On August 30, 2013, LabStyle Innovation Ltd., our Israeli subsidiary, entered into an amendment to a Personal Employment Agreement with Mr. Raphael in connection with his August 2013 appointment as our President and Chief Executive Officer. Pursuant to the terms of his employment agreement as amended, Mr. Raphael is entitled to a monthly salary of NIS 137,466 (approximately $37,078 per month).

On July 25, 2017, we, through our Israeli subsidiary, LabStyle Innovation Ltd., executed an Amended and Restated Employment Agreement with Mr. Raphael. Pursuant to the agreement, Mr. Raphael kept his monthly salary and shall be eligible for an annual bonus equal to up to 60% of his annual base salary. Mr. Raphael's employment agreement expires on December 31, 2020. In the event Mr. Raphael's employment agreement is terminated by us at will, by Mr. Raphael for good reason as provided thereby, or in conjunction with a change of control, Mr. Raphael shall be entitled to receive 24 months base salary and severance payment pursuant to applicable Israeli severance law, provided, however, that in the event such termination occurs during the final year of the term, or within the last 6 months of a renewal period of the term, Mr. Raphael shall be entitled to receive 12 months base salary and severance payment pursuant to applicable Israeli severance law. In the event the employment agreement is terminated by us for cause, Mr. Raphael will only be entitled to a severance pay under applicable Israeli severance law. Mr. Raphael's employment agreement also includes a one-year non-competition and non-solicitation provision, certain confidentiality covenants and assignment of any of his company-related inventions. Under the terms of the agreement, Mr. Raphael is entitled to certain expense reimbursements and other standard benefits, including vacation, sick leave, contributions to a manager's insurance policy and study fund and car and mobile phone allowances. On February 12, 2020, we extended the term of Mr. Raphael's employment to expire on December 31, 2022.

On April 7, 2021, the Compensation Committee of our Board of Directors approved an increase to Mr. Raphael's target bonus to 75% of his annual base salary.

Zvi Ben David, *Chief Financial Officer, Treasurer and Secretary* – On January 8, 2015, LabStyle Innovation Ltd., our Israeli subsidiary, entered into a Personal Employment Agreement with Mr. Ben David. Pursuant to his employment agreement, Mr. Ben David was initially entitled to a monthly salary and additional compensation (excluding social benefits under applicable Israeli law) of NIS 31,200 (approximately $8,415) for providing eighty percent of his working time to our company. Beginning on March 1, 2015, Mr. Ben David began working for us on a full-time basis pursuant to the terms

of his employment agreement at which point Mr. Ben David's salary was increased to NIS 39,000 (approximately $10,519). Commencing April 1, 2016, Mr. Ben David's Salary was updated to NIS 60,000 (approximately $16,183) per month. Commencing June 1, 2018, his monthly salary was updated to NIS 67,200 (approximately $18.215), and commencing April 1, 2021, his monthly salary was updated to NIS 74,620 (approximately $20.127).

Mr. Ben David's employment agreement may be terminated by either party at will upon 90 days prior written notice or terminated by us for cause, as defined under the employment agreement. In the event the employment agreement is terminated by us at will, Mr. Ben David shall be entitled to receive 90 days of severance plus any required severance payment pursuant to applicable Israeli severance law. In the event the employment agreement is terminated by us for cause, Mr. Ben David will only be entitled to a severance pay under applicable Israeli severance law. The employment agreement also includes a twelve-month non-competition and non-solicitation provision, certain confidentiality covenants and assignment of any of his company-related inventions to the company. Under the terms of the employment agreement, Mr. Ben David is entitled to certain expense reimbursements and other standard benefits, including vacation, sick leave, contributions to a manager's insurance policy and study fund and mobile phone allowances.

On April 7, 2021, the Compensation Committee of our Board of Directors approved an increase of Mr. Ben-David's annual salary by $27,000 in the aggregate and increased his target bonus to 40% of his annual base salary.

Richard Anderson, President and General Manager of North America – On January 7, 2020, we appointed Mr. Anderson as our President and General Manager of North America. In connection with Mr. Anderson's appointment, the Company agreed to pay Mr. Anderson an annual base salary of $335,000. Mr. Anderson shall also be subject to a six-month non-competition and one-year non-solicitation provision, certain confidentiality covenants and assignment of any of his company-related inventions. Mr. Anderson will also be entitled to certain expense reimbursements and other standard benefits, including vacation and sick leave. On April 1, 2022 Mr. Anderson's base salary was increased to $400,000. In addition, Mr. Anderson will be entitled to receive an annual incentive bonus of up to $250,000, subject to certain milestones and performance targets. In addition, and in conjunction with his appointment as President and General Manager of North America, the Company agreed to issue Mr. Anderson a stock option to purchase up to 90,000 shares of common stock at an exercise price of $8.41 per share, subject to vesting. Mr. Anderson was also issued a stock option to purchase up to 90,000 shares of common stock at an exercise price of $8.41 per share, subject to vesting and the achievement of certain business revenue targets. In that regard, Mr. Anderson's option will vest as follows: (i) 22,500 shares shall vest following fiscal year 2020 if our business-to-business revenues reach or exceed $6 million in the aggregate, or a pro-rated amount equal to the percentage achievement of such target, assuming the Company's GAAP revenues in 2020 will reach at least $11 million in the aggregate; (ii) 22,500 shares shall vest following fiscal year 2021 if our business-to-business revenues reach or exceed $15 million in the aggregate, or a pro-rated amount equal to the percentage achievement of such target, assuming the Company's GAAP revenues in 2021 will reach at least $19.5 million in the aggregate; (iii) 22,500 shares shall vest following fiscal year 2022 if our business-to-business revenues reach or exceed $40 million in the aggregate, or a pro-rated amount equal to the percentage achievement of such target, assuming the Company's GAAP revenues in 2022 will reach at least $38 million in the aggregate; and (iv) 22,500 shares shall vest following fiscal year 2023 if our business-to-business revenues reach or exceed $80 million in the aggregate, or a pro-rated amount equal to the percentage achievement of such target, assuming the Company's GAAP revenues in 2023 will reach at least $62 million in the aggregate. The performance options for 2020, 2021,2022 and 2023 did not vest and have expired.

On October 16, 2020, the Compensation Committee of our Board of Directors approved the issuance to Mr. Anderson of 5,182 shares of our Common Stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $23,333 of salary otherwise payable to Mr. Anderson from April to July 2020.

On June 8, 2022, the Compensation Committee authorized the Company to redeem 17,957 shares of restricted stock held by Mr. Anderson, in compliance with Rule 16b-3 promulgated by the SEC. The redemption is part of previously granted 91,652 and 20,000 shares of restricted stock granted in January and July 2021, in exchange for the aggregate redemption price equal to the withholding tax obligation in the amount of $170,000.

Tomer Ben-Kiki, Chief Operating Officer. On February 15, 2024, we appointed Mr. Ben-Kiki as Chief Operating Officer. In connection with his appointment as Chief Operating Officer, we entered into an employment agreement with Mr. Ben-Kiki. Mr. Ben-Kiki will earn an annual salary of $212,000 for his work in the United States, and 65,000 NIS per

month for his work in Israel. Mr. Ben-Kiki will be entitled to a bonus of up to 20% of his base salary, subject to certain performance objectives as defined by the Board of Directors. In addition, he will be entitled to receive a stock option to purchase up to 1,017,947 shares of Common Stock, at an exercise price of $2.55 per share, which were granted as an inducement material to Mr. Ben-Kiki becoming an employee of the company, in accordance with Nasdaq Listing Rule 5635(c)(4). Time-based options to purchase up to 717,947 shares of common stock shall vest as follows: 291,742 shares shall vest immediately, and the remaining 426,205 shares will vest over two years in eight equal quarterly amounts, subject to Mr. Ben-Kiki's continued employment by the Company on the applicable vesting date. The performance-based option to purchase up to 300,000 shares of Common Stock will vest immediately upon achieving certain milestones relating to the achievement of revenues (on a U.S. generally accepted account principals basis) relating to Twill products for the year ending December 31, 2024, the achievement of certain operating expense targets for the years ending December 31, 2024 and December 31, 2025, the ability to generate software value from funds invested and meet product roadmap and the retention of key employees post transaction, subject in each case to Mr. Ben-Kiki's continued employment by us on the applicable vesting date. Mr. Ben-Kiki will be employed at-will with a 90 days' notice period, unless it is terminated for cause.

Outstanding Equity Awards at December 31, 2023

Name	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Equity incentive plan awards: Number of securities underlying unexercised unearned options (#)	Option exercise price ($)	Option expiration date
Erez Raphael	45	—	—	$ 3,330	January 6, 2024
(Chief Executive Officer)	234	—	—	$ 1,764	July 6, 2024
Zvi Ben David	27,827	— (1)		$ 7.736	February 12, 2026
(Chief Financial Officer, Secretary and Treasurer)					
Richard Anderson	90,000	— (2)	—	$ 8.41	January 30, 2026
(President and General Manager of North America)	84,018	7,634 (1)	—	$ 17.89	January 19, 2031
	67,500	67,500 (1)	—	$ 7.19	May 18, 2032
Total Option Shares	**269,624**	**75,134**		$	

(1) Vests in 12 equal quarterly installments over a three-year period.

(2) Vests in 3 equal annual installments over a three-year period.

Non-Employee Director Remuneration Policy

In March 2013, our Board of Directors adopted the following non-employee director remuneration policy:

Cash Awards

Our non-employee directors (currently Messrs. Shaked, Matheis, McGrath, Prof. Stone (till his pass away on May 30, 2022) and Ms. Karah) will receive the following cash payments for each fiscal year: (i) $50,000 per year, to be paid quarterly in arrears and (ii) $20,000 for Board committee service, to be paid quarterly in arrears.

Stock and Option Awards

On May 18, 2022, the Compensation Committee of our Board of Directors approved the following issuances, each was done under our 2020 Equity Incentive Plan: (i) 60,000 restricted shares of our common stock to Mr. Shaked; (ii) 80,000 restricted shares of our common stock to Ms. Karah; (iii) 17,620 restricted shares of our common stock to Mr. Matheis; (iv) 55,000 restricted shares of our common stock to each of Mr. Stern and Mr. McGrath; and (v) 35,000 options to purchase shares of our common stock with an exercise price of $7.19 per share, to each of Prof. Stone and Mr. Matheis.

Compensation Committee Review

The Compensation Committee shall, if it deems necessary or prudent in its discretion, reevaluate and approve in January of each such year (or in any event prior to the first board meeting of such fiscal year) the cash and equity awards (amount and manner or method of payment) to be made to non-employee directors for such fiscal year. In making this determination, the Compensation Committee shall utilize such market standard metrics as it deems appropriate, including, without limitation, an analysis of cash compensation paid to independent directors of our peer group.

The Compensation Committee shall also have the power and discretion to determine in the future whether non-employee directors should receive annual or other grants of options to purchase shares of common stock or other equity incentive awards in such amounts and pursuant to such policies as the Compensation Committee may determine utilizing such market standard metrics as it deems appropriate, including, without limitation, an analysis of equity awards granted to independent directors of our peer group.

Participation of Employee Directors; New Directors

Unless separately and specifically approved by the Compensation Committee in its discretion, no employee director of our company shall be entitled to receive any remuneration for service as a director (other than expense reimbursement as per prevailing policy).

New directors joining our Board of Directors shall be entitled to a pro-rated portion (based on months to be served in the fiscal year in which they join) of cash and stock option or other equity incentive awards (if applicable) for the applicable fiscal year at the time they join the board.

Summary Director Compensation Table

The following table summarizes the annual compensation paid to our non-employee directors for the fiscal year ended December 31, 2022:

Name and Principal Position	Year	Fees Paid or Earned in Cash ($)	Stock Awards	Option Awards ($)*	Non-equity incentive plan compensation	Non-qualified deferred compensation earnings	All other compensation ($)	Total ($)
Dennis McGrath	2023	$ 70,000	$ — (1)	$ — (2)	$ —	$ —	$ —	$ 70,000
Jon Kaplan	2023	$ 42,778	$ — (3)	$ — (4)	$ —	$ —	$ —	$ 42,778
Dennis Matheis	2023	$ 70,000	$ — (5)	$ — (6)	$ —	$ —	$ —	$ 70,000
Hila Karah	2023	$ 70,000	$ — (7)	$ — (8)	$ —	$ —	$ —	$ 70,000
Yoav Shaked	2023	$ 70,000	$ — (9)	$ — (10)	$ —	$ —	$ —	$ 70,000
Adam Stern	2023	$ 50,000	$ — (11)	$ — (12)	$ —	$ —	$ —	$ 50,000

* Amount shown does not reflect dollar amount actually received. Instead, this amount reflects the aggregate grant date fair value of each stock option granted in the fiscal year ended December 31, 2023, computed in accordance with the

provisions of ASC 718. Assumptions used in accordance with ASC 718 are included in Note 9 to our consolidated financial statements included in this Annual Report.

(1) 74,744 stock awards are outstanding as of December 31, 2023.

(2) 98 option awards are outstanding as of December 31, 2023.

(3) No stock awards are outstanding as of December 31, 2023.

(4) No option awards are outstanding as of December 31, 2023.

(5) 32,620 stock awards are outstanding as of December 31, 2023.

(6) 55,000 option awards are outstanding as of December 31, 2023.

(7) 148,751 stock awards are outstanding as of December 31, 2023.

(8) No option awards are outstanding as of December 31, 2023.

(9) 163,896 stock awards are outstanding as of December 31, 2023.

(10) No option awards are outstanding as of December 31, 2023.

(11) 108,341 stock awards are outstanding as of December 31, 2023.

(12) No option awards are outstanding as of December 31, 2023.

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

The following table sets forth information regarding the beneficial ownership of our common stock as of March 22, 2024 by:

each person known by us to be the beneficial owner of more than 5% of our outstanding shares of common stock;

- each of our named executive officers and directors; and
- all our executive officers and directors as a group.

Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to the securities. Except as otherwise indicated, each person or entity named in the table has sole voting and investment power with respect to all shares of our capital shown as beneficially owned, subject to applicable community property laws.

In computing the number and percentage of shares beneficially owned by a person, shares that may be acquired by such person within 60 days of the date of this Annual Report are counted as outstanding, while these shares are not

counted as outstanding for computing the percentage ownership of any other person. Unless otherwise indicated, the address of each person listed below is c/o DarioHealth Corp., 18 W. 18th St., New York, New York 10011.

Name of Beneficial Owner	Shares of Common Beneficially Stock Owned	Percent of Common Stock Beneficially Owned [1]
Officers and Directors		
Erez Raphael [2]	1,517,458	5.2 %
Zvi Ben David [3]	568,982	1.9 %
Richard Anderson [4]	740,530	2.5 %
Tomer Ben Kiki [5]	345,018	1.2 %
Dennis M. McGrath [6]	96,509	* %
Jon Kaplan [7]	43,910	— %
Hila Karah [8]	161,999	* %
Yoav Shaked [9]	208,981	* %
Adam Stern [10]	797,452	2.7 %
Dennis Mathies [11]	175,804	* %
All Executive Officers and Directors as a group (10 persons) **	**4,656,643**	**15.7 %**
5% Stockholders		
Nantahala Capital Management, LLC. [12]	2,934,375	9.9 %

* less than 1%.

(1) Percentage ownership is based on 29,442,532 shares of our common stock outstanding as of March 22, 2024 and, for each person or entity listed above, warrants or options to purchase shares of our common stock which exercisable within 60 days of such date.

(2) Includes 234 vested options to purchase common stock and 1,046,492 vested restricted shares. Also includes 37,876 shares of our common stock, held by Dicilyon Consulting and Investment Ltd. Erez Raphael is the natural person with voting and dispositive power over our securities held by Dicilyon Consulting and Investment Ltd. The address of Dicilyon Consulting and Investment Ltd. is 10 Nataf St., Ramat Hasharon 4704063, Israel.

(3) Includes 27,827 vested options to purchase common stock and 399,562 vested restricted shares. Includes 1,786 shares owned by his spouse, for which Mr. Ben David disclaims beneficial ownership except to the extent of his pecuniary interest therein.

(4) Includes 646,652 vested options to purchase common stock and 78,696 vested restricted shares. Excludes 740,000 options which are not vested.

(5) Includes 345,018 vested options to purchase common stock. Excludes 672,929 options which are not vested.

(6) Includes 98 vested options to purchase common stock and 96,411 vested restricted shares.

(7) Includes 35,000 vested restricted shares.

(8) Includes 112,856 vested restricted shares.

(9) Includes 107,234 vested restricted shares. Includes 1,667 shares owned by his spouse, for which Mr. Shaked disclaims beneficial ownership except to the extent of his pecuniary interest therein.

(10) Includes 115,517 vested restricted shares. Includes warrants exercisable into 409,535 shares of common stock, subject to a contractual beneficial ownership limitation of 4.99%.

(11) Includes 43,334 vested options to purchase common stock and 52,620 vested restricted shares. Excludes 11,666 options which have not vested.

(12) Based solely on information contained in Form 13G/A filed with the SEC on February 14, 2024, and data provided by the holder. Includes 197,622 pre-funded warrants to purchase common stock issued in May 2019, subject to a contractual beneficial ownership limitation of 9.99% and excludes preferred shares convertible into 4,737,198 shares of common stock, 79,924 pre-funded warrants issued on May 24, 2019, 386,129 pre-funded warrants issued on July 31, 2020, and 619,117 pre-funded warrants issued on February 28, 2022.

Item 13. Certain Relationships and Related Party Transactions

Executive Officers and Directors

We have entered into employment and consulting agreements and granted stock awards to our executive officers and directors as more fully described in "Executive Compensation" above.

Executive Officers and Directors

We have entered into employment agreements and granted stock awards to our executive officers as more fully described in "Executive Compensation" above.

Statement of Policy

All transactions (if any) between us and our officers, directors or five percent stockholders, and respective affiliates will be on terms no less favorable than could be obtained from unaffiliated third parties and will be approved by a majority of our independent directors who do not have an interest in the transactions and who had access, at our expense, to our legal counsel or independent legal counsel.

On December 28, 2023, we entered into a placement agency agreement (the "Placement Agency Agreement") with Aegis Capital Corp. ("Aegis"), as amended on January 31, 2024, with respect to the offering of the Series C Preferred Stock. Pursuant to the terms of the Placement Agency Agreement, in connection with each closing of the offering, we agreed to pay Aegis an aggregate cash fee representing 10% of aggregate proceeds raised in the offering (and fees representing 5% and 1.5% for certain company introduced investors), non-accountable expense allowance representing 3% of aggregate proceeds raised in the offering (and fees representing 1.5% and none for certain Company introduced investors). In addition, we will issue to Aegis or its designees warrants (the "Placement Agent Warrant") to purchase shares of common stock representing 14.5% of the equivalent shares of Common Stock issuable upon initial conversion of the Series C Preferred Stock at an exercise price equal to the consolidated bid price of the common stock as of the date of such closing. The Placement Agent Warrant provides for a cashless exercise feature and are exercisable for a period of five years from the date of closing. We also granted the Placement Agent the right of first refusal, for a twelve (12) month period after the final closing of the offering, to serve as the Company's lead or co-placement agent for any proposed private placement of our securities (equity or debt) that is proposed to be consummated to investors in the United States with the assistance of a registered broker dealer.

Adam Stern, a member of our Board of Directors, has an interest, and will receive fees due to, Aegis.

On April 3, 2020, we entered into a financial advisory agreement with Aegis Capital Corp., pursuant to which we agreed to pay Aegis Capital Corp. ("Aegis") certain a fee of up to 3% of any proceeds from sales derived by us through commercial transactions entered into with parties introduced by Aegis. In addition, on April 3, 2020, we entered into a Sales Fee Agreement with Aegis, pursuant to which we agreed to pay Aegis a fee of up 4.5% of consideration we may receive in a business development transaction (including, any joint-venture, partnership, strategic collaboration or investment, licensing transaction, co-promotion or distribution agreement or other profit or revenue sharing, or similar business arrangement) from parties introduced by Aegis. To date, we have not paid Aegis any fees as a result of these agreements. Adam Stern, a member of our Board, has an interest, and will receive fees due to, Aegis.

To the best of our knowledge, other than as set forth above, there were no material transactions, or series of similar transactions, or any currently proposed transactions, or series of similar transactions, to which we were or are to be a party, in which the amount involved exceeds the lesser of $120,000 or 1% of the average of our total assets at year-end for the last two completed fiscal years, and in which any director or executive officer, or any security holder who is known by us to own of record or beneficially more than 5% of any class of our common stock, or any member of the immediate family of any of the foregoing persons, has an interest (other than compensation to our officers and directors in the ordinary course of business).

Item 14. Principal Accounting Fees and Services

The following table sets forth fees billed to us by Kost Forer Gabbay & Kasierer, a member of Ernst & Young Global, our independent registered public accounting firm, during the fiscal years ended December 31, 2022 and December 31, 2022 for: (i) services rendered for the audit of our annual financial statements and the review of our quarterly financial statements; (ii) services by our independent registered public accounting firms that are reasonably related to the performance of the audit or review of our financial statements and that are not reported as audit fees; (iii) services rendered in connection with tax compliance, tax advice and tax planning; and (iv) all other fees for services rendered.

	December 31, 2023	December 31, 2022
Audit Fees	$ 303,296	$ 236,443
Audited Related Fees	$ —	$ —
Tax Fees (1)	$ 16,686	$ 55,980
All Other Fees (2)	$ 102,250	$ 16,750
Total	$ 422,232	$ 309,173

(1) Consists of fees relating to our tax compliance and tax planning.

(2) Consists of fees relating to our private placements.

Audit Committee Policies

The Audit Committee of our Board of Directors is solely responsible for the approval in advance of all audit and permitted non-audit services to be provided by the independent auditors (including the fees and other terms thereof), subject to the de minimus exceptions for non-audit services provided by Section 10A(i)(1)(B) of the Exchange Act, which services are subsequently approved by the Board of Directors prior to the completion of the audit. None of the fees listed above are for services rendered pursuant to such de minimus exceptions.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

The following exhibits are filed with this Annual Report.

Exhibit No.	Description
3.1	Composite copy of Certificate of Incorporation, as amended (incorporated by reference to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 17, 2020).
3.2	Bylaws (incorporated by reference to the Company's Quarterly Report on Form 10-Q filed with the Commission on August 16, 2021).
3.3	Certificate of Designation of Preferences, Rights and Limitations of Series A-1 Convertible Preferred Stock of the Company (incorporated by reference to the Company's Current Report on Form 8-K/A filed with the Securities and Exchange Commission on December 3, 2019).
3.4	Amended and Restated Certificate of Designation of Preferences, Rights and Limitations of Series B Preferred Stock (incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 20, 2023).
3.5	Amended and Restated Certificate of Designation of Preferences, Rights and Limitations of Series B-1 Preferred Stock (incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 20, 2023).
3.6	Amended and Restated Certificate of Designation of Preferences, Rights and Limitations of Series B-2 Preferred Stock (incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 20, 2023).
3.7	Amended and Restated Certificate of Designation of Preferences, Rights and Limitations of Series B-3 Preferred Stock (incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 20, 2023).
3.8	Certificate of Designation of Preferences, Rights and Limitations of Series C Preferred Stock (incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 21, 2024).
3.9	Certificate of Designation of Preferences, Rights and Limitations of Series C-1 Preferred Stock (incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 21, 2024).
3.10	Certificate of Designation of Preferences, Rights and Limitations of Series C-2 Preferred Stock (incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 21, 2024).
4.1	Form of Representatives' Warrant (incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 9, 2016).
4.2	Form of Warrant (incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 18, 2018).
4.3	Form of Pre-Funded Warrant (incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 22, 2019).
4.4	Amendment No. 1 To Pre-Funded Warrant (incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 9, 2019).
4.5	Description of Securities (incorporated by reference to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 17, 2020).
4.6	Form of Placement Agent Warrant (incorporated by reference to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 17, 2020).
4.7	Form of 2022 Pre-Funded Warrant (incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 2, 2022).
4.8	Form of Warrant to be issued to OrbiMed Royalty and Credit Opportunities III, LP (incorporated by reference to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 15, 2022).

4.9	Form of Warrant issued to Avenue Venture Opportunities Fund L.P. (incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 5, 2023).
4.10	Form of Warrant Amendment Agreement, dated June 14, 2023 (incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 20, 2023).
4.11	Form of Pre-Funded Warrant (incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 21, 2024).
4.12	Form of Placement Agent Warrant (incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 21, 2024).
10.1+	Personal Employment Agreement, dated January 8, 2015, between the Company and Zvi Ben David (incorporated by reference to the Company's Current Report on Form 8-K, filed with the Securities and Exchange Commission on January 9, 2015).
10.2+	Amended and Restated 2012 Equity Incentive Plan of the Company (incorporated by reference to the Company's Definitive Proxy Statement filed with the Securities and Exchange Commission on October 19, 2016).
10.3+	Amendment to the Amended and Restated 2012 Equity Incentive Plan of the Company+ (incorporated by reference to the Company's Current Report on Form 8-K, filed with the Securities and Exchange Commission on November 6, 2019).
10.4+	2020 Equity Incentive Plan of the Company (incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 14, 2020).
10.5+	Amended and Restated Employment Agreement, dated as of July 25, 2017, between Erez Raphael and LabStyle Innovation Ltd. (incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 26, 2017).
10.6+	Employment Agreement, dated as of September 22, 2013, and as amended on August 1, 2014, April 27, 2015 and May 1, 2016, between Dror Bacher and Labstyle Innovation Ltd. (incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 26, 2017).
10.7+	Amendment No. 1 to Amended and Restated Employment Agreement, dated as of February 12, 2020, between Erez Raphael and LabStyle Innovation Ltd. (incorporated by reference to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 17, 2020).
10.8+	Stock Option Agreement between DarioHealth Corp. and Richard Anderson (incorporated by reference to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 17, 2020).
10.9+	Conditional Stock Option Agreement between DarioHealth Corp. and Richard Anderson (incorporated by reference to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 17, 2020).
10.10+	Representative Form of Indemnification Agreements between DarioHealth Corp. and each of its directors and officers (incorporated by reference to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 17, 2020).
10.11	Share Purchase Agreement by and among DarioHealth Corp., LabStyle Innovation Ltd., Upright Technologies Ltd., Vertex C (C.I.) Fund L.P., as holder representative and certain holders of Upright's outstanding securities, dated January 26, 2021 (incorporated by reference to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 7, 2021).
10.12+	First Amendment to the 2020 Equity Incentive Plan (incorporated by reference to Annex A to the Company's Proxy Statement on Schedule 14A filed with the Securities and Exchange Commission on April 26, 2021).
10.13^	Form of 2022 Securities Purchase Agreement (incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 2, 2022).
10.14	Termination of Employment and Separation Agreement dated January 23, 2023, by and between Dror Bacher and Labstyle Innovation Ltd. (incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on January 27, 2023).

10.15+	Amendment to the Company's Amended and Restated 2020 Equity Incentive Plan (incorporated by reference to the Company's Definitive Proxy Statement filed with the Securities and Exchange Commission on October 14, 2022).
10.16	Agreement and Plan of Merger by and among DarioHealth Corp., WF Merger Sub, Inc., PsyInnovations, Inc., and certain representatives of the former equity holders of PsyInnovations, Inc., dated May 15, 2021 (incorporated by reference to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 15, 2022).
10.17	Amendment to Agreement and Plan of Merger by and between the Company and certain representatives of the former equity holders of PsyInnovations, Inc., dated July 7, 2022 (incorporated by reference to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 15, 2022).
10.18^	Credit Agreement, dated June 9, 2022, by and among the Company, as borrower, and OrbiMed Royalty and Credit Opportunities III, LP, as lender (incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 13, 2022).
10.19	Pledge and Security Agreement, dated June 9, 2022, by and among the Company, Labstyle Innovation Ltd, Upright Technologies, Inc., Psyinnovations, Inc., and OrbiMed Royalty and Credit Opportunities III, LP (incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 13, 2022).
10.20	Registration Rights Agreement, dated June 9, 2022, by and between the Company and OrbiMed Royalty and Credit Opportunities III, LP (incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 13, 2022).
10.21^	Exclusive Preferred Partner, Co-Promotion, Development Collaboration and License Agreement by and between Sanofi US Services, Inc. and DarioHealth Corp., dated February 28, 2022 (incorporated by reference to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 11, 2022).
10.22	Technology Purchase Agreement by and among Physimax Technologies Ltd., Labstyle Innovation Ltd. and DarioHealth Corp., dated January 18, 2022 (incorporated by reference to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 11, 2022).
10.23	Redemption Agreement by and between DarioHealth Corp. and Richard Allan Anderson dated June 9, 2022.
10.24	Form of Preferred Exchange Agreement by and between DarioHealth Corp. and certain holders of Series A-1 Preferred Stock, dated September 20, 2022.
10.25	Form of Securities Purchase Agreement for Series B, Series B-1, and Series B-2 Preferred Stock (incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 5, 2023).
10.26	Loan and Security Agreement, dated May 1, 2023, by and among the Company, as borrower, and Avenue Venture Opportunities Fund II, L.P., as lender (incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 5, 2023).
10.27	Form of Preferred Agreement with Series A-1 Convertible Preferred Stockholders (incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 5, 2023).
10.28	Amended and Restated Exclusive Preferred Partner, Co-Promotion, Development Collaboration and License Agreement by and between Sanofi US Services, Inc. and DarioHealth Corp., dated July 10, 2023 (incorporated by reference to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 10, 2023).
10.29	Agreement and Plan of Merger dated February 15, 2024, by and among DarioHealth Corp., Twill Merger Sub, Inc., Twill, Inc. and Bilal Khan solely in his capacity as holders' representative (incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 21, 2024).
10.30	Lock Up/Leak Out Agreement dated February 15, 2024, by and among DarioHealth Corp., Titan Trust 2024 I, a Delaware statutory trust, and WhiteHawk Capital Partners LP, a Delaware limited partnership (incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 21, 2024).

10.31	Series C Securities Purchase Agreement (incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 21, 2024).
10.32	Amendment No. 1 to Placement Agency Agreement dated January 31, 2024 (incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 21, 2024).
10.33	First Amendment to Loan and Security Agreement and Supplement, dated February 15, 2024, by and among DarioHealth Corp., PsyInnovations, Inc., LabStyle Innovation Ltd., Avenue Venture Opportunities Fund II, L.P. and Avenue Venture Opportunities Fund, L.P. (incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 21, 2024).
10.34*+	Personal Employment Agreement, dated February 16, 2024, between DarioHealth Corp. and Tomer Ben-Kiki
10.35*+	Personal Employment Agreement, dated February 16, 2024, between LabStyle Innovation Ltd. and Tomer Ben-Kiki
21.1*	List of Subsidiaries of the Company
23.1*	Consent of Kost Forer Gabbay and Kaiserer
31.1*	Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934.
31.2*	Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934.
32.1**	Certification of the Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. 1350.
97.1*	Clawback Policy.
101*	The following financial statements from the Company's annual report on Form 10-K for the year ended December 31, 2023, formatted in Inline XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Comprehensive Loss, (iii) Statements of Changes in Stockholders' Equity, (iv) Consolidated Statements of Cash Flows and (v) the Notes to Consolidated Financial Statements, tagged as blocks of text and in detail.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

\+ Management contract or compensatory plan or arrangement
* Filed herewith
** Furnished herewith

^ Certain identified information in the exhibit has been excluded from the exhibit because it is both (i) not material and (ii) would likely cause competitive harm to DarioHealth Corp. if publicly disclosed

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, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 28, 2024

DARIOHEALTH CORP.

By: /s/ Erez Raphael
Name: Erez Raphael
Title: Chief Executive Officer

By: /s/ Zvi Ben David
Name: Zvi Ben David
Title: Chief Financial Officer, Secretary and Treasurer

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

Person	Capacity	Date
/s/ Erez Raphael Erez Raphael	Chief Executive Officer and Director (Principal Executive Officer)	March 28, 2024
/s/ Zvi Ben David Zvi Ben David	Chief Financial Officer, Secretary and Treasurer (Principal Financial and Accounting Officer)	March 28, 2024
/s/ Yoav Shaked Yoav Shaked	Chairman of the Board	March 28, 2024
/s/ Dennis Matheis Dennis Matheis	Director	March 28, 2024
/s/ Hila Karah Hila Karah	Director	March 28, 2024
/s/ Dennis M. McGrath Dennis M. McGrath	Director	March 28, 2024
/s/ Jon Kaplan Jon Kaplan	Director	March 28, 2024
/s/ Adam Stern Adam Stern	Director	March 28, 2024

DARIOHEALTH CORP. AND ITS SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

AS OF DECEMBER 31, 2023

INDEX

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of

DARIOHEALTH CORP.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of DarioHealth Corp. and its subsidiaries (the Company) as of December 31, 2023 and 2022, the related consolidated statements of comprehensive loss, changes in stockholders' equity and cash flows for each of the two years in the period ended December 31, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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 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 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 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 financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (i) relate to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

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Revenue Recognition

Description of the Matter

As described in Note 2 and Note 6 to the consolidated financial statements, a significant portion of the Company's revenue is derived from agreements with enterprise business market groups to provide a mobile and web-based digital therapeutics health management programs, data license and related development and implementation services. The Company contracts with customers often include promises to transfer multiple promises to provide goods and services, which are accounted for separately if they are distinct performance obligations. In such contracts, the transaction price is then allocated to the distinct performance obligations on a relative standalone selling price basis and revenue is recognized when control of the distinct performance obligation is transferred.

The accounting for contracts with multiple promises requires the company to exercise significant judgment in determining revenue recognition for these contracts and includes: (a) identification and determination of whether products and services are considered distinct performance obligations that should be accounted for separately based on the terms and conditions of the relevant agreements, (b) determination of stand-alone selling prices for each distinct performance obligation that are not sold separately. (c) the pattern of transferring control (i.e., timing of when revenue is recognized) for each distinct performance obligation.
Given these factors, the related audit effort in evaluating management's judgments in determining revenue recognition for these customer contracts was extensive and required a high degree of auditor judgment.

How We Addressed the Matter in Our Audit

For a sample of customers, we: (1) obtained and read contract source documents, including master agreements, and other documents that were part of the agreement and evaluating management's identification of the contract and the distinct performance obligations based on the terms of the arrangements and the company's accounting policies, (2) tested management's identification of significant terms for completeness, including the identification and determination of distinct performance obligations, (3) evaluating the methodology and reasonableness of management's assumptions used for the estimate of stand-alone selling prices on a sample basis for products and services that are not sold separately (4) tested management's calculations of revenue and the associated timing of revenue recognition. In addition, We have also evaluated the Company's disclosures in relation to this matter.

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Going concern assessment

Description of the Matter

As discussed in Note 1 to the consolidated financial statements, the Company has incurred operating losses and negative cash-flow from operations since inception. The Company's operations are dependent on its ability to raise additional funds. This dependency will continue until the Company will be able to completely finance its operations by generating revenue from its products and services. Management has concluded that, based on its current projections and plans, the Company will be able to satisfy its liquidity requirements for at least one year from the date these financial statements were issued.

We identified the assessment of liquidity and the Company's ability to continue as a going concern as a critical audit matter due to the subjective judgments required of management to conclude the Company would have sufficient liquidity to sustain itself for at least a year beyond the date of the issuance of the consolidated financial statements. This in turn led to a high degree of auditor subjectivity and judgment to evaluate the audit evidence supporting the liquidity conclusions.

How We Addressed the Matter in Our Audit

In addressing the matter, our audit procedures included, among others, assessing the reasonableness of forecasted revenue, operating expenses and sources of cash used in management's assessment to determine whether the company has sufficient liquidity to fund operations for at least one year from the consolidated financial statement issuance date. This testing included inquiries with management, comparison of prior period forecasts to actual results and consideration of positive and negative evidence impacting management's forecasts and liquidity. We also performed sensitivity analyses to assess the impact of changes in the key assumptions included in management's liquidity forecast models. In addition, we assessed the adequacy of the company's going concern disclosures included in note 1 to the consolidated financial statements.

/s/ KOST FORER GABBAY & KASIERER
A Member of Ernst & Young Global

We have served as the Company's auditor since 2012.
Tel-Aviv, Israel
March 28, 2024

DARIOHEALTH CORP. AND ITS SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS
U.S. dollars in thousands

	December 31,	
	2023	2022
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 36,797	$ 49,357
Short-term restricted bank deposits	292	165
Trade receivables, net	3,155	6,416
Inventories	5,062	7,956
Other accounts receivable and prepaid expenses	2,024	1,630
Total current assets	47,330	65,524
NON-CURRENT ASSETS:		
Deposits	6	6
Operating lease right of use assets	967	1,206
Long-term assets	143	111
Property and equipment, net	899	788
Intangible assets, net	5,404	9,916
Goodwill	41,640	41,640
Total non-current assets	49,059	53,667
Total assets	$ 96,389	$ 119,191

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

DARIOHEALTH CORP. AND ITS SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS
U.S. dollars in thousands (except stock and stock data)

	December 31,	
	2023	2022
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 1,131	$ 2,322
Deferred revenues	997	1,320
Operating lease liabilities	111	293
Other accounts payable and accrued expenses	6,300	6,592
Current maturity of long term loan	3,954	8,823
Total current liabilities	12,493	19,350
NON-CURRENT LIABILITIES		
Operating lease liabilities	885	827
Long-term loan	24,591	18,105
Warrant liability	240	910
Other long-term liabilities	36	—
Total non-current liabilities	25,752	19,842
STOCKHOLDERS' EQUITY		
Common stock of $0.0001 par value - authorized: 160,000,000 shares; issued and outstanding: 27,191,849 and 25,724,470 shares on December 31, 2023 and December 31, 2022, respectively	3	3
Preferred stock of $0.0001 par value - authorized: 5,000,000 shares; issued and outstanding: 18,959 and 3,567 shares on December 31, 2023 and December 31, 2022, respectively	*) -	*) -
Additional paid-in capital	407,502	365,846
Accumulated deficit	(349,361)	(285,850)
Total stockholders' equity	58,144	79,999
Total liabilities and stockholders' equity	$ 96,389	$ 119,191

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

*) Represents an amount lower than $1.

DARIOHEALTH CORP. AND ITS SUBSIDIARIES

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
U.S. dollars in thousands (except stock and stock data)

	Year ended December 31,	
	2023	2022
Revenues:		
Services	$ 13,084	$ 17,859
Consumer hardware	7,268	9,797
Total revenues	20,352	27,656
Cost of revenues:		
Services	4,679	5,324
Consumer hardware	5,303	8,320
Amortization of acquired intangible assets	4,386	4,357
Total cost of revenues	14,368	18,001
Gross profit	5,984	9,655
Operating expenses:		
Research and development	$ 20,248	$ 19,649
Sales and marketing	23,785	30,323
General and administrative	18,140	16,493
Total operating expenses	62,173	66,465
Operating loss	56,189	56,810
Total financial expenses, net	3,174	5,379
Loss before taxes	59,363	62,189
Income Tax	64	4
Net loss	$ 59,427	$ 62,193
Deemed dividend	$ 4,084	$ 1,643
Net loss attributable to shareholders	$ 63,511	$ 63,836
Net loss per share:		
Basic and diluted loss per share of common stock	$ 1.93	$ 2.54
Weighted average number of common stock used in computing basic and diluted net loss per share	28,371,979	23,635,038

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

DARIOHEALTH CORP. AND ITS SUBSIDIARIES

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
U.S. dollars in thousands (except stock and stock data)

	Common Stock		Preferred Stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Number	Amount	Number	Amount			
Balance as of January 1, 2022	16,573,420	$ 2	11,927	$ *) -	$307,561	$ (222,014)	$ 85,549
Exercise of warrants	81,221	*) -	—	—	—	—	—
Issuance of common stock to consultants and service provider	62,926	*) -	—	—	377	—	377
Issuance of common stock to directors and employees	29,755	*) -	—	—	190	—	190
Deemed dividend related to issuance of Preferred Stock	—	—	—	—	1,643	(1,643)	—
Conversion of preferred stock to common stock	2,778,450	*) -	(8,360)	*) -	—	—	*) -
Issuance of warrants to service providers	—	—	—	—	3,105	—	3,105
Issuance of common stock, net of issuance cost	4,747,761	1	—	—	38,287	—	38,288
Issuance of Common Stock, net of issuance cost upon Acquisitions	378,492	*) -	—	—	1,186	—	1,186
Earnout resolution	—				328		328
Repurchase and retirement of common stock	(58,657)				(134)		(134)
Stock-based compensation	1,131,102	—	—	—	13,303	—	13,303
Net loss	—	—	—	—	—	(62,193)	(62,193)
Balance as of December 31, 2022	25,724,470	$ 3	3,567	$ *) -	$365,846	$ (285,850)	$ 79,999
Exercise of Options	4,800	*) -	—	—	—	—	—
Exercise of warrants	86,983	*) -	—	—	—	—	—
Extinguishment of preferred stock in connection with preferred stock modification	—		—		984	(984)	
Deemed dividend related to Preferred Stock	—	—	—	—	3,100	(3,100)	—
Conversion of preferred stock to common stock	3,582	*) -	(10)	*) -	—	—	*) -
Issuance of warrants to service providers	—	—	—	—	3,516	—	3,516
Issuance of common and preferred stock, net of issuance cost	408,043	—	15,402	—	16,482	—	16,482
Issuance of warrants related to loan agreement, net of issuance cost	—	—	—	—	1,389	—	1,389
Common stock related to earnout consideration	76,637	*) -	—	—	—	—	—
Stock-based compensation	887,334	*) -	—	—	16,185	—	16,185
Net loss	—	—	—	—	—	(59,427)	(59,427)
Balance as of December 31, 2023	27,191,849	$ 3	18,959	$ *) -	$407,502	$ (349,361)	$ 58,144

*) Represents an amount lower than $1.

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

DARIOHEALTH CORP. AND ITS SUBSIDIARIES

CONSOLIDATED STATEMENT OF CASH FLOWS
U.S. dollars in thousands

	Year ended December 31,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (59,427)	$ (62,193)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Stock-based compensation, common stock, and payment in stock to directors, employees, consultants, and service providers	19,701	16,975
Depreciation	473	356
Change in operating lease right of use assets	239	(919)
Amortization of acquired intangible assets	4,512	4,361
Decrease (increase) in trade receivables	3,261	(5,106)
Increase in other accounts receivable, prepaid expense and long-term assets	(426)	(3)
Decrease (increase) in inventories	2,894	(1,728)
Decrease in trade payables	(1,191)	(2,787)
Decrease in other accounts payable and accrued expenses	(256)	(1,314)
Increase (Decrease) in deferred revenues	(323)	125
Change in operating lease liabilities	(124)	833
Remeasurement of earn-out	-	(497)
Non cash financial expenses	528	4,052
Other	(240)	—
Net cash used in operating activities	(30,379)	(47,845)
Cash flows from investing activities:		
Purchase of property and equipment	(584)	(442)
Purchase of short-term investments	(4,996)	-
Proceeds from redemption of short-term investments	5,033	-
Purchase of intangible assets	-	(131)
Net cash used in investing activities	(547)	(573)
Cash flows from financing activities:		
Proceeds from issuance of common stock and prefunded warrants, net of issuance costs	1,614	38,288
Proceeds from issuance of preferred stock, net of issuance costs	14,868	-
Proceeds from borrowings on Loan agreement	29,604	23,786
Repayment of long-term loan	(27,833)	—
Repurchase and retirement of common stock	—	(134)
Net cash provided by financing activities	18,253	61,940
Increase in cash, cash equivalents and restricted cash and cash equivalents	(12,673)	13,522
Cash, cash equivalents and restricted cash and cash equivalents at beginning of period	49,470	35,948
Cash, cash equivalents and restricted cash and cash equivalents at end of period	36,797	49,470
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest on long-term loan	4,031	1,876
Non-cash activities:		
Right-of-use assets obtained in exchange for lease liabilities	136	1,269
Earn-out extinguishment as part of WayForward acquisition	-	328

DARIOHEALTH CORP. AND ITS SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
U.S. dollars in thousands

NOTE 1:- GENERAL

a. DarioHealth Corp. (the "Company" or "DarioHealth") was incorporated in the State of Delaware and commenced operations on August 11, 2011.

DarioHealth is a global digital therapeutics (DTx) company delivering personalized evidence-based interventions that are driven by precision data analytics, software, and personalized coaching, DarioHealth has developed an approach with the intent to empower individuals to adjust their lifestyle in holistic way.

DarioHealth's cross-functional team operates at the intersection of life sciences, behavioral science, and software technology to deliver seamlessly integrated and highly engaging digital therapeutics interventions. Our platform and suite of solutions deliver personalized and dynamic interventions driven by data analytics and one-on-one coaching for diabetes, hypertension, weight management, musculoskeletal pain, and behavioral health.

DarioHealth's digital therapeutic platform has been designed with a 'user-first' strategy, focusing on the user's needs first and foremost, and user experience and satisfaction. User satisfaction is constantly measured and drives, all company processes, including our technology design.

The Company has one reporting unit and one operating segment.

b. The Company has a wholly owned subsidiary, LabStyle Innovation Ltd. ("LabStyle"), which was incorporated and commenced operations on September 14, 2011, in Israel. Its principal business activity is to hold the Company's intellectual property and to perform research and development, manufacturing, marketing, and other business activities.

c. The Company has incurred net losses since its inception. As of December 31, 2023, The Company has incurred recurring losses and negative cash flows since inception and has an accumulated deficit of $349,361 as of December 31, 2023. For the year ended December 31, 2023, the Company used approximately $30,379 of cash in operations. Management believes the Company has sufficient funds to support its operation for at least a period of twelve months from the date of the issuance of these consolidated financial statements. The Company expect to incur future net losses and our transition to profitability is dependent upon, among other things, the successful development and commercialization of the Company's products and the achievement of a level of revenues adequate to support the cost structure. Until the Company achieves profitability or generates positive cash flows, it will continue to be dependent on raising additional funds. The Company intends to fund its future operations through cash on hand, additional private and/or public offerings of debt or equity securities or a combination of the foregoing. There are no assurances, however, that the Company will be able to obtain an adequate level of financial resources that are required for the long-term development and commercialization of its product offerings.

d. The Company's Common Stock is listed on the Nasdaq Capital Market under the symbol "DRIO".

DARIOHEALTH CORP. AND ITS SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
U.S. dollars in thousands

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES

The consolidated financial statements are prepared according to United States generally accepted accounting principles ("U.S. GAAP").

a. Use of estimates:

The preparation of the consolidated financial statements and related disclosures in conformity with U.S. GAAP requires the Company's management to make judgments, assumptions and estimates that affect the amounts reported in its consolidated financial statements and accompanying notes. Management bases its estimates on historical experience and on various other assumptions it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Actual results may differ from these estimates, and such differences may be material.

These estimates, judgments and assumptions can affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the dates of the financial statements including other accounts receivable and prepaid expenses and other accounts payable and accrued expenses, and the reported amounts of revenue, cost of revenues and operational expenses during the reporting period. Actual results could differ from those estimates.

b. Financial statements in U.S. dollars ("$," "dollar" or "dollars"):

The functional currency of the Company and its subsidiaries is the U.S dollar.

The Company's revenues and financing activities are incurred in U.S. dollars. Although a portion of LabStyle expenses is denominated in New Israeli Shekels ("NIS") (mainly cost of personnel), a substantial portion of its expenses is denominated in dollars. Accordingly, the Company's management believes that the currency of the primary economic environment in which the Company and its subsidiaries operate is the dollar; thus, the dollar is the functional currency of the Company. Transactions and balances denominated in dollars are presented at their original amounts. Monetary accounts denominated in currencies other than the dollar are re-measured into dollars in accordance with ASC 830, "Foreign Currency Matters". All transaction gains and losses of the re-measurement of monetary balance sheet items are reflected in the consolidated statements of comprehensive loss as financial income or expenses, as appropriate.

c. Principles of consolidation:

The consolidated financial statements include the accounts of the Company and its subsidiaries. Intercompany accounts and transactions have been eliminated upon consolidation.

d. Segment information:

Operating segments are defined as components of an enterprise about which separate financial information is evaluated regularly by the chief operating decision maker in deciding how to allocate resources and assessing performance. The Company defines the term "chief operating decision maker" to be its Chief Executive Officer. The Company's Chief Executive Officer reviews the financial information presented on consolidated basis for purposes of allocating resources and evaluating its financial performance. Accordingly, the Company has determined that it operates as a single reportable segment.

e. Cash and cash equivalents:

The Company considers all highly liquid investments, which are readily convertible to cash with a maturity of three months or less at the date of acquisition, to be cash equivalents.

U.S. dollars in thousands

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

f. Short-term restricted bank deposits:

Short-term restricted bank deposits are restricted deposits with maturities of up to one year and are pledged in favor of the bank as a security for the bank guaranties issued to the landlords of the Company's offices and credit card payments. The short-term restricted bank deposits are denominated in NIS and USD and bear interest at an average rate of 5.2% and 0.61% as of December 31, 2023 and 2022, respectively. The short-term restricted bank deposits are presented at their cost, including accrued interest.

As of December 31, 2023, and 2022, the Company had a short-term restricted bank deposit which are used as collateral for rent and gratuity in the amount of $229 and $113, respectively.

As of December 31, 2023, and 2022, the Company had short-term restricted bank deposits which are used as collateral for credit payments in amounts of $63 and $52, respectively.

The following table provides a reconciliation of the cash balances reported on the balance sheets and the cash, cash equivalents and short-term restricted bank deposits balances reported in the statements of cash flows:

	December 31,	
	2023	2022
Cash, and cash equivalents as reported on the balance sheets	$ 36,797	$ 49,357
Short-term restricted bank deposits	$ —	$ 113
Cash, restricted cash, cash equivalents, and restricted cash and cash equivalents as reported in the statements of cash flows	$ 36,797	$ 49,470

g. Trade receivables, net:

The Company records trade receivables for amounts invoiced and yet unbilled invoices. The Company's expected loss allowance methodology for trade receivables is based upon its assessment of various factors, including historical experience, the age of the trade receivable balances, credit quality of its customers, current economic conditions, reasonable and supportable forecasts of future economic conditions, and other factors that may affect its ability to collect from customers. The estimated credit loss allowance is recorded as general and administrative expenses on the Company's Consolidated Statements of Comprehensive Loss. As of December 31, 2023, and 2022, credit loss allowance was immaterial.

h.Inventories:

Inventories are stated at the lower of cost or net realized value. Cost is determined on a first in first out ("FIFO") basis. Inventory write-downs are provided to cover technological obsolescence, excess inventories and discontinued products. Inventory write-downs represent the difference between the cost of the inventory and net realizable value. Inventory write-downs are charged to the cost of revenues when a new lower cost basis is established. Subsequent changes in facts and circumstances do not result in the restoration or increase in that newly established cost basis.

Work-in-process is immaterial, given the typically short manufacturing cycle, and therefore is disclosed in conjunction with raw materials.

Total write-downs during the years ended December 31, 2023, and 2022 amounted to $121 and $88, respectively.

DARIOHEALTH CORP. AND ITS SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
U.S. dollars in thousands

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

i. Property and equipment:

Property and equipment are stated at cost, net of accumulated depreciation. Depreciation is calculated using the straight-line method over the estimated useful lives of the assets at the following annual rates:

	%
Computers, and peripheral equipment	15-33
Office furniture and equipment	6-15
Production lines	14-20
Leasehold improvements	Over the shorter of the lease term or useful economic life

j. Impairment of long-lived assets:

The Company's long-lived assets are reviewed for impairment in accordance with ASC 360, "Property, Plant and Equipment," whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted cash flows expected to be generated by the assets. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. For the years ended December 31, 2023, and 2022, no impairment was recorded.

k. Revenue recognition

The Company recognizes revenue in accordance with ASC 606, "Revenue from contracts with customers," when (or as) it satisfies performance obligations by transferring promised products or services to its customers in an amount that reflects the consideration the Company expects to receive. The Company applies the following five steps: (1) identify the contract with a customer, (2) identify the performance obligations in the contract, (3) determine the transaction price, (4) allocate the transaction price to the performance obligations in the contract, and (5) recognize revenue when a performance obligation is satisfied.

The Company applied the practical expedient in ASC 606 and did not evaluate payment terms of one year or less for the existence of a significant financing component.

If the contract contains a single performance obligation, the entire transaction price is allocated to the single performance obligation. For contracts that contain multiple performance obligations, the Company allocates the transaction price to each performance obligation based on the relative standalone selling price ("SSP") for each performance obligation. The Company uses judgment in determining the SSP for its hardware and services. To determine SSP, the Company maximizes the use of observable standalone sales and observable data, where available. In instances where performance obligations do not have observable standalone sales, the Company may use alternative methods to estimate the standalone selling price, such as cost plus margin approach.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

Consumers revenue

The Company considers customer and distributor purchase orders to be contracts with a customer. For each contract, the Company considers the promise to transfer tangible products and/or services, each of which are distinct, to be the identified performance obligations. In determining the transaction price, the Company evaluates whether the price is subject to rebates and adjustments to determine the net consideration to which the Company expects to receive. Revenue from tangible products is recognized when control of the product is transferred to the customer (i.e., when the Company's performance obligation is satisfied), which typically occurs at shipment. The revenues from fixed-price services are recognized ratably over the contract period.

Commercial revenue – B2B2C

The Company provides mobile and web-based digital therapeutics health management programs to employers and health plans for their employees or covered individuals. Such programs include among others, content, automated journeys, hardware, and lifestyle coaching, currently supporting diabetes, prediabetes and obesity, hypertension, behavioral health (BH) and musculoskeletal health (MSK). At contract inception, the Company assesses the type of services being provided and assesses the performance obligations in the contract. These solutions integrate access to the Company's web-based platform, and clinical and data services to provide an overall health management solution. The promises to transfer these goods and services are not separately identifiable and is considered a single continuous service comprised of a series of distinct services that are substantially the same and have the same pattern of transfer (i.e., distinct days of service). These services are consumed as they are received, and the Company recognizes revenue each month using the variable consideration allocation exception. Revenue is recognized either on a per engaged member per month (PEMPM) or a per employee per month (PEPM) basis.

Certain of the Company's contracts include client performance guarantees and a portion of the fees in those contracts are subject to performance-based metrics such as clinical outcomes or minimum member utilization rates. The Company includes in the transaction price some or all of an amount of variable consideration only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved. Refunds to a customer that result from performance levels that were not met by the end of the measurement period are adjusted to the transaction price, and therefore estimated at the outset of the arrangement.

Commercial revenue - Strategic partnerships

The Company has also entered into contracts (Note 6) with a preferred partner and a health plan provider in which the Company provides data license, development and implementation services.

l. Cost of revenues:

Cost of revenues is comprised of the cost of production, data center costs, shipping and handling inventory, hosting services, personnel and related overhead costs, depreciation of production line and related equipment costs, amortization of costs to fulfill a contract and inventory write-downs.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

m. Concentrations of credit risk:

Financial instruments that potentially subject the Company to credit risk primarily consist of cash and cash equivalents, short-term deposits, restricted deposits, and trade receivables. For cash and cash equivalents, the Company is exposed to credit risks in the event of default by the financial institutions to the extent that amounts recorded on the accompanying consolidated balance sheets exceed federally insured limits. The Company places its cash and cash equivalents and short-term deposits with financial institutions with high-quality credit ratings and has not experienced any losses in such accounts.

For trade receivables, the Company is exposed to credit risk in the event of non-payment by customers to the extent of the amounts recorded on the accompanying consolidated balance sheets.

As of December 31, 2023, the Company's major customer accounted for 66.5% of the Company's accounts receivable balance.

For the year ended December 31, 2023 and December 31, 2022, the Company's major customer accounted for 29.9% and 39.8%, respectively, of the Company's revenue in the period.

n. Income taxes:

The Company accounts for income taxes in accordance with ASC 740, “Income Taxes” (“ASC 740”). This guidance prescribes the use of the liability method whereby deferred tax asset and liability account balances are determined based on differences between financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company provides a valuation allowance, if necessary, to reduce deferred tax assets to amounts that are more likely than not to be realized.

ASC 740 contains a two-step approach to recognizing and measuring a liability for uncertain tax positions. The first step is to evaluate the tax position taken or expected to be taken in a tax return by determining if the weight of available evidence indicates that it is more likely than not that, on an evaluation of the technical merits, the tax position will be sustained on audit, including resolution of any related appeals or litigation processes. The second step is to measure the tax benefit as the largest amount that is more than 50% likely to be realized upon ultimate

settlement. As of December 31, 2023, and 2022, no liability for unrecognized tax benefits was recorded.

o. Research and development costs:

Research and development costs are charged to the consolidated statements of comprehensive loss, as incurred.

DARIOHEALTH CORP. AND ITS SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
U.S. dollars in thousands

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

p. Accounting for stock-based compensation:

The Company accounts for stock-based compensation in accordance with ASC 718, "Compensation - Stock Compensation" ("ASC 718"), which requires companies to estimate the fair value of equity-based payment awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as an expense over the requisite service periods in the Company's consolidated statement of comprehensive loss.

The Company recognizes compensation expenses for the value of its awards granted based on the straight-line method over the requisite service period of each of the awards, net of estimated forfeitures. ASC 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

The Company estimates the fair value of stock options granted using the Black-Scholes-Merton option-pricing model. The option-pricing model requires a number of assumptions, of which the most significant are the expected stock price volatility and the expected option term. Expected volatility was calculated based upon historical volatility of the Company. The expected option term represents the period that the Company's stock options are expected to be outstanding and is determined based on the simplified method until sufficient historical exercise data will support using expected life assumptions. The risk-free interest rate is based on the yield from U.S. treasury bonds with an equivalent term. The Company has historically not paid dividends and has no foreseeable plans to pay dividends.

q. Fair value of financial instruments:

The Company applies ASC 820, "Fair Value Measurements and Disclosures" ("ASC 820"). Under this standard, fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (i.e., the "exit price") in an orderly transaction between market participants at the measurement date.

In determining fair value, the Company uses various valuation approaches. ASC 820 establishes a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability developed based on market data obtained from sources independent from the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the assumptions market participants would use in pricing the asset or liability developed based on the best information available in the circumstances.

The hierarchy is broken down into three levels based on the inputs as follows:

Level 1 - Valuations based on quoted prices in active markets for identical assets that the Company has the ability to access. Valuation adjustments and block discounts are not applied to Level 1 instruments. Since valuations are based on quoted prices that are readily and regularly available in an active market, valuation of these products does not entail a significant degree of judgment.

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

Level 3 - Valuations based on inputs that are unobservable and significant to the overall fair value measurement.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

The availability of observable inputs can vary from instrument to instrument and is affected by a wide variety of factors, including, for example, the type of investment, the liquidity of markets and other characteristics particular to the transaction. To the extent that valuation is based on models or inputs that are unobservable in the market, the determination of fair value requires more judgment, and the fair value are categorized as Level 3.

The carrying amounts of cash and cash equivalents, short-term restricted bank deposits, trade receivables, other accounts receivable and prepaid expenses, trade payables and other accounts payable and accrued expenses approximate their fair value due to the short-term maturity of such instruments. The Company's Loan Facility, and warrants liability were measured at fair value using Level 3 unobservable inputs (see note 8).

r. Warrants:

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance. The assessment considers whether the warrants are freestanding financial instruments, meet the definition of a liability under ASC 480, and meet all of the requirements for equity classification, including whether the warrants are indexed to the Company's own common stock and whether the warrant holders could potentially require "net cash settlement" in a circumstance outside of the Company's control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent reporting period end date while the warrants are outstanding. Warrants that meet all the criteria for equity classification, are required to be recorded as a component of additional paid-in capital. Warrants that do not meet all the criteria for equity classification, are required to be recorded as liabilities at their initial fair value on the date of issuance and remeasured to fair value at each balance sheet date thereafter. The liability-classified warrants are recorded under non-current liabilities. Changes in the estimated fair value of the warrants are recognized in "Financial expenses, net" in the consolidated statements of operations.

s. Basic and diluted net loss per share:

The Company computes net loss per share using the two-class method required for participating securities. The two-class method requires income available to common stockholders for the period to be allocated between shares of Common Stock and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed. The Company's Convertible Preferred shares would be entitled to dividends that would be distributed to the holders of Common Stock, based on the conversion ratio, assuming conversion of all Convertible Preferred shares into shares of Common Stock.

The Company's basic net loss per share is calculated by dividing net loss attributable to common and preferred stockholders by the weighted-average number of shares, without consideration of potentially dilutive securities. The diluted net loss per share is calculated by giving effect to all potentially dilutive securities outstanding for the period using the treasury share method or the if-converted method based on the nature of such securities. Diluted net loss per share is the same as basic net loss per share in periods when the effects of potentially dilutive shares of Common Stock are anti-dilutive.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

t. Severance pay:

Since inception date, all Ltd. employees who are entitled to receive severance pay in accordance with the applicable law in Israel, have been included under section 14 of the Israeli Severance Compensation Law ("Section 14"). Under this section, they are entitled only to monthly deposits, at a rate of 8.33% of their monthly salary, made by the employer on their behalf with insurance companies. Payments in accordance with Section 14 release Ltd. from any future severance payments in respect of those employees. Payments under Section 14 are not recorded as an asset in the Company's balance sheet.

Severance pay expense for the year ended December 31, 2023 and 2022 amounted to $947 and $1,136, respectively.

The Company has a 401(k) defined contribution plan covering certain employees in the U.S. All eligible employees may elect to contribute up to $22.5 per year (for certain employees over 50 years of age the maximum contribution is $30 per year), of their annual compensation to the plan through salary deferrals, subject to Internal Revenue Service limits.

u. Legal and other contingencies:

The Company accounts for its contingent liabilities in accordance with ASC 450 "Contingencies". A provision is recorded when it is both probable that a liability has been incurred and the amount of the loss can be reasonably estimated. With respect to legal matters, provisions are reviewed and adjusted to reflect the impact of negotiations, estimated settlements, legal rulings, advice of legal counsel and other information and events pertaining to a particular matter. As of December 31, 2023, and 2022, the Company is not a party to any litigation that could have a material adverse effect on the Company's business, financial position, results of operations or cash flows. Legal costs incurred in connection with loss contingencies are expensed as incurred.

v. Leases:

Lessee accounting:

The Company determines if an arrangement is a lease and the classification of that lease at inception based on: (1) whether the contract involves the use of a distinct identified asset, (2) whether the Company obtains the right to substantially all the economic benefits from the use of the asset throughout the period, and (3) whether the Company has a right to direct the use of the asset. The Company elected to not recognize a lease liability or right-of-use ("ROU") asset for leases with a term of twelve months or less. The Company also elected the practical expedient to not separate lease and non-lease components for its leases.

ROU assets represent the right to use an underlying asset for the lease term and lease liabilities represent the obligation to make lease payments arising from the lease. ROU assets are initially measured at amounts, which represents the discounted present value of the lease payments over the lease, plus any initial direct costs incurred. The ROU assets are reviewed for impairment. The lease liability is initially measured at lease commencement date based on the discounted present value of the lease payments over the lease term. The implicit rate within the operating leases is generally not determinable; therefore, the Company uses the Incremental Borrowing Rate ("IBR") based on the information available at commencement date in determining the present value of lease payments. The Company's IBR is estimated to approximate the interest rate on similar terms and payments and in economic environments where the leased asset is located.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

Certain leases include options to extend or terminate the lease. An option to extend the lease is considered in connection with determining the ROU asset and lease liability when it is reasonably certain that the Company will exercise that option. An option to terminate is considered unless it is reasonably certain that the Company will not exercise the option. See also Note 9.

w. Business combination and asset acquisitions:

The Company applies the provisions of ASC 805, "Business Combination" and allocates the fair value of purchase consideration to the tangible assets acquired, liabilities assumed, and intangible assets acquired based on their estimated fair values. The excess of the fair value of purchase consideration over the fair values of these identifiable assets and liabilities is recorded as goodwill. When determining the fair values of assets acquired and liabilities assumed, management makes significant estimates and assumptions, especially with respect to intangible assets.

Acquisition-related expenses are recognized separately from the business combination and are expensed as incurred.

The Company accounts for a transaction as an asset acquisition when substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets, or otherwise does not meet the definition of a business. Asset acquisition-related direct costs are capitalized as part of the asset or assets acquired.

x. Goodwill:

Goodwill represents the excess of the purchase price in a business combination over the fair value of the net tangible and intangible assets acquired. Under ASC 350, "Intangible - Goodwill and Other" ("ASC 350"), goodwill is not amortized, but rather is subject to an annual impairment test.

ASC 350 allows an entity to first assess qualitative factors to determine whether it is necessary to perform the quantitative goodwill impairment test. If the qualitative assessment does not result in a more likely than not indication of impairment, no further impairment testing is required. If the Company elects not to use this option, or if the Company determines that it is more likely than not that the fair value of a reporting unit is less than its carrying value, then the Company prepares a quantitative analysis to determine whether the carrying value of a reporting unit exceeds its estimated fair value. If the carrying value of a reporting unit would exceed its estimated fair value, the Company would have recognized an impairment of goodwill for the amount of this excess.

For the years ended December 31, 2023 and 2022, no impairment of goodwill has been recorded.

DARIOHEALTH CORP. AND ITS SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
U.S. dollars in thousands

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

y. Recently Adopted Accounting Pronouncements

(i) In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2016-13, Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments ("ASU 2016-13"). ASU 2016-13 amends the impairment model to utilize an expected loss methodology in place of the currently used incurred loss methodology, which will result in the timelier recognition of losses, with an effective date for the first quarter of fiscal year 2020. In November 2019, the FASB issued ASU No. 2019-10 which delayed the effective date of ASU 2016-13 for smaller reporting companies (as defined by the SEC) and other non- Securities and Exchange Commission ("SEC") reporting entities to fiscal years beginning after December 15, 2022, including interim periods within those fiscal periods. The Company adopted the standard effective as of January 1, 2023, and the adoption of this standard did not have material impact on the Company's consolidated financial statements.

(ii) In August 2020, the FASB issued 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)" ("ASC470-20"). The new standard reduces the number of accounting models in ASC 470-20 that require separate accounting for non-bifurcated embedded conversion features. As a result, convertible instruments will no longer be subject to the cash conversion features model or to the beneficial conversion features model and be accounted for as a single unit of account as long as no other features require bifurcation and recognition as derivatives, The Company adopted ASU 2020-06, effective January 1, 2023, using the modified retrospective method. The prior period consolidated financial statements have not been retrospectively adjusted and continue to be reported under the accounting standards in effect for those periods. The adoption of this standard did not have a material impact on the Company's consolidated financial statements.

(iii) In October 2021, the FASB issued ASU 2021-08, which requires companies to apply ASC 606 to recognize and measure contract assets and contract liabilities from contracts with customers acquired in a business combination. This creates an exception to the general recognition and measurement principle in ASC 805. requires companies to apply ASC 606 to recognize and measure contract assets and contract liabilities from contracts with customers acquired in a business combination. For the Company, the guidance is effective for fiscal years beginning after 15 December 2022 and interim periods within those fiscal years. The Company completed its evaluation of ASU 2021-08, which we adopted on January 1, 2023. The adoption of ASU 2021-08 did not have a material impact on the Company's consolidated financial statements and related disclosures.

z. Recently issued accounting pronouncements, not yet adopted:

(i) In November 2023, the FASB issued ASU 2023-07, Segment Reporting (Topic 280), Improvements to Reportable Segment Disclosures, which expands annual and interim disclosure requirements for reportable segments, primarily through enhanced disclosures about significant segment expenses. In addition, it provides new segment disclosure requirements for entities with a single reportable segment. The guidance will be effective for the Company for annual periods beginning January 1, 2024 and for interim periods beginning January 1, 2025. Early adoption is permitted. The Company is currently evaluating the impact on its financial statement disclosures.

(ii) In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740), Improvements to Income Tax Disclosures, which requires disaggregated information about the effective tax rate reconciliation as well as information on income taxes paid. The guidance will be effective for the Company for annual periods beginning January 1, 2025, with early adoption permitted. The Company is currently evaluating the impact on its financial statement disclosures.

DARIOHEALTH CORP. AND ITS SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
U.S. dollars in thousands

NOTE 3:- OTHER ACCOUNTS RECEIVABLE AND PREPAID EXPENSES

	December 31,	
	2023	2022
Prepaid expenses	$ 1,536	$ 908
Costs to fulfill a contract	238	483
Government authorities	250	239
	$ 2,024	$ 1,630

NOTE 4:- ACQUISITIONS

Technology Purchase of Physimax Technologies Ltd.

On March 31, 2022 (the "Acquisition Date"), the Company completed the acquisition, through its subsidiary LabStyle, of a technology from Physimax Technologies Ltd ("Physimax Technology"). The Company considered this transaction as an asset acquisition.

The consideration transferred included the issuance of 256,660 shares of its common stock subjected to certain terms of lock-up periods valued at $1,186, a cash payment of $500, of which $400 was paid during the fourth quarter of 2021, and the remaining during the second quarter of 2022, The total consideration transferred in the acquisition of Physimax Technology was $1,686. In addition, the Company incurred acquisition-related costs in an amount of $131.

U.S. dollars in thousands

NOTE 4:- ACQUISITIONS (Cont.)

Purchase price allocation:

Under asset acquisition accounting principles, the total purchase price was allocated to Physimax Technology as set forth below.

		Amortization period (Years)
Technology	$ 1,817	3

NOTE 5:- INVENTORIES

Inventory consists of the following:

	December 31,	
	2023	2022
Raw materials	$ 1,015	$ 1,346
Finished products	4,047	6,610
	$ 5,062	$ 7,956

NOTE 6:- REVENUE

The Company is operating a multi-condition healthcare business, empowering individuals to manage their chronic conditions and take steps to improve their overall health. The Company generates revenue directly from individuals through a la carte offering and membership plans. The Company also contracts with enterprise business market groups to provide digital therapeutics solutions for individuals to receive access to services through the Company's commercial arrangements.

Agreement with Preferred Partner

On February 28, 2022, the Company entered into an exclusive preferred partner, co-promotion, development and license agreement for a term of five (5) years (the "Exclusive Agreement"). Pursuant to the Exclusive Agreement, the Company will provide a license to access and use certain Company data. In addition, the Company may provide development services for new products of the other party.

The aggregate consideration under the contract is up to $30 million over the initial term of the Exclusive Agreement, consisting of (i) an upfront payment, (ii) payments for development services per development plan to be agreed upon annually and (iii) certain contingent milestone payments upon meeting certain net sales and enrollment rate milestones at any time during the term of the Exclusive Agreement.

NOTE 6: - REVENUES (Cont.)

Since the contract consideration includes variable consideration, as of December 31, 2023, the Company excluded the variable payments from the transaction price since it is not probable that a significant reversal in the amount of cumulative revenue recognized will occur when the uncertainty associated with the variable consideration is resolved.

In 2022, the first development plan was approved and completed. The Company concluded that the first development plan should be accounted for as a separate contract. As such, for the year ended December 31, 2022, the Company recognized $4,000 in revenues for the completion of the first development plan.

On December 13, 2022, the second development plan was approved by the parties. The Company concluded that the second development plan should be accounted for as a separate contract which includes development services performance obligations, satisfied over time, based on labor hours. As such, for the year ended December 31, 2022, the Company recognized $1,506 in revenues, and for the year ended December 31, 2023, the Company recognized $2,494 in revenues for the completion of the second development plan.

On June 15, 2023, the third development plan (initiated in April 2023), was approved by the parties. The Company concluded that the third development plan should be accounted for as a separate contract which includes development services performance obligations, satisfied over time, based on labor hours. The Company determined that this method under ASC 606 best measures progress towards satisfying the performance obligation and faithfully depicts the transfer of goods and services. For the year ended December 31, 2023, the Company recognized $2,098 in revenues, with additional revenues from the third development plan of $602 expected to be recognized by the end of June 2024.

In July 2023, the Company entered into an amended and restated strategic agreement with the preferred partner. Pursuant to the amendment, the parties adjusted certain pre-agreed economic parameters, including revenue share adjustments and to allow to expedite certain development milestones agreed upon in the parties' initial agreement.

Agreement with National Health Plan

On October 1, 2021, the Company entered into a Master Service Agreement ("MSA") and into a SOW ("October SOW") with a national health plan ("Health Plan"). Pursuant to the October SOW, the Company will provide the Health Plan access to web and app-based platform, for behavioral health. The Company has concluded that the Contract contained a single performance obligation – to provide access to the Company's platform. The consideration in the Contract was based entirely on customer usage.

On August 2022, the Company entered into an additional SOW ("August SOW") with the Health Plan according to which, the Company will provide implementation service and shall develop additional features to be included in the platform.

The Company concluded that the August SOW should be accounted for as a separate contract. The Company has concluded that the August SOW contained two performance obligations as follows:

(i) Digital Behavioral Health Navigation Platform Implementation. This performance obligation includes configuration and implementation of the platform.

(ii) Enhancements to the Digital Behavioral Health Navigation Platform. This performance obligation includes adding additional features and capabilities to the Platform.

U.S. dollars in thousands

NOTE 6:- REVENUE (Cont.)

The August SOW includes a fixed consideration in the amount of $2,650. The Company allocated the consideration between the two performance obligations based on standalone selling prices. The Company determined the standalone selling prices based on the expected cost plus a margin approach.

On February 21, 2023, the Company entered into a change order with the Health Plan according to which the Company will provide additional implementation services and shall develop additional features to be included in the platform. The change order includes a fixed consideration in the amount of $90.

For the years ended December 31, 2023, and December 31, 2022 the Company recognized revenues of $962 and $1,778 respectively for the completion of the August SOW.

Revenue Source:

The following tables represent the Company total revenues for the year ended December 31, 2023 and 2022 disaggregated by revenue source:

	December 31,	
	2023	2022
Commercial - Business-to-Business-to-Consumer (“B2B2C”)	$ 5,005	$ 3,593
Commercial - Strategic partnerships	7,054	12,784
Consumers	8,293	11,279
	$ 20,352	$ 27,656

Deferred Revenue

The Company recognizes contract liabilities, or deferred revenues, when it receives advance payments from customers prior to the satisfaction of the Company's performance obligations. The balance of deferred revenues approximates the aggregate amount of the transaction price allocated to the unsatisfied performance obligations at the end of the reporting period. The company expects all remaining performance obligations to be satisfied in less than a year.

The following table presents the significant changes in the deferred revenue balance during the year ended December 31, 2023:

Balance, beginning of the period	$ 1,320
New performance obligations	5,353
Reclassification to revenue as a result of satisfying performance obligations	(5,676)
Balance, end of the period	$ 997

Costs to fulfill a contract

The Company defers costs incurred to fulfill contracts that: (1) relate directly to the contract; (2) are expected to generate resources that will be used to satisfy the Company’s performance obligations under the contract; and (3) are expected to be recovered through revenue generated under the contract. Contract fulfillment costs are expensed as the Company satisfies its performance obligations and recorded into cost of revenue.

Costs to fulfill a contract are recorded in other accounts receivable and prepaid expenses and long-term assets.

U.S. dollars in thousands

NOTE 6:- REVENUE (Cont.)

Costs to fulfill a contract consist of (1) deferred consumer hardware costs incurred in connection with the delivery of services that are deferred, and (2) deferred costs incurred, related to future performance obligations which are capitalized.

Costs to fulfill a contract as of December 31, 2023, consisted of the following:

	December 31, 2023	December 31, 2022
Costs to fulfill a contract, current	$ 238	$ 483
Costs to fulfill a contract, noncurrent	59	41
Total costs to fulfill a contract	$ 297	$ 524

Costs to fulfill a contract were as follows:

	Costs to fulfill a contract
Beginning balance as of December 31, 2022	$ 524
Additions	474
Cost of revenue recognized	(701)
Ending balance as of December 31, 2023	297

NOTE 7:- DEBT

Loan Facility

On May 1, 2023, the Company refinanced its existing $25,000 credit facility with a new $30,000 credit facility in the LSA by and between Borrowers and the Avenue Lenders. The LSA provides for a four-year secured credit facility in an aggregate principal amount of up to $40,000, of which $30,000 was made available on the closing date and up to $10,000 may be made available on the later of July 1, 2023, or the date the Avenue Lenders approve the issuance of the Discretionary Tranche. On May 1, 2023, the Borrowers closed on the Initial Tranche, less certain fees and expenses payable to or on behalf of the Avenue Lenders.

During the term of the Avenue Loan Facility, interest payable in cash by the Borrowers shall accrue on any outstanding balance due under the Avenue Loan Facility at a rate per annum equal to the higher of (x) the sum of four one-half percent (4.50%) plus the prime rate as published in the Wall Street Journal and (y) twelve and one-half percent (12.50%). During an event of default, any outstanding amount under the Avenue Loan Facility will bear interest at a rate of 5.00% in excess of the otherwise applicable rate of interest. The Borrowers will pay certain fees with respect to the Avenue Loan Facility, including an upfront commitment fee, an administration fee, and a prepayment premium, as well as certain other fees and expenses of the Avenue Lenders. On the closing date, and with respect to the Initial Tranche only, the Company agreed to issue for each Avenue Lender a warrant (the "Warrant") to purchase up to 292,442 shares of the Company's common stock, at an exercise price of $3.334 per share (also see note 20f), which shall have a term of five years from the issuance date. The Warrant contains customary share adjustment provisions, as well as adjustments to the number of shares issuable upon exercise of the Warrant and the exercise price in the event of a bona fide equity raise prior to September 30, 2023, at a price less than the then current exercise price. As of December 31, 2023, the customary share adjustment provisions and adjustments related to a bona fide equity raise prior to September 30, 2023, remain unchanged.

The Avenue Lenders have the right, at any time while the Avenue Loan Facility is outstanding, to convert an amount of up to $2,000 of the principal amount of the outstanding Avenue Loan Facility into Borrower's unrestricted shares of the Company's common stock at a price per share equal to 120% of the then effective exercise price of the Avenue Warrant(Also see note 20f). On the closing date, and with respect to the Initial Tranche only, the Company agreed to issue each Avenue Lender the Avenue Warrant to purchase up to 292,442 shares of the Company's common stock, at an exercise price of $3.334 per share, which shall have a term of five years from the issuance date.

The Company concluded that Avenue Loan and the Avenue Warrants are freestanding financial instruments since these instruments are legally detachable and separately exercisable. The Company has concluded that the warrants meet all the conditions to be classified as equity pursuant to ASC 480 and ASC 815-40. In addition, the Company elected to account for the Avenue Loan under the fair value option in accordance with ASC 825, "Financial Instruments." Under the fair value option, changes in fair value are recorded in earnings except for fair value adjustments related to instrument specific credit risk, which are recorded as other comprehensive income or loss. As such, the proceeds were first allocated to the Loan at fair value in the amount of $28,215 and the remaining amount of $1,389 was allocated to the warrants.

During the year ended December 31, 2023 and 2022, the Company recognized $187 of remeasurement income related to the Initial Commitment Amount, which was included as part of financial expenses in the Company's statements comprehensive loss. During the year ended December 31, 2023, the Company did not recognize any instrument specific credit risk fair value adjustment.

DARIOHEALTH CORP. AND ITS SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
U.S. dollars in thousands

NOTE 7: - DEBT (Cont.)

Warrant Liability

On June 9, 2022 (the closing date of the Orbimed Loan), the Company agreed to issue Orbimed a warrant (the "Orbimed Warrant") to purchase up to 226,586 shares of the Company's common stock, at an exercise price of $5.79 per share, which shall have a term of 7 years from the issuance date. The Orbimed Warrant contains customary share adjustment provisions, as well as weighted average price protection in certain circumstances but in no event will the exercise price of the Warrant be adjusted to a price less than $4.00 per share.

The Company has concluded that the warrants are not indexed to the Company's own stock and should be recorded as a liability measured at fair value with changes in fair value recognized in earnings.

DARIOHEALTH CORP. AND ITS SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
U.S. dollars in thousands

NOTE 8:- FAIR VALUE MEASUREMENTS

The carrying amounts of cash and cash equivalents, short-term restricted bank deposits, trade receivables, other accounts receivable and prepaid expenses, trade payables and other accounts payable and accrued expenses approximate their fair value due to the short-term maturity of such instruments. The Company's Avenue Loan Facility (as defined herein), and warrant liability were measured at fair value using Level 3 unobservable inputs until the payoff date of May 1, 2023. Subsequently, a new loan agreement (Note 7) was obtained, and both the new loan and the warrant liability were measured at fair value.

The following tables present information about the Company's financial liabilities measured at fair value on a recurring basis and indicate the level of the fair value hierarchy used to determine such fair values:

	December 31, 2023			
	Fair Value	Level 1	Level 2	Level 3
		(in thousands)		
Financial liabilities:				
Current maturity of long term loan	$ 3,954	$ —	$ —	$ 3,954
Long term loan	24,591	—	—	24,591
Warrant liability	240	—	—	240
Total financial liabilities	$ 28,785	$ —	$ —	$ 28,785

	December 31, 2022			
	Fair Value	Level 1	Level 2	Level 3
		(in thousands)		
Financial liabilities:				
Current maturity of long term loan	8,823	—	—	8,823
Long term loan	18,105	—	—	18,105
Warrant liability	$ 910	—	—	910
Total financial liabilities	$ 27,838	$ —	$ —	$ 27,838

Loan Facilities

On June 9, 2022, the Company entered into a Credit Agreement (the "Credit Agreement"), by and between the Company, as borrower, and OrbiMed Royalty and Credit Opportunities III, LP, as the lender (the "Orbimed Lender"). The Credit Agreement provides for a five-year senior secured credit facility in an aggregate principal amount of up to $50,000 (the "Orbimed Loan"), of which $25,000 was made available on the closing date (the "Initial Commitment Amount") and up to $25,000 was available on or prior to June 30, 2023, subject to certain revenue requirements (the "Delayed Draw Commitment Amount"). On June 9, 2022, the Company closed on the Initial Commitment Amount, less certain fees and expenses payable to or on behalf of the Orbimed Lender. The company did not draw the Delayed Draw Commitment Amount.

U.S. dollars in thousands

NOTE 8:- FAIR VALUE MEASUREMENTS (Cont.)

On May 1, 2023, the Company entered into a Loan and Security Agreement, and Supplement thereto (the "LSA"), by and between the Company and its subsidiary PsyInnovations Inc. ("PsyInnovations"), collectively as the borrowers (the "Borrowers") and Avenue Venture Opportunities Fund II, L.P. and Avenue Venture Opportunities Fund, L.P., collectively as the lenders (the "Avenue Lenders") (Note 6). Upon the initial closing of the LSA, the Company repaid the Orbimed Loan to the Orbimed Lender. The LSA provides for a four-year secured credit facility in an aggregate principal amount of up to $40,000 (the "Avenue Loan Facility"), of which $30,000 was made available on the closing date (the "Initial Tranche") and up to $10,000 (the "Discretionary Tranche") may be made available on the later of July 1, 2023, or the date the Avenue Lenders approve the issuance of the Discretionary Tranche. On May 1, 2023, the Borrowers closed on the Initial Tranche, less certain fees and expenses payable to or on behalf of the Avenue Lenders

The fair value of the Avenue Loan Facility is recognized in connection with the Company's LSA with respect to the Initial Commitment Amount only (Note 7). The fair value of the Avenue Loan Facility was determined based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The fair value of the Avenue Loan Facility, which is reported within non-current liabilities (Maturity Date - May 1, 2027) on the consolidated balance sheets, is estimated by the Company at each reporting date based on significant inputs that are generally determined based on relative value analyses.

The Avenue Loan Facility incorporates comparisons to instruments with similar covenants, collateral, and risk profiles and was obtained using a discounted cash flow technique. On the date of Avenue Loan Facility origination, or May 1, 2023, the discount rate was arrived at by calibrating the loan amount of $30 million with the fair value of the warrants of $1,413 and the loan terms interest rate equal to the greater of (i) the sum of four and one-half percent (4.50%) plus the Prime Rate, and (ii) twelve and one-half percent (12.50%). During an event of default, any outstanding amount under the Avenue Loan Facility will bear interest at a rate of 5.00% in excess of the otherwise applicable rate of interest. The fair value of the Avenue Loan Facility, as of December 31, 2023, was estimated using a discount rate of 19% which reflects the internal rate of return of the Avenue Loan Facility at closing, as of May 1, 2023. For the year ended December 31, 2023, the change in the fair value of the loan was recorded in earnings since the Company concluded that those were not related to instrument-specific credit risk was required.

Warrant Liability

The fair value of the warrant liability is recognized in connection with the Company's Credit Agreement with the Orbimed Lender and with respect to the Initial Commitment Amount only (Note 8). The fair value of the warrant liability was determined based on significant inputs not observable in the market, which represents a Level 3 measurement within the fair value hierarchy. The fair value of the warrant liability, which is reported within non-current liabilities on the consolidated balance sheets, is estimated by the Company based on the Monte-Carlo simulation valuation technique, in order to predict the probability of different outcomes that rely on repeated random variables.

The fair value of the warrant liability was estimated using a Monte-Carlo simulation valuation technique, with the following significant unobservable inputs (Level 3):

	December 31, 2023	December 31, 2022
Stock price	$ 1.72	$ 7.45
Exercise price	5.79	6.62
Expected term (in years)	5.44	7.00
Volatility	96.8%	148.8%
Dividend rate	—	—
Risk-free interest rate	3.88%	3.13%

U.S. dollars in thousands

NOTE 8:- FAIR VALUE MEASUREMENTS (Cont.)

The following tables present the summary of the changes in the fair value of our Level 3 financial instruments:

	December 31, 2023	
	Long-Term Loan	Warrant Liability
Balance as of January 1, 2023	$ 26,928	$ 910
Issuance	28,587	—
Principal repayments on long-term loan	(27,833)	—
Change in fair value	863	(670)
Balance as of December 31, 2023	$ 28,545	$ 240

NOTE 9:- LEASES

The Company has entered into various non-cancelable operating lease agreements for certain of its offices and car leases. The Company's leases have original lease periods expiring between 2024 and 2028. Many leases include one or more options to renew. The Company does not assume renewals in determination of the lease term unless the renewals are deemed to be reasonably certain at lease commencement. The Company's lease agreements do not contain any material residual value guarantees or material restrictive covenants, the Company elected to not recognize a lease liability and a ROU asset for lease with a term of twelve months or less.

The components of lease costs, lease term and discount rate are as follows:

	Year ended December 31, 2023
Operating lease cost	$ 392
Short term lease cost	278
Variable lease cost	10
Total lease cost	$ 680
Weighted Average Remaining Lease Term	
Operating leases	4.37 years
Weighted Average Discount Rate	
Operating leases	9.38 %

DARIOHEALTH CORP. AND ITS SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
U.S. dollars in thousands

NOTE 9:- LEASES

The following is a schedule, by years, of maturities of lease liabilities as of December 31, 2023:

	Operating Leases
2024	$ 124
2025	305
2026	279
2027	279
2028	284
Total undiscounted cash flows	1,271
Less imputed interest	(275)
Present value of lease liabilities	$ 996

Supplemental cash flow information related to leases are as follows:

	Year ended December 31, 2023
Cash payments related to operating lease	$ 328
New right-of-use assets obtained in exchange for operating lease obligations	$ 136

NOTE 10:- PROPERTY AND EQUIPMENT, NET

Composition of assets, grouped by major classification, is as follows:

	December 31,	
	2023	2022
Cost:		
Computers and peripheral equipment	$ 937	$ 944
Office furniture and equipment	137	154
Production lines	988	988
Leasehold improvement	326	141
	2,388	2,227
Accumulated depreciation:		
Computers and peripheral equipment	542	534
Office furniture and equipment	43	60
Production lines	874	773
Leasehold improvement	30	72
	1,489	1,439
Property and equipment, net	$ 899	$ 788

DARIOHEALTH CORP. AND ITS SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
U.S. dollars in thousands

NOTE 10:- PROPERTY AND EQUIPMENT, NET

Depreciation expenses for the year ended December 31, 2023 and 2022 amounted to $392 and $356, respectively.

During 2023 the Company recorded a reduction of $81 to the cost and accumulated depreciation of fully depreciated computers equipment no longer in use.

NOTE 11:- OTHER INTANGIBLE ASSETS, NET

a. Finite-lived other intangible assets:

	December 31, 2023	December 31, 2022	Weighted Average Remaining Life
Original amounts:			
Technology	$ 16,936	$ 16,936	1.2
Brand	376	376	0.4
	17,312	17,312	
Accumulated amortization:			
Technology	11,586	7,199	
Brand	322	197	
	11,908	7,396	
Other intangible assets, net	$ 5,404	$ 9,916	

b. Amortization expenses for the years ended December 31, 2023 and December 31, 2022 amounted to $4,512 and $4,361, respectively.

c. Estimated amortization expense:

For the year ended December 31,	
2024	4,452
2025	952
	$ 5,404

NOTE 12:- OTHER ACCOUNTS PAYABLE AND ACCRUED EXPENSES

	December 31,	
	2023	2022
Employees and payroll accruals	$ 4,073	$ 4,407
Accrued expenses	2,227	2,185
	$ 6,300	$ 6,592

DARIOHEALTH CORP. AND ITS SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
U.S. dollars in thousands

NOTE 13:- COMMITMENTS AND CONTINGENT LIABILITIES

From time to time, the Company is involved in claims and legal proceedings. The Company reviews the status of each matter and assesses its potential financial exposure. If the potential loss from any claim or legal proceeding is considered probable and the amount can be reasonably estimated, the Company accrues a liability for the estimated loss.

Royalties

The company has a liability to pay future royalties to the Israeli Innovation Authority (the "IIA") for participated in programs sponsored by the Israeli government for the support of research and development activities. The Company is obligated to pay royalties to the IIA, amounting to 3% of the sales of the products and other related revenues (based on the US dollar) generated from such projects, up to 100% of the grants received. Royalty payment obligations also bear interest at the LIBOR rate. The obligation to pay these royalties is contingent on actual sales of the products and in the absence of such sales, no payment is required.

In connection with specific research and development activities, Physimax, prior to its acquisition by the Company, received $1,011 of participation payments from the IIA. The Company's total commitment for royalties payable with respect to future sales, based on IIA participations received, net of royalties accrued or paid, totaled $932 as of December 31, 2023.

During the Year ended December 31,2023 and December 31, 2022 the company recorded IIA royalties related to the acquisition of Physimax Technology in amount of $1 and $120, respectively.

NOTE 14:- LONG-LIVED ASSETS

As of December 31, 2023, substantially all of the Company long live assets are located in Israel.

NOTE 15:- TAXES ON INCOME

The Company and its subsidiaries are separately taxed under the domestic tax laws of the country of incorporation of each entity.

Tax Reform

On December 22, 2017, the U.S. Tax Cuts and Jobs Act of 2017 (the "TCJA") was signed into law. The TCJA makes broad and complex changes to the Internal Revenue Code of 1986 (the "Code") that may impact the Company's provision for income taxes. The changes include, but are not limited to:

- Decreasing the corporate income tax rate from 35% to 21% effective for tax years beginning after December 31, 2017 ("Rate Reduction");
- The Deemed Repatriation Transition Tax; and
- Taxation of Global Intangible Low-Taxed Income ("GILTI") earned by foreign subsidiaries beginning after December 31, 2017. The GILTI tax imposes a tax on foreign income in excess of a deemed return on tangible assets of foreign corporations.

Net Operating Losses- Before the TCJA, taxable losses generated in the U.S. were able to be carried back for two years or carried forward for 20 years to offset prior/future year taxable income. TCJA changes the rule, and allows losses generated after 2017 (i.e. starting in 2018) to be carried forward indefinitely, but only to offset 80% of future year income. Carryback losses are no longer allowed.

NOTE 15:- TAXES ON INCOME (Cont.)

In response to the COVID-19 pandemic, the U.S. passed the Coronavirus Aid, Relief, and Economic Security Act (CARES) in March 2020. The CARES Act changed the treatment of net operating losses ("NOLS") generated in tax years 2018, 2019 and 2020. Losses generated in these years are able to be carried backward for 5 years, and carried forward indefinitely, without the 80% limitation.

Tax rates applicable to Labstyle and Upright:

The Corporate tax rate in Israel in 2022 and 2023 was 23%.

Net operating loss carryforward:

Labstyle has accumulated net operating losses for Israeli income tax purposes as of December 31, 2023, in the amount of approximately $189,653. The net operating losses may be carried forward and offset against taxable income in the future for an indefinite period.

As of December 31, 2023, the Company and WayForward had a U.S. federal net operating loss carryforward of approximately $36,786 and $8,084, of which $7,120 and $371, respectively, were generated from tax years 2011-2017 and can be carried forward and offset against taxable income and that expires during the years 2031 to 2037. Under Sections 382 and 383 of the IRC, utilization of the U.S. loss carryforward may be subject to substantial annual limitation due to the "change in ownership" provisions of the Code and similar state provisions. The annual limitations may result in the expiration of losses before utilization. Since the Company has not yet utilized the losses to offset income, no study has been performed to assess the potential limitations, but when relevant, a study will be performed.

The remaining NOLs of the Company and WayForward are approximately $29,666 and $7,713, were generated in years 2018-2022, and are subject to the TCJA, which modified the rules regarding utilization of NOLs. NOLs generated after December 31, 2017, can only be used to offset 80% of taxable income with an indefinite carryforward period for unused carryforwards (i.e., they should not expire). Utilization of the federal and state net operating losses and credits may be subject to a substantial annual limitation due to an additional ownership change. The annual limitation may result in the expiration of net operating losses and credits before utilization and in the event, the Company has a change of ownership, utilization of the carryforwards could be restricted.

As discussed above, under the CARES Act, the losses from 2018-2023 are excluded from the limitation and can be carried forward indefinitely to offset 100% of future net income.

U.S. dollars in thousands

NOTE 15:- TAXES ON INCOME (Cont.)

Deferred income taxes:

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets are as follows:

	December 31,	
	2023	2022
Deferred tax assets:		
Net operating loss and capital losses carry forward	$ 51,533	$ 45,790
Temporary differences - Research and development expenses	3,815	4,058
Temporary differences - Accrued employees costs	370	366
Temporary differences - Stock-based compensation	4,328	3,734
Temporary differences - Credit Facility	—	723
Temporary differences - Loan	306	—
Temporary differences - Intangible Assets	152	65
Temporary differences - Lease Liability	229	253
Deferred tax assets:	60,733	54,989
Less: Valuation allowance	(58,303)	(52,504)
Deferred tax assets	2,430	2,485
Deferred tax liability:		
Temporary differences - Intangible Assets	(2,208)	(2,208)
Temporary differences - Lease Right of Use Assets	(222)	(277)
Deferred tax liability	(2,430)	(2,485)
Net deferred tax asset	$ —	$ —

The deferred tax balances included in the consolidated financial statements as of December 31, 2023, are calculated according to the tax rates that were in effect as of the reporting date and do not take into account the potential effects of the changes in the tax rate.

The net change in the total valuation allowance for the year ended December 31, 2023, was an increase of $5,798 and is mainly relates to increase in deferred taxes on net operating loss for which a full valuation allowance was recorded. In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets depends on the generation of future taxable income during the periods in which those temporary differences and tax loss carryforward are deductible. Management considers the projected taxable income and tax-planning strategies in making this assessment. In consideration of the Company's accumulated losses and the uncertainty of its ability to utilize its deferred tax assets in the future, management currently believes that it is more likely than not that the Company will not realize all of its deferred tax assets and accordingly recorded a valuation allowance to offset the deferred tax assets.

DARIOHEALTH CORP. AND ITS SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
U.S. dollars in thousands

NOTE 15:- TAXES ON INCOME (Cont.)

a. Loss before taxes on income consists of the following:

	Year ended December 31,	
	2023	2022
Domestic	$ 23,477	$ 22,902
Foreign	35,886	39,287
	$ 59,363	$ 62,189

b. The main reconciling item between the statutory tax rate of the Company and the effective tax rate is the recognition of valuation allowance in respect of deferred taxes relating to accumulated net operating losses carried forward due to the uncertainty of the realization of such deferred taxes.

DARIOHEALTH CORP. AND ITS SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
U.S. dollars in thousands (except stock and stock data)

NOTE 16:- STOCKHOLDERS' EQUITY

a. The holders of Common Stock have the right to one vote for each share of Common Stock held of record by such holder with respect to all matters on which holders of Common Stock are entitled to vote, to receive dividends as they may be declared at the discretion of the Company's Board of Directors and to participate in the balance of the Company's assets remaining after liquidation, dissolution or winding up, ratably in proportion to the number of shares of Common Stock held by them after giving effect to any rights of holders of preferred stock. Except for contractual rights of certain investors, the holders of Common Stock have no pre-emptive or similar rights and are not subject to redemption rights and carry no subscription or conversion rights.

b. On January 4, 2022, out of the pre-funded warrants that were issued in May 2019 private placement, 81,233 were exercised on a cashless basis into 81,221 shares of the Company's common stock. As of December 31, 2022, the Company's total outstanding prefunded warrants were exercisable into 1,769,794 shares of common stock.

   On July 11, 2023, out of the pre-funded warrants that were issued in July 2020 and February 2022, 86,985 were exercised on a cashless basis into 86,983 shares of common stock.

c. In April 2023, the Company issued 76,637 shares of common stock to settle an earn-out payment owed in connection with the acquisition of PsyInnovations, Inc. (dba wayForward).

d. In November and December, 2019, the Company entered into subscription agreements (the "Series A, A-1, A-2, A-3 and A-4 Subscription Agreement") for a sale of an aggregate of 21,375 shares of newly designated Series A, A-1, A-2, A-3 and A-4 Preferred Stock (the "Series A Preferred Stock"), at a purchase price of $1,000 per share (the "Stated Value"), for aggregate gross proceeds, of approximately $21,375 ($18,689 net of issuance expenses). The initial conversion price for the Series A, A-1, A-2, A-3 and A-4 Preferred Stock was $4.05, $4.05, $4.28, $4.98 and $5.90, respectively, subject to adjustment in the event of stock splits, stock dividends, and similar transactions). As such, the Company recorded a deemed dividend during 2019 in the amount of $2,860 for the benefit created to the series A-2, A-3 and A-4 holders.

NOTE 16:- STOCKHOLDERS' EQUITY (Cont.)

The Series A Preferred Stock automatically converted into shares of Common Stock, on the 36-month anniversary of the Series A Effective Date. During the year ended December 31, 2022, the Company accounted for the dividend as a deemed dividend in a total amount of $1,580.

Pursuant to the Placement Agency Agreement (the "Placement Agency Agreement") executed by and between the Company and the registered broker dealer retained to act as the Company's exclusive placement agent (the "Placement Agent") for the offering of the Series A Preferred Stock, the Company paid the Placement Agent an aggregate cash fee of $1,788, non-accountable expense allowance of $641 and was required to issue to the Placement Agent or its designees warrants to purchase 719,243 shares of Common Stock at an exercise price ranging from $4.05 to $5.90 per share (the "Placement Agent Warrants"). The Placement Agent Warrants are exercisable for a period of five years from the date of the final closing of the Series A Preferred Stock Offering.

As of December 31, 2023, out of the Placement Agent Warrants that were issued in December 2019 and July 2020, 451,226 were exercised into 333,077 shares of Common Stock.

On September 20, 2022, the Board of Directors authorized the Company to enter into an exchange agreement with a certain preferred stockholder to exchange 885 shares of the Company's Series A-1 Preferred Stock for 308,711 shares of the Company's common stock. During the year ended 31, 2022, the investor exchanged those certain shares. The Company has accounted for the exchange as a modification and recorded the increase in fair value as a deemed dividend in the amount of $62.

During the year ended December 31, 2022 a total of 1,130 of certain Series A Convertible Preferred Stock, were converted into 339,417 shares of Common Stock, including issuance of dividend shares.

In November, to December 2022 and January 2023, 6,355 Series A Preferred Stock automatically converted into 2,133,904 shares of Common Stock after completing 36-month anniversary of each the Series A Preferred Stock. The conversion included accumulative dividends payable available upon conversion of each Series A Preferred Stock.

On May 1, 2023, the Company entered into agreements with certain holders of 3,557 of the Company's Series A-1 Preferred Stock pursuant to a subscription agreement dated November 27, 2019, which are convertible to 1,273,498 shares of common stock. In consideration for deferring the conversion of the Series A-1 Convertible Preferred Stock, the Company agreed to issue additional shares of common stock upon the deferred conversion of the Series A-1 Convertible Preferred Stock as follows: 63,676 shares, in the aggregate, if not converted for at least one quarter, 127,350 shares, in the aggregate, if not converted for at least two quarters, 191,026 shares, in the aggregate, if not converted for at least three quarters, 254,700 shares, in the aggregate, if not converted for at least four quarters and 382,050 shares, in the aggregate, if not converted for at least five quarters.

NOTE 16:- STOCKHOLDERS' EQUITY (Cont.)

The Company has concluded that the Series A-1 preferred shares modification should be accounted for as an extinguishment transaction and recorded the increase in fair value as a deemed dividend in the amount of $984.

During the year ended December 31, 2023, the Company accounted for the dividend shares of common stock upon the deferred conversion of the Series A-1 Convertible Preferred Stock as a deemed dividend in a total amount of $618.

e. During the year ended December 31, 2023, options were exercised into 4,800 shares of Common Stock.

f. On October 22, 2021, the Company entered into an At-The-Market Equity Offering Sales Agreement (the "ATM"), allowing the Company to sell its common stock for aggregate sales proceeds of up to $50,000 from time to time and at various prices, subject to the conditions and limitations set forth in the sales agreement. If shares of the Company's common stock are sold, there is a three percent (3%) fee paid to the sales agent. During the year ended December 31, 2023 and 2022, the Company received net proceeds of $1,614 and $260 from the sale of 408,043 and 73,037 shares of the Company's common stock, respectively. As of December 31, 2023, there were $47,971 remaining funds available under the ATM.

g. On February 28, 2022, the Company entered into securities purchase agreements with institutional accredited investors relating to an offering with respect to the sale of an aggregate of 4,674,454 shares of the Company's common stock, and pre-funded warrants to purchase an aggregate of 667,559 shares of the Company's common stock at an exercise price of $0.0001 per share, at a purchase price of $7.49 per share (or share equivalent). The aggregate gross proceeds were approximately $40,000 ($38,023, net of issuance expenses).

h. On May 1, 2023, the Company entered into securities purchase agreements with accredited investors relating to an offering and the sale of an aggregate of 6,200 shares of newly designated Series B Preferred Stock (the "Series B Preferred Stock"), an aggregate of 7,946 shares of Series B-1 Preferred Stock (the "Series B-1 Preferred Stock"), and an aggregate of 150 shares of Series B-2 Preferred Stock (the "Series B-2 Preferred Stock") at a purchase price of $1,000 for each share of preferred stock. Certain of our executive officers and directors purchased shares of Series B-2 Preferred Stock in the offering. On May 5, 2023, the Company entered into purchase agreements with accredited investors, relating to the offering of 1,106 shares of newly designated Series B-3 Preferred Stock (the "Series B-3 Preferred Stock" and, collectively with the Series B Preferred Stock, the Series B-1 Preferred Stock, and the Series B-2 Preferred Stock, the "Preferred Stock"), at a purchase price of $1,000 for each share of Preferred Stock. The initial conversion price for the Series B, B-1, B-2, and B-3 Preferred Stock was $3.334, $3.334, $3.370 and $3.392, respectively, subject to adjustment in the event of stock splits, stock dividends, and similar transactions. As a result of the sale of the Preferred Stock, the aggregate gross proceeds to the Company from the offerings were approximately $15,402 ($14,868 net of issuance expenses).

The Preferred Stock will automatically convert into shares of common stock, on the 15-month anniversary of the issuance date. The holders of Preferred Stock will also be entitled dividends payable as follows: (i) a number of shares of common stock equal to five percent (5.0%) of the number of shares of common stock issuable upon conversion of the Preferred Stock then held by such holder for each full quarter anniversary of holding for a total of four (4) quarters from the closing date, and (ii) a number of shares of common stock equal to ten percent (10%) of the number of shares of common stock issuable upon conversion of the Preferred Stock then held by such holder on the fifth full quarter from the closing. The Series B-2 Preferred Stock dividend is subject to receipt of the approval of the Company's shareholders. The Preferred Stock has been accounted for as an equity instrument.

During the year ended December 31, 2023, the Company accounted for the dividend shares of common stock upon the dividend shares earned by Series B Preferred Stock as a deemed dividend in a total amount of $2,482.

DARIOHEALTH CORP. AND ITS SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
U.S. dollars in thousands (except stock and stock data)

NOTE 16:- STOCKHOLDERS' EQUITY (Cont.

i. Stock-based compensation:

On January 23, 2012, the Company's 2012 Plan was adopted by the Board of Directors of the Company and approved by a majority of the Company's stockholders, under which options to purchase shares of Common Stock have been reserved. Under the 2012 Plan, options to purchase shares of Common Stock may be granted to employees and non-employees of the Company or any affiliate, each option granted can be exercised to one share of Common Stock.

On February 5, 2020, the Company's stockholders approved an amendment to the 2012 Plan to increase the number of shares authorized for issuance under the 2012 Plan by 1,350,000 shares, from 618,650 to 1,968,650.

On October 14, 2020, the Company's stockholders approved the 2020 Equity incentive Plan (the "2020 Plan") and the immediate reservation of 900,000 shares under this Plan for the remainder of the 2020 fiscal year. Under the 2020 Plan, options to purchase shares of Common Stock may be granted to employees and non-employees of the Company or any affiliate, each option granted can be exercised to one share of Common Stock.

During 2021, pursuant to the terms of the 2020 Plan as approved by the Company's stockholders, the number of shares authorized for issuance under the 2020 Plan increased by 1,628,890 shares, from 900,000 to 2,528,890.

In January 2022, pursuant to the terms of the 2020 Plan as approved by the Company's stockholders, the Company increased the number of shares authorized for issuance under the 2020 Plan by 1,339,624 shares, from 2,528,890 to 3,868,514.

In January 2023, pursuant to the terms of the 2020 Plan as approved by the Company's stockholders, the Company increased the number of shares authorized for issuance under the 2020 Plan by 1,994,346 shares, from 3,868,514 to 5,862,860.

On May 1, 2023, the Company repaid its existing $25,000 credit facility to the Orbimed Lender with a new $30,000 credit facility in the LSA, by and between the Company and the Avenue Lenders. On the closing date, and with respect to the Initial Tranche only, the Company agreed to issue each Avenue Lender the Avenue Warrant to purchase up to 292,442 shares of the Company's common stock, at an exercise price of $3.334 per share, which shall have a term of five years from the issuance date. The Company accounted the Avenue Warrants as equity instruments and recorded it in fair value as of May 1, 2023, using the relative fair value method in the amount of $1,389. (See also note 20f(

NOTE 16:- STOCKHOLDERS' EQUITY (Cont.)

In December 2021, the Compensation Committee authorized the Company to issue warrants to purchase up to 8,000 shares of Common Stock, to certain consultants of the Company, at a purchase price of $13.60. As such, during the year ended December 31, 2023 and 2022 the Company recorded compensation expense for service providers in the amount of $28 and $29, respectively.

In May 2022 and June 2022, the Compensation Committee authorized the Company to grant warrants to purchase up to 70,000, and 175,000 shares (of which warrants to purchase 87,500 shares have expired) of the Company's common stock which shall vest over 12 months and 24-month periods, respectively, to certain consultants of the Company, with an exercise price of $6.45 and $7.20, respectively. As such, during the year ended December 31, 2023 and 2022 the Company recorded compensation expense for service providers in the amount of $263 and $375, respectively

In December 2022, the Compensation Committee authorized the Company to issue warrants to purchase up to 500,000, shares of Common Stock, to a certain consultant of the Company, at a purchase price of $5.00. In November 2023, the Compensation Committee approved a reduction in the exercise price of said warrants to an exercise price of $1.08 per share, subject to the performance of additional services. The Company has accounted for the change as a modification and recorded increase in warrants fair value. As such, during the year ended December 31, 2023 and 2022 the Company recorded compensation expense for a certain consultant in the amount of $1,502 and $29, respectively.

In January 2023, the Compensation Committee approved the grant of warrants to purchase up to 280,000 shares of common stock, with an exercise price of $5.20, per share to certain consultants. The warrants are exercisable into common stock on or before December 31, 2026. During the year ended December 31, 2023, the Company recorded compensation expenses for certain consultants in the amount of $650.

In January 2023, the Compensation Committee approved a reduction in the exercise price of warrants to purchase up to 350,000 shares of common stock issued to certain consultants in the past at exercise prices between $7.50 to $30.00 per share, to an exercise price of $5.20 per share, subject to the performance of additional services. The Company has accounted for the change as a modification and recorded the increase in fair value as compensation expense for those certain consultants in the amount of $960.

On July 25, 2023, the Compensation Committee approved the grant of warrants to purchase up to 40,000 shares of common stock, with an exercise price of $3.46, per share to a certain consultant, the stock options vests over a three-year period. The warrants are exercisable into common stock on or before December 31, 2026. During the year ended December 31, 2023, the Company recorded compensation expenses for this certain consultant in the amount of $29.

DARIOHEALTH CORP. AND ITS SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
U.S. dollars in thousands (except stock and stock data)

NOTE 16:- STOCKHOLDERS' EQUITY (Cont.)

The table below summarizes the outstanding warrants as of December 31, 2023:

	Warrants outstanding as of December 31, 2023	Exercise price $	Expiration date
Consultants	400,000	25.00	February 16, 2024
Consultants	10,000	5.20	April 6, 2024
Consultants	12,500	18.57	April 13, 2024
Consultants	10,000	5.20	June 17, 2024
Consultants	10,000	5.20	September 9, 2024
Consultants	20,000	5.20	November 9, 2024
Consultants	35,000	16.06	December 1, 2024
Consultants	3,000	16.06	December 1, 2024
Agent warrants A-1 December 2019	233,347	4.05	December 19, 2024
Agent warrants A-2 December 2019	25,034	4.28	December 19, 2024
Agent warrants A-3 December 2019	47,527	4.98	December 19, 2024
Agent warrants A-4 December 2019	5,839	5.90	December 19, 2024
Consultants	60,000	6.39	February 12, 2025
Consultants	30,000	5.20	April 1, 2025
Consultants	87,500	7.20	June 8, 2025
Consultants	30,000	5.20	July 1, 2025
Agent warrants B-1 July 31 2020	150,070	7.47	July 31, 2025
Agent warrants B-1 July 31 2020	2,393	7.94	July 31, 2025
Consultants	25,000	13.88	September 26, 2025
Consultants	40,000	5.20	October 1, 2025
Consultants	500,000	1.08	December 16, 2025
Consultants	100,000	5.20	December 31, 2025
Consultants	8,000	13.60	December 31, 2025
Consultants	70,000	6.45	May 19, 2026
Consultants	250,000	5.20	December 31, 2026
Consultants	40,000	3.46	December 31, 2026
Consultants	100,000	5.20	December 31, 2026
Consultants	30,000	5.20	December 31, 2026
Lender of loan facility	292,442	3.33	May 1, 2028
Lender of loan facility	292,442	3.33	May 1, 2028
Lender of loan facility	226,586	5.79	June 9, 2029
Consultants	13,750	12.00	August 1, 2029
Total outstanding	3,160,430		

NOTE 16:- STOCKHOLDERS' EQUITY (Cont.)

In April 2020, the Compensation Committee of the Board of Directors approved a monthly grant of shares of the Company's Common Stock equal to $18.00 of restricted shares to certain service providers per month, to be granted monthly during the period that the certain consulting agreement remains in effect. During the years ended December 31, 2023 and 2022, a total of 69,180 and 32,926 restricted unregistered shares of Common Stock, respectively, were issued to certain service provider under this approval the Company recorded compensation expense in the amount of $181 and $172, respectively

On April 23, 2022, the Company released 56,788 holdback shares of the Company's common stock to a certain employee of the Company. The holdback release was part of a separation agreement with the employee, pursuant to which the Company waived the lock-up period.

On June 8, 2022, the Compensation Committee authorized the Company to redeem 17,957 shares of restricted stock held by a certain officer, in compliance with Rule 16b-3 promulgated by the SEC, the redemption is part of previously granted 91,652 and 20,000 shares of restricted stock granted in January and July 2021, in exchange for the aggregate redemption price equal to the withholding tax obligation in the amount of $170.

On December 15, 2022, the Compensation Committee authorized the Company to issue 30,000 shares, to a certain consultant of the Company. As such, during the year ended December 31, 2022 the Company recorded compensation expense for service providers in the amount of $106.

During the year ended December 31, 2022, the Company's Compensation Committee of the Board of Directors approved the grant of 29,755 shares of the Company's common stock to employees of the Company, and the grant of 1,268,050 restricted shares of the Company's common stock to employees and consultants. The shares vest over a period of three years commencing on the respective grant dates. The Compensation Committee also approved the grant of options to purchase up to 1,009,550 shares of the Company's common stock to employees and a consultant of the Company, at exercise prices between $4.30 and $8.10 per share. The stock options vest over a three-year period commencing on the respective grant dates. The options have a ten-year term and were issued under the 2020 Equity Incentive Plan, as amended (the "2020 Plan").

In January 2023 and March 2023, the Compensation Committee approved the grant of a non-qualified stock option awards to purchase 200,000 shares of the Company's common stock, as well as an additional non-qualified performance-based stock option award to purchase an additional 180,000 shares of the Company's common stock outside of the Company's 2020 Plan, pursuant to Nasdaq Listing Rule 5635(c)(4), in connection with the employment of its Senior Vice President of Growth and its Chief Product Officer.

In January 2023 and April 2023, the Board of Directors approved the acceleration of the unvested portion of 42,500 restricted shares of the Company's common stock to a certain employee of the Company. The share acceleration was part of a separation agreement with the employee. The Company has accounted for the acceleration as a type-3 modification and recorded compensation expenses in the amount of $153.

During the year ended December 31, 2023, the Company's Compensation Committee approved the grant of 927,100 restricted shares of the Company's common stock to employees and consultants of which 537,100 are under the Company's 2020 Equity Incentive Plan, as amended ("2020 Plan"). Out of the restricted shares granted, 235,000 restricted shares will vest immediately, 30,000 restricted shares will vest over a period of six months, and the remaining 662,100 restricted shares will vest over a period between two to four years commencing on the respective grant dates. The Compensation Committee also approved the grant of options to purchase up to 833,900 shares of common stock for employees and consultants of the Company, at exercise prices between $3.69 and $4.48 per share. Stock options to purchase 528,900 shares of common stock vest over a three-year period commencing on the respective grant dates, and options to purchase 305,000 shares of common stock are performance-based. The options have a ten-year term and were issued under the 2020 Plan.

U.S. dollars in thousands (except stock and stock data)

NOTE 16:- STOCKHOLDERS' EQUITY (Cont.)

Transactions related to the grant of options to employees, directors and non-employees under the above plans and non-plan options during the year ended December 31, 2023 were as follows:

	Number of options	Weighted average exercise price	Weighted average remaining contractual life	Aggregate Intrinsic value
		$	Years	$
Options outstanding at beginning of period	2,124,302	13.38	6.98	121
Options granted	1,213,900	4.33	—	—
Options exercised	(6,821)	—	—	—
Options expired	(221,313)	30.51	—	—
Options forfeited	(559,239)	5.86	—	—
Options outstanding at end of period	2,550,829	9.27	7.02	36
Options vested and expected to vest at end of period	2,089,935	9.61	6.88	36
Exercisable at end of period	1,326,486	12.45	5.39	36

Weighted average grant date fair value of options granted during the year ended December 31, 2023 and 2022 is $2.14 and $4.43, respectively.

The aggregate intrinsic value in the table above represents the total intrinsic value (the difference between the Company's closing stock price on the last day of fiscal 2023 and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options on December 31, 2023. This amount is impacted by the changes in the fair market value of the Common Stock

Transactions related to restricted shares granted\forfeited during the year ended December 31, 2023 were as follows

	Number of Restricted shares
Restricted shares outstanding at beginning of the period	2,207,772
Restricted shares granted	572,100
Restricted shares forfeited	(143,946)
Restricted shares outstanding at end of period	2,635,926

U.S. dollars in thousands (except stock and stock data)

NOTE 16:- STOCKHOLDERS' EQUITY (Cont.)

The Company estimates the fair value of stock options granted using the Black-Scholes option-pricing model.

The assumptions used are determined as follows:

Volatility. The expected volatility was derived from the historical volatilities of the Company's stock price over a period equivalent to the expected term of the stock option grants.

Expected Term. The expected term represents the period that the stock-based awards are expected to be outstanding. When establishing the expected term assumption, the Company utilizes historical data.

Risk-Free Interest Rate. The risk-free interest rate is based on U.S. Treasury zero-coupon issues with terms similar to the expected term on the options.

Dividend Yield. The Company has never declared or paid any cash dividends and does not plan to pay cash dividends in the foreseeable future, and therefore, it used an expected dividend yield of zero.

The following table presents the assumptions used to estimate the fair values of the options granted to employees, non-employees and directors in the period presented:

	Year ended December 31,	
	2023	2022
Volatility	90.90-92.62 %	91.11-92.60 %
Risk-free interest rate	3.45-4.13 %	1.89-3.62 %
Dividend yield	0 %	0 %
Expected life (years)	5.81-5.88	5.81-6.00

As of December 31, 2023, the total unrecognized estimated compensation cost related to non-vested stock options and restricted shares granted prior to that date was $9,407, which is expected to be recognized over a weighted average period of approximately 0.82 year.

The total compensation cost related to all the Company's equity-based awards, recognized during year ended December 31, 2023 and 2022 were comprised as follows:

	Year ended December 31,	
	2023	2022
Cost of revenues	$ 327	$ 66
Research and development	3,803	3,608
Sales and marketing	6,468	6,042
General and administrative	9,103	7,259
Total stock-based compensation expenses	$ 19,701	$ 16,975

DARIOHEALTH CORP. AND ITS SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
U.S. dollars in thousands (except stock and stock data)

NOTE 17:- SELECTED STATEMENTS OF OPERATIONS DATA

Financial losses, net:

	Year ended December 31,	
	2023	2022
Bank charges	$ 112	$ 83
Foreign currency adjustments expenses, net	210	(243)
Interest income	(1,868)	(506)
Revaluation of short-term investments	(37)	—
Loan Interest Expenses	—	1,876
Remeasurement of long-term loan	4,894	3,858
Remeasurement of warrant liability	(670)	(1,020)
Debt issuance cost	533	724
Remeasurement of financial commitment asset	—	607
Total Financial expenses, net	$ 3,174	$ 5,379

DARIOHEALTH CORP. AND ITS SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
U.S. dollars in thousands (except stock and stock data)

NOTE 18: - BASIC AND DILUTED NET LOSS PER COMMON STOCK

We compute net loss per share of common and preferred stock using the two-class method. Basic and diluted net earnings or loss per share is computed using the weighted-average number of shares outstanding during the period. This calculation includes the total weighted average number of the common stock, which includes prefunded warrants. The total number of potential common shares related to the outstanding options, warrant and preferred shares excluded from the calculations of diluted net loss per share due to their anti-dilutive effect was 12,188,189 and 5,744,428 for the year ended December 31, 2023 and 2022, respectively.

The following table sets forth the computation of the Company's basic net loss per common and preferred stock:

	Year ended December 31, 2023					
	Common Stock	Preferred A-1	Preferred B	Preferred B-1	Preferred B-2	Preferred B-3
Basic and diluted loss per share						
Numerator:						
Allocation of undistributed loss	$ 54,860,245	$ 2,528,086	$ 2,476,171	$ 3,173,493	$ 59,308	$ 413,441
Denominator:						
Number of shares used in per share computation	28,371,979	3,557	4,094	5,247	99	697
Basic earnings (loss) per share amounts:						
Distributed earnings - deemed dividends	—	450.47	244.63	244.63	242.18	248.52
Undistributed loss - allocated	(1.93)	(710.74)	(604.87)	(604.87)	(598.83)	(593.23)
Basic and diluted loss per share	$ (1.93)	$ (260.26)	$ (360.24)	$ (360.24)	$ (356.64)	$ (344.71)

	Year ended December 31, 2022
	Common Stock
Basic and diluted loss per share	
Numerator:	
Allocation of undistributed loss	$ 59,957,966
Denominator:	
Number of shares used in per share computation	23,635,038
Basic loss per share amounts:	
Distributed earnings - deemed dividends	—
Undistributed loss - allocated	(2.54)
Basic and diluted loss per share	$ (2.54)

For the year ended December 31, 2022 the basic and diluted net loss per share of Preferred A, A-1, A-2, A-3 and A-4 was 590.97, 599.21, 524.32, 381.15 and 286.94 respectively.

NOTE 19:- SUBSEQUENT EVENTS

a. In January 2024, pursuant to the terms of the 2020 Plan as approved by the Company's stockholders, the Company increased the number of shares authorized for issuance under the 2020 Plan by 2,493,764 shares, from 5,862,860 to 8,356,624.

b. In January and March 2024, the Compensation Committee of the Board of Directors approved the grant of 1,941,500 restricted shares subject to time vesting to directors, officers and employees of the Company and approved the grant of 1,100,400 options to purchase Common Stock, and 320,000 performance-based options to purchase Common Stock to officers, employees and consultants of the Company, at exercise prices between $1.68 and $2.14 per share. The time vesting restricted shares and stock options vest over various periods between two to three years commencing on the respective grant dates. The options have a ten-year term. The restricted shares and the options were issued under the 2020 Plan.

c. On January 30, 2024, out of the pre-funded warrants that were issued in July 2020, 400,017 were exercised on a cashless basis into 400,000 shares of common stock.

d. On February 15, 2024 (the "Closing Date"), The Company, TWILL Merger Sub, Inc. ("Merger Sub"), Twill, Inc. ("Twill") and Bilal Khan, solely in his capacity as the representatives of Twill's stockholders and other equity holders, entered into an Agreement and Plan of Merger (the "Merger Agreement"), Pursuant to the provisions of the Merger Agreement, on the Closing Date, (i) Merger Sub was merged with and into Twill (the "Merger"), the separate corporate existence of Merger Sub ceased and Twill continued as the surviving company and a wholly owned subsidiary of the Company, (ii) the Company paid to Twill's debt holders and equity holders aggregate consideration ("Merger Consideration") of (A) $10.0 million in cash, (B) pre-funded warrants (the "Pre-Funded Warrants") to purchase up to 10,000,400 shares (the "Warrant Shares") of Company common stock, par value $0.0001 per share (the "Common Stock"), issuable to a trust (the "Trust") formed for the benefit of certain equity and debt holders of Twill, issuable in 4 equal tranches, (C) stock options to purchase up to 2,963,459 shares of Common Stock issued to employees of Twill as an inducement to their employment with the Company, issued outside of the Company's equity compensation plans, pursuant to Nasdaq Rule 5635(c)(4), with an exercise price of $2.55 per share, and (D) a combination of warrants and restricted stock units ("RSUs") to acquire up to 1,766,508 shares of Common Stock issued to certain outgoing board members, consultants and outgoing officers of Twill (all of such RSUs and warrants being subject to the approval of the Company's stockholders, pursuant to Nasdaq Rule 5635), and (iii) the parties to the Merger Agreement consummated the transactions contemplated thereby. The Merger Agreement contains various customary representations, warranties and covenants. As a result of the Merger, Twill will operate as a wholly owned subsidiary of the Company.

   In addition, the Company executed certain consulting agreements (the "Consulting Agreements") with Ofer Leidner and Bilal Khan, each former officers of Twill. Pursuant to the terms of the Consulting Agreements, the Company agreed to retain their services. Leidner and Khan for a period of at least 14 months and 6 months respectively, in exchange for monthly consulting fees of $35,416 and $35,417, respectively. In addition, the Company agreed to issue to Mr. Leidner warrants to purchase up to 1,032,946 shares of Common Stock, of which 717,946 are subject to time vesting and 315,000 are subject to certain performance-based metrics, and to issue to Mr. Khan 350,000 fully vested RSUs which shall be vest subject to stockholder approval.

DARIOHEALTH CORP. AND ITS SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
U.S. dollars in thousands (except stock and stock data)

NOTE 19:- SUBSEQUENT EVENTS (Cont.)

e. On February 15, 2024, the Company entered into securities purchase agreements (each, a "Series C Purchase Agreement") with accredited investors relating to an offering (the "Offering") and the sale of an aggregate of (i) 17,307 shares of newly designated Series C Preferred Stock (the "Series C Preferred Stock"), and (ii) 4,000 shares of Series C-1 Preferred Stock (the "Series C-1 Preferred Stock"), at a purchase price of $1,000 for each share of Preferred Stock. In addition, on February 16, 2024, the Company entered into Series C Purchase Agreements with accredited investors relating to the Offering and the sale of an aggregate of 1,115 shares of Series C-2 Preferred Stock (the "Series C-2 Preferred Stock" and together with the Series C Preferred Stock and the Series C-1 Preferred Stock, the "Preferred Stock"), at a purchase price of $1,000 for each share of Preferred Stock. The Series C and C-1 Preferred Stock are convertible into Common Stock at $2.02 per Common Stock. The Series C-2 Preferred Stock is convertible into Common Stock at $2.14 per Common Stock. As a result of the sale of the Preferred Stock, the aggregate gross proceeds to the Company from the Offering are approximately $22,422 thousands. The closing of the Series C Preferred Stock, Series C-1 Preferred Stock and Series C-2 Preferred Stock occurred on February 21, 2024.

f. On February 15, 2024, the Company and its subsidiaries, PsyInnovations, Inc. and LabStyle Innovation Ltd., entered into the First Amendment to Loan and Security Agreement and Supplement (the "Avenue Amendment") with Avenue Venture Opportunities Fund II, L.P. and Avenue Venture Opportunities Fund, L.P., as lenders. Pursuant to the Avenue Amendment, the parties agreed to include the Merger Sub and Twill as parties to the Company's existing loan facility with the lenders.

In addition, the Avenue Amendment provides (i) that the Company will seek stockholder approval to reprice the warrants issued to the lenders on May 1, 2023 to permit an amendment to the exercise price of such warrants to the "minimum price" as defined by Nasdaq rules as of the closing of the Twill Agreement and (ii) permit the lenders, subject to Nasdaq rules, to convert up to two million of the principal amount of its loan to the Company at a conversion price of $4.0001 per share.

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Exhibit 10.23

REDEMPTION AGREEMENT

This Redemption Agreement, effective as of June 9, 2022 (this "***Agreement***"), is entered into by and between Richard Allan Anderson ("***Executive***") and DarioHealth Corp. ("***Dario***").

WHEREAS, pursuant to that certain Restricted Stock Award Agreements, dated as of January 19, 2021 and July 18, 2021, respectively (collectively, the "***Restricted Stock Agreements***") issued pursuant to Dario's 2020 Equity Incentive Plan, Dario granted to Executive 91,652 and 20,000 shares of restricted stock of Dario, respectively (collectively, the **"*Restricted Stock***"), 33,885 of which have vested during the 2022 fiscal year.

WHEREAS, under the Restricted Stock Agreements, Executive agreed to pay to Dario, or make arrangements satisfactory to Dario's Compensation Committee regarding the payment of, any federal, state, social security, Medicare and local taxes of any kind required by law to be withheld or paid with respect to the Restricted Stock (the "***Withholding Tax Obligation***").

WHEREAS, as a result of the vesting of the Restricted Stock, Executive recognized approximately $321,500 in compensation income for United States federal, state, social security, Medicare and local tax purposes, which income is subject to approximately $170,275 in Withholding Tax Obligation.

WHEREAS, the Executive and Dario desire that Dario redeem sufficient shares of Restricted Stock from Executive for an aggregate redemption price equal to the Withholding Tax Obligation in satisfaction of the same on the terms and conditions set forth herein, and Dario's Compensation Committee has approved such arrangement.

NOW, THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending to be legally bound, hereby agree as follows:

1. **Redemption of Shares.** Upon the terms and subject to the conditions of this Agreement, Dario hereby redeems from Executive **17,957** shares of Restricted Stock for an aggregate redemption price equal to the Withholding Tax Obligation. For avoidance of doubt, the redemption price shall be paid by Dario by deeming the Withholding Tax Obligation to be fully satisfied.

2. **Representations and Warranties.** Each of the parties hereby represents and warrants, severally as to himself or itself and not jointly, as follows:

(a) Executive has full power and authority to execute and deliver this Agreement and the other agreements and instruments contemplated hereby, to consummate the transactions contemplated hereby and to perform his obligations hereunder. This Agreement has been duly executed and delivered by Executive and constitutes the legal, valid and binding obligation of Executive, enforceable against him in accordance with its terms. Executive owns beneficially and of record the Restricted Stock and has good and valid title to the Restricted Stock, free and clear of all liens, encumbrances and adverse claims. The execution and delivery of this Agreement and each other agreement or instrument contemplated hereby by Executive, the performance by Executive of his obligations hereunder and the consummation by Executive of the transactions contemplated hereunder do not and will not (with or without notice or passage of time, or both), violate, conflict with, or result in a breach of, any of the terms or provisions of, or constitute a default under, or give rise to a right of termination, acceleration, violation or loss of rights under, or result in the creation or imposition of any liens, encumbrances or other adverse claims upon, any of the Restricted Stock under (i) any contract, agreement, note, bond, debenture or other instrument to which Executive is a party or by which he is bound, or (ii) applicable law. Executive acknowledges that Dario has not made any representation or

warranty regarding the value of the Restricted Stock. Executive (i) is a sophisticated individual familiar with transactions similar to those contemplated by this Agreement, (ii) has adequate information concerning the business and financial condition of Dario to make an informed decision regarding the redemption of the Restricted Stock, (iii) has voluntarily agreed to the redemption of the Restricted Stock, and has had an opportunity to consult with his legal, tax and financial advisors concerning this Agreement and its subject matter and (iv) has independently and without reliance upon Dario, and based on such information and the advice of such advisors as Executive has deemed appropriate, made its own analysis and decision to enter into this Agreement.

(b) Dario has full power and authority to execute and deliver this Agreement and the other agreements and instruments contemplated hereby, to consummate the transactions contemplated hereby and to perform its obligations hereunder. This Agreement has been duly executed and delivered Dario and constitutes the legal, valid and binding obligation of Dario, enforceable against Dario in accordance with its terms.

3. **Further Assurances**. Each party hereto, without additional consideration, shall cooperate, shall take such further action and shall execute and deliver such further documents as may be reasonably requested by the other party hereto in order to carry out the provisions and purposes of this Agreement.

4. **Counterparts**. This Agreement may be signed in counterparts with the same effect as if the signature on each counterpart were upon the same instrument. In the event that any signature is delivered by facsimile transmission or by e-mail delivery of a ".pdf" format data file, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or ".pdf" signature page were an original thereof.

5. **Headings**. The headings of Articles and Sections in this Agreement are provided for convenience only and will not affect its construction or interpretation.

6. **Waiver**. Neither any failure nor any delay by any party in exercising any right, power or privilege under this Agreement or any of the documents referred to in this Agreement will operate as a waiver of such right, power or privilege, and no single or partial exercise of any such right, power or privilege will preclude any other or further exercise of such right, power or privilege.

7. **Severability**. The invalidity or unenforceability of any provisions of this Agreement pursuant to any applicable law shall not affect the validity of the remaining provisions hereof, but this Agreement shall be construed as if not containing the provision held invalid or unenforceable in the jurisdiction in which so held, and the remaining provisions of this Agreement shall remain in full force and effect. If the Agreement may not be effectively construed as if not containing the provision held invalid or unenforceable, then the provision contained herein that is held invalid or unenforceable shall be reformed so that it meets such requirements as to make it valid or enforceable.

8. **Governing Law**. This Agreement shall be governed by and construed in accordance with Section 18 of the 2020 Equity Incentive Plan.

[signature page follows]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first above written.

By: /s/ Richard Allan Anderson
Name: Richard Allan Anderson

DARIOHEALTH CORP.

By: /s/ Zvi Ben-David
Name: Chief Financial Officer

Exhibit 10.24

EXCHANGE AGREEMENT

EXCHANGE AGREEMENT (the " ***Agreement*** ") is made as of the 20th day of September 2022, by and between DarioHealth Corp., a Delaware corporation (the " ***Company*** "), and the investor signatory hereto (the " ***Investor*** ").

WHEREAS , the Investor was issued shares of Series A-1 Convertible Preferred Stock ("***Preferred Stock***") of the Company pursuant to a subscription agreement entered into on November 27, 2019 (the "***Purchase Agreement*** ");

WHEREAS, the Investor holds a number of shares of Preferred Stock of the Company set forth an on the Investor's signature page attached hereto;

WHEREAS, subject to the terms and conditions set forth in this Agreement and in reliance on Section 3(a)(9) of the Securities Act of 1933, as amended (the " ***Securities Act*** ") and/or Section 4(a)(2) of the Securities Act, the Company desires to exchange with the Investor, and the Investor desires to exchange with the Company, all shares of Preferred Stock for certain shares of the Company's common stock listed on the signature page hereto (the "***Exchange Shares***"); and

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and in consideration of the premises and the mutual agreements, representations and warranties, provisions and covenants contained herein, the parties hereto, intending to be legally bound hereby, agree as follows:

1. Exchange; Waiver. On Closing Date (as defined below), subject to the terms and conditions of this Agreement, the Investor shall, and the Company shall, pursuant to Section 3(a) (9) of the Securities Act and/or 4(a)(2) of the Securities Act, exchange all shares of Preferred Stock held by the Investor for the Exchange Shares. The Investor hereby expressly waives any and all rights to any dividends payable pursuant to the terms, rights and preferences of the Preferred Stock. Subject to the conditions set forth herein, the exchange of the shares of Preferred Stock for the Exchange Shares shall take place at the offices of Sullivan & Worcester LLP, within 2 Trading Days (as defined below) of the date hereof, or at such other time and place as the Company and the Investor mutually agree (the "***Closing***" and such date, the "***Closing Date***"). At the Closing, the following transactions shall occur (such transaction an "***Exchange***"):

   a. Within two trading days following the Closing Date, in exchange for the shares of Preferred Stock, the Company shall deliver the Exchange Shares to the Investor or its designee in accordance with the Investor's delivery instructions set forth on the Investor signature page hereto. Upon receipt of the Exchange Shares in accordance with this Section 1.1, all of the Investor's rights under the shares of Preferred Stock shall be extinguished. The Investor shall tender to the Company the shares of Preferred Stock within three Trading Days of the Closing Date.

   b. On the Closing Date, the Investor shall be deemed for all corporate purposes to have become the holder of record of the Exchange Shares, and the shares of Preferred Stock shall be deemed for all corporate purposes to have been cancelled, irrespective of the date such Exchange Shares are delivered to the Investor in accordance herewith. Until the shares of Preferred Stock have been delivered to the Company, the Investor shall bear the risk that they are acquired by a bona fide purchaser with no notice of the Investor's and the Company's claims.

As used herein, "***Common Stock***" means the common stock of the Company, par value $0.001 per share, and any other class of securities into which such securities may hereafter be reclassified or changed.

As used herein, "***Person***" means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

As used herein, "***Trading Day***" means any day on which the Common Stock is traded on the principal securities exchange or securities market on which the Common Stock is then traded.

c. The Company and the Investor shall execute and/or deliver such other documents and agreements as are customary and reasonably necessary to effectuate the Exchanges, including, at the request of the Company or its transfer agent, executed stock powers in customary form.

d. Investor hereby waives any requirements or non-compliance with that certain Registration Rights Agreement executed by and between the Company dated November 27, 20219 (the " ***Registration Rights Agreement*** ") in connection with the transactions contemplated by this Agreement. In addition, Investor hereby waives any payment of liquidated damages and any accrued and unpaid interest that may be due and payable due to any non-compliance or breach by the Company of the Registration Rights Agreement in connection with the transactions contemplated by this Agreement and the Purchase Agreement.

2. Closing Conditions.

a. Conditions to Investor's Obligations. The obligation of the Investor to consummate the Exchange is subject to the fulfillment, to the Investor's reasonable satisfaction, prior to or at the Closing, of each of the following conditions:

i. Representations and Warranties. The representations and warranties of the Company contained in this Agreement shall be true and correct in all material respects on the date hereof and on and as of the Closing Date as if made on and as of such date.

ii. No Actions. No action, proceeding, investigation, regulation or legislation shall have been instituted, threatened or proposed before any court, governmental agency or authority or legislative body to enjoin, restrain, prohibit or obtain substantial damages in respect of, this Agreement or the consummation of the transactions contemplated by this Agreement.

iii. Proceedings and Documents. All proceedings in connection with the transactions contemplated hereby and all documents and instruments incident to such transactions shall be satisfactory in substance and form to the Investor, and the Investor shall have received all such counterpart originals or certified or other copies of such documents as they may reasonably request.

b. Conditions to the Company's Obligations. The obligation of the Company to consummate the Exchange is subject to the fulfillment, to the Company's reasonable satisfaction, prior to or at the Closing, of each of the following conditions:

i. Representations and Warranties. The representations and warranties of the Investor contained in this Agreement shall be true and correct in all material respects on the date hereof and on and as of the Closing Date as if made on and as of such date.

ii. No Actions. No action, proceeding, investigation, regulation or legislation shall have been instituted, threatened or proposed before any court, governmental agency or authority or legislative body to enjoin, restrain, prohibit, or obtain substantial damages in respect of, this Agreement or the consummation of the transactions contemplated by this Agreement.

iii. Proceedings and Documents. All proceedings in connection with the transactions contemplated hereby and all documents and instruments incident to such transactions shall be satisfactory in substance and form to the Company and the Company shall have received all such counterpart originals or certified or other copies of such documents as the Company may reasonably request.

3. Representations and Warranties of the Company. The Company hereby represents and warrants to Investor that:

a. Organization, Good Standing and Qualification. The Company is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware. The Company is duly qualified to transact business and is in good standing in each jurisdiction in which the failure to so qualify would have a material adverse effect on its business or properties.

b. Consents; Waivers. No consent, waiver, approval or authority of any nature, or other formal action, by any Person, not already obtained, is required in connection with the execution and delivery of this Agreement by the Company or the consummation by the Company of the transactions provided for herein and therein.

c. Bring- Down of Representations and Warranties . All legal and factual representations and warranties made by the Company to the Investor in any prior agreements pursuant to which the shares of Preferred Stock were originally issued are accurate and complete in all material respects as of the date hereof, unless as of a specific date therein in which case they shall be accurate as of such date (or, to the extent representations or warranties are qualified by materiality or Material Adverse Effect (as defined in such agreements), in all respects).

d. No Commission Paid. Neither the Company nor any of its affiliates nor any Person acting on behalf of or for the benefit of any of the foregoing, has paid or given, or agreed to pay or give, directly or indirectly, any commission or other remuneration (within the meaning of Section 3(a) (9) of the Securities Act and the rules and regulations of the Securities and Exchange Commission promulgated thereunder) for soliciting the Exchange.

e. Tacking. The Company acknowledges and agrees that in accordance with Rule 144(d)(3)(ii) of the Securities Act, the Exchange Shares shall take on the characteristics of

the Preferred Stock, and the holding period of the Exchange Shares being issued may be tacked on to the holding period of the Preferred Stock.

4. Representations and Warranties of the Investor. The Investor hereby represents, warrants and covenants that:

   a. Authorization. The Investor has full power and authority to enter into this Agreement, to perform its obligations hereunder and to consummate the transactions contemplated hereby and has taken all action necessary to authorize the execution and delivery of this Agreement, the performance of its obligations hereunder and the consummation of the transactions contemplated hereby.

   b. Investment Experience. The Investor can bear the economic risk of its investment in the Exchange Shares and has such knowledge and experience in financial and business matters that it is capable of evaluating the merits and risks of an investment in the Exchange Shares.

   c. Information. The Investor and its advisors, if any, have been furnished with all materials relating to the business, finances and operations of the Company and materials relating to the offer and issuance of the Exchange Shares which have been requested by the Investor. The Investor has had the opportunity to review the Company's filings with the Securities and Exchange Commission. The Investor and its advisors, if any, have been afforded the opportunity to ask questions of the Company. Neither such inquiries nor any other due diligence investigations conducted by the Investor or its advisors, if any, or its representatives shall modify, amend or affect the Investor's right to rely on the Company's representations and warranties contained herein. The Investor understands that its investment in the Exchange Shares involves a high degree of risk. The Investor has sought such accounting, legal and tax advice as it has considered necessary to make an informed investment decision with respect to its acquisition of the Exchange Shares. The Investor is relying solely on its own accounting, legal and tax advisors, and not on any statements of the Company or any of its agents or representatives, for such accounting, legal and tax advice with respect to its acquisition of the Exchange Shares and the transactions contemplated by this Agreement.

   d. No Governmental Review. The Investor understands that no United States federal or state agency or any other government or governmental agency has passed on or made any recommendation or endorsement of the Exchange Shares or the fairness or suitability of the investment in the Shares nor have such authorities passed upon or endorsed the merits of the offering of the Exchange Shares.

   e. Validity; Enforcement; No Conflicts. This Agreement and each Transaction Document to which the Investor is a party have been duly and validly authorized, executed and delivered on behalf of the Investor and shall constitute the legal, valid and binding obligations of the Investor enforceable against the Investor in accordance with their respective terms, except as such enforceability may be limited by general principles of equity or to applicable bankruptcy, insolvency, reorganization, moratorium, liquidation and other similar laws relating to, or affecting generally, the enforcement of applicable creditors' rights and remedies. The execution, delivery and performance by the Investor of this Agreement and each Transaction Document to which the Investor is a party and the consummation by the Investor of the transactions contemplated hereby and thereby will not (i) result in a violation of the organizational documents of the Investor or (ii) conflict with, or constitute a default (or an event which with notice or lapse of time or both would become a default)

under, or give to others any rights of termination, amendment, acceleration or cancellation of, any agreement, indenture or instrument to which the Investor is a party, or (iii) result in a violation of any law, rule, regulation, order, judgment or decree (including federal and state securities or "blue sky" laws) applicable to the Investor, except in the case of clause (ii) above, for such conflicts, defaults or rights which would not, individually or in the aggregate, reasonably be expected to have a material adverse effect on the ability of the Investor to perform its obligations hereunder.

f. Bring- Down of Representations and Warranties. All legal and factual representations and warranties made by the Investor to the Company in any prior agreements pursuant to which the shares of Preferred Stock were originally issued are accurate and complete in all material respects as of the date hereof, unless as of a specific date therein in which case they shall be accurate as of such date (or, to the extent representations or warranties are qualified by materiality or Material Adverse Effect (as defined in such agreements), in all respects).

5. Miscellaneous.

a. Successors and Assigns. Except as otherwise provided herein, the terms and conditions of this Agreement shall inure to the benefit of and be binding upon the parties hereto and the respective successors and assigns of the parties. Nothing in this Agreement, express or implied, is intended to confer upon any party, other than the parties hereto or their respective successors and assigns, any rights, remedies, obligations or liabilities under or by reason of this Agreement, except as expressly provided in this Agreement.

b. Governing Law; Jurisdiction; Jury Trial. All questions concerning the construction, validity, enforcement and interpretation of this Agreement shall be governed by the internal laws of the State of New York, without giving effect to any choice of law or conflict of law provision or rule (whether of the State of New York or any other jurisdictions) that would cause the application of the laws of any jurisdictions other than the State of New York. Each party hereby irrevocably submits to the exclusive jurisdiction of the state or federal courts sitting in The City of New York, Borough of Manhattan, for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is brought in an inconvenient forum or that the venue of such suit, action or proceeding is improper. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof to such party at the address for such notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any manner permitted by law. **EACH PARTY HEREBY IRREVOCABLY WAIVES ANY RIGHT IT MAY HAVE, AND AGREES NOT TO REQUEST, A JURY TRIAL FOR THE ADJUDICATION OF ANY DISPUTE HEREUNDER OR IN CONNECTION WITH OR ARISING OUT OF THIS AGREEMENT OR ANY TRANSACTION CONTEMPLATED HEREBY** .

c. Titles and Subtitles. The titles and subtitles used in this Agreement are used for convenience only and are not to be considered in construing or interpreting this Agreement.

d. Fees and Expenses. Each party shall pay the fees and expenses of its advisers, counsel, accountants and other experts, if any, and all other expenses incurred by such party incident to the negotiation, preparation, execution, delivery and performance of this Agreement.

e. Notices. Any notices, consents, waivers or other communications required or permitted to be given under the terms of this Agreement must be in writing and will be deemed to have been delivered pursuant to the terms of the Purchase Agreement.

f. Amendments and Waivers. Any term of this Agreement may be amended and the observance of any term of this Agreement may be waived (either generally or in a particular instance and either retroactively or prospectively), only with the written consent of the Company and the Investor. Any amendment or waiver effected in accordance with this paragraph shall be binding upon Investor and the Company, provided that no such amendment shall be binding on a holder that does not consent thereto to the extent such amendment treats such party differently than any party that does consent thereto.

g. Severability. If one or more provisions of this Agreement are held to be unenforceable under applicable law, such provision shall be excluded from this Agreement and the balance of the Agreement shall be interpreted as if such provision were so excluded and shall be enforceable in accordance with its terms.

h. Entire Agreement. This Agreement represents the entire agreement and understanding between the parties concerning the Exchange and the other matters described herein and therein and supersede and replaces any and all prior agreements and understandings solely with respect to the subject matter hereof and thereof.

i. Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

j. Interpretation. Unless the context of this Agreement clearly requires otherwise, (a) references to the plural include the singular, the singular the plural, the part the whole, (b) references to any gender include all genders, (c) “including” has the inclusive meaning frequently identified with the phrase “but not limited to” and (d) references to “hereunder” or “herein” relate to this Agreement.

k. No Third Party Beneficiaries. This Agreement is intended for the benefit of the parties hereto and their respective permitted successors and assigns, and is not for the benefit of, nor may any provision hereof be enforced by, any other Person.

l. Survival. The representations, warranties and covenants of the Company and the Investor contained herein shall survive the Closing and delivery of the Exchange Shares.

m. Further Assurances. Each party shall do and perform, or cause to be done and performed, all such further acts and things, and shall execute and deliver all such other agreements, certificates, instruments and documents, as any other party may reasonably request in order to carry out the intent and accomplish the purposes of this Agreement and the consummation of the transactions contemplated hereby.

n. No Strict Construction. The language used in this Agreement will be deemed to be the language chosen by the parties to express their mutual intent, and no rules of strict construction will be applied against any party.

[SIGNATURES ON THE FOLLOWING PAGES]

IN WITNESS WHEREOF, the parties have caused this Agreement to be duly executed and delivered as of the date provided above.

THE COMPANY

DARIOHEALTH CORP.

By:
Name:
Title:

INVESTOR

Nantahala Capital Partners II Limited Partnership

By:
Name:
Title:

No. of Series A-1 Preferred: 885
No. of Exchange Shares: 308,711

Exhibit 10.34

DARIOHEALTH CORP.

February 16, 2024

Tomer Ben Kiki

Dear Tomer,

I am pleased to offer you employment with **Dario Health (** "Company") in the position of **COO** and you will report to the **CEO**. This letter confirms our offer of employment and includes details on the financial arrangements.

Your employment with the Company will commence on February 16, 2024. For your services for the Company, you will receive the following compensation and benefits:

1. Compensation.

a. Salary. The Company will pay you an annual salary of **$212,000**. You will be paid in accordance with the Company's usual payroll practice. You authorize the Company to make all legally required deductions and withholdings. During the Term, your salary shall be subject to an annual review and potential adjustment as the CEO shall deem appropriate. Such annual review shall take place no later than 90 days following the end of a calendar year. Any change in salary shall be and become the salary for purposes of this agreement.

b. Bonus. You will be entitled to receive an annual performance bonus of up to **20%** (the "Bonus Amount") subject to the Company reaching annual Company goals as defined by the Board of Directors and your personal objectives.

c. Stock Options. You will be entitled to a stock option grant to purchase up to **358,973** shares of the Company's common stock, subject to the approval of the Company's Board of Directors. **145,871** of these options will vest on the grant date and the remining **213,102** options will vest over two years in eight equal quarterly amounts elapsed from the grant date. This Option grant is subject, in all respects, to the approval of the Company's Board of Directors. The options will serve as an inducement grant pursuant to Nasdaq Listing Rule 5635(c)(4) and will be issued outside of the Company's 2020 Equity Incentive Plan (the "Plan") but will otherwise follow the material terms of similar grants issuable pursuant to the Plan. The vesting period shall immediately end, and all shares shall immediately vest, in the event a Change in Control (as defined in the Plan) occurs prior to, or within 180 days of, the termination of a grantee's employment or retention with the Company.

d. Performance options. You will be granted options to purchase up to **150,000** performance options which will vest upon achieving personal objectives as follows:

Area	Milestone	Grants
Commercial Transition Support	Achieve GAAP revenues at $18M from Twill products for the year ending December 31, 2024 as reported in the Company's form 10K for that year.	• 22,500 options will vest upon achievement of 100% of this milestone. Employee shall be entitled to a pro-rated vesting upon reaching at least 70% of this milestone.
OPEX targets 2024	2024 OPEX – not higher than $56M for the year ending December 31, 2024	• 22,500 options will vest upon achievement of 100% of this milestone. Employee shall be entitled to 50% vesting upon maintaining expense level below 105% of goal.
OPEX targets 2025	Q1-2025 OPEX run rate enabling $50M of OPEX in 2025, and not higher than $13M.	• 20,000 options will vest upon achievement of 100% of this milestone. Employee shall be entitled to 50% vesting upon maintaining expense level below 105% of goal
Product Development and Life Cycle and Delivery	Generate software value from funds invested and meet product roadmap	• 42,500 options will vest upon achievement of 100% of this milestone. Employee shall be entitled to a pro-rated vesting upon reaching at least 70% of this milestone.
Key talent retention	Retain 15 key Twill/Dario employees according to a list to be agreed between the Employee and the Chief of Stuff.	• 42,500 options will vest upon achievement of 100% of this milestone. Employee shall be entitled to a pro-rated vesting upon reaching at least 70% of this milestone.

e. This Option grant is subject, in all respects, to the approval of the Company's Board of Directors. The options will serve as an inducement grant pursuant to Nasdaq Listing Rule 5635(c)(4) and will be issued outside of the Company's 2020 Equity Incentive Plan (the "Plan") but will otherwise follow the material terms of similar grants issuable pursuant to the Plan. The options grant is subject, in all respects, to the approval of the Company's Board of Directors.

You also hereby acknowledge that all equity based grants are subject to the Company's Clawback Policy, which provides for the recoupment (or clawback) of certain executive compensation in the event of an accounting restatement resulting from material noncompliance with financial reporting requirements under the federal securities laws of the United States.

You hereby agree and acknowledge that other than the compensation set forth herein you shall not be entitled to any additional compensation irrespective of the number of hours and/or scope of employment actually worked by you.

2. Benefits. You will be eligible to participate in the various employee benefit plans, programs and arrangements that the Company may offer to its U.S. employees from time to time, in accordance with the terms of those plans, programs and arrangements.

3. Time Off. You will accrue **11** days of paid time off each year, which will accrue pro rata on a monthly basis, paid holidays annually in accordance with the Company holiday schedule.

4. Business Expenses. You will be reimbursed for travel, entertainment and other customary operating expenses pursuant to the Company's reimbursement policy.

5. Company Policies. You shall comply with, and be subject to, both the spirit and the letter of the Company's policies and procedures as in effect from time to time. Such policies are subject to change and modification by the Company unilaterally from time to time.

6. At-will Employment. The foregoing describes the compensation that you will receive during your employment with the Company (unless changed by written agreement between you and the Company), but is not a contract or guarantee of employment for any particular period of time. At all times you will be an employee at will, which means that you and the Company are each free to terminate your employment at any time and for any reason.

7. Return of Company Property. Upon the termination of the employment relationship or at any given time as requested by the Company, you shall return to the Company all property and material belonging to the Company or its group companies, including but not limited to files, documents, keys, credit cards and all material in whatever form, containing Company Confidential Information (as defined in the agreement referred to in Paragraph 8 below), including possible copies thereof. In connection with this obligation, you undertake to transfer all work-related emails from your email account allocated for your personal use to the use of the Company as separately instructed by the Company.

8. Confidentiality, Proprietary Information and Non-Solicitation Agreement. As a material term of your employment, you agree to be bound by, and shall execute and delivered to the Company, [the Confidentiality, Proprietary Information and Non-Solicitation] Agreement, attached as Exhibit A.

9. Taxes. All of the compensation and benefits that the Company provides to you will be paid subject to applicable income and employment taxes and withholdings. You are solely responsible for all income and employment tax obligations arising out of your performance of services for the Company including, without limitation, any obligations arising under Internal Revenue Code Section 409A and/or 4999. Any payments to be made under this agreement upon a termination of employment will only be made upon a "separation from service" under Internal Revenue Code Section 409A. Notwithstanding anything in the agreement to the contrary, if You are a "specified employee" within the meaning of Internal Revenue Code Section 409A(a)(2)(B)(i), no payments that are "deferred compensation" subject to Internal Revenue Code Section 409A that would otherwise be payable upon Your "separation from service" (as defined in Internal Revenue Code Section 409A) shall be made to You prior to the date that is six (6) months after the date of Your "separation from service" or, if earlier, Your death. Following any applicable six (6) month delay, all such delayed payments will be paid in a single lump sum on the earliest date permitted under Internal Revenue Code Section 409A that is also a business day.

10. Notice. The foregoing describes the compensation and benefits that you will receive for so long as you remain employed by Dario or until such terms are modified by mutual written agreement of you and Dario, but is not a contract or guarantee of employment for any particular period of time. At all times you will be an employee at-will, which means that you and Dario are each free to terminate your employment at any time for any reason, with a 90 days prior written notice (such period after notice is given is referred to as the "Notice Period"). If your employment terminates for any reason, you will be entitled to receive only your salary through the date of your termination and such other compensation or benefits to which you may be

entitled by law or under the terms of Dario's benefit plans and programs then in effect. During the Notice Period and unless otherwise determined by the Company in a written notice, the employment relationship hereunder shall remain in full force and effect, you shall be obligated to continue to discharge and perform all your duties and obligations with Company, and you shall cooperate with the Company and assist the Company with the integration into the Company of the person who will assume your responsibilities.

Because Federal law requires you to provide the Company with documentation of your eligibility to work in the United States, this offer is further conditioned upon your providing such documentation within three business days of your commencing work.

By accepting this offer of employment, you represent that you are not subject to any agreement, court decision, arrangement or undertaking (for example, a non-competition or non-solicitation obligation) that would prevent you from performing the duties agreed in this Agreement and that you will not unlawfully or in an unjustified way use trade secrets belonging to others while performing the duties under this Agreement.

* * * * *

To indicate your acceptance of this offer, please sign and date this letter in the space below and the attached Exhibit A and return the signed copy of this letter and Exhibit A to me.

Sincerely,

Erez Raphael, CEO

I ACCEPT EMPLOYMENT BASED ON THE TERMS STATED ABOVE AND THE TERMS SET FORTH IN THE ATTACHED CONFIDENTIALITY, PROPRIETARY INFORMATION AND NON-SOLICITATION AGREEMENT INCORPORATED HEREIN.

	Feb 16, 2023
Tomer Ben Kiki	Date

EXHIBIT A

DARIOHEALTH CORP.

CONFIDENTIALITY, PROPRIETARY INFORMATION AND NON-SOLICITATION AGREEMENT

In consideration and as a condition of employment with DarioHealth Corp. and/or by companies which it owns, controls, or by which it is owned or controlled, or with which it is affiliated, or their successors in business (the "**Company**"), and the compensation paid therefor:

1. Confidentiality.

Except as the Company may otherwise consent in writing, the undersigned agrees to keep confidential and not disclose or make any use of, except for the benefit of the Company, at any time either during or subsequent to the term of the undersigned engagement with the Company, any trade secrets or confidential or proprietary information of the Company, including without limitation knowledge, data, or other information relating to products, processes, know-how, techniques, designs, formulae, test data, costs, customer lists, employees, business plans, marketing plans and strategies, pricing, or other subject matter pertaining to any past, existing or contemplated business of the Company or any of its employees, clients, customers, consultants, agents, licensees, or affiliates, which the undersigned may produce, obtain or otherwise acquire during the course of or in connection with the undersigned service (collectively, "**Company Confidential Information**") or otherwise relating to the business, products, software, technologies, techniques, processes, services, or research and development of the Company. The undersigned further agree not to deliver, reproduce, or in any way allow any Company Confidential Information or any documentation relating thereto to be delivered or used by any third parties without specific direction or consent of the Company.

The foregoing shall not prevent the disclosure of information that does not comprise proprietary information or trade secrets of the Company in the context of academic publications or presentations, subject to the prior confirmation of the Company that such publication will not be adverse to the Company's interests.

In the event of termination of the undersigned's engagement with the Company for any reason whatsoever, the undersigned agrees to promptly surrender and deliver to the Company all copies of records, materials, equipment, drawings, documents, and data of any nature pertaining to Company or obtained in connection with the undersigned's relationship with the Company.

As set forth in 18 U.S.C. § 1833(b), an individual shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret that—(A) is made—(i) in confidence to a Federal, State or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. Nothing in this Agreement is intended to conflict with 18 U.S.C. § 1833(b) or create liability for disclosures of trade secrets that are expressly allowed by 18 U.S.C. § 1833(b).

2. Assignment of Inventions.

As used in this Agreement, "**Invention**" shall include but not be limited to ideas, improvements, designs, discoveries, developments and works of authorship or artistry (including without limitation software, integrated circuit, printed circuit board or computer design, and documentation) developed or created while employed by the Company and related to the undersigned's responsibilities as an employee of the Company.

The undersigned hereby assigns and transfers to the Company, its successors and assigns, its entire right, title, and interest in and to all Inventions, insofar as any such Invention, by operation of law, may not be considered work made for hire for Company, whether or not protectable by patent, trademark, copyright, or mask work right, and whether or not used by the Company, which are reduced to practice, made or conceived by the undersigned (solely or jointly with others) during the period of and in connection with the undersigned's service with the Company or with the use of the Company's resources (including Company's Confidential Information). The undersigned agrees that all such Inventions shall belong exclusively to the Company and that the undersigned does not and shall not have any right to royalties or other additional payment from the Company with regard to the assigned Inventions.

3. Assignment and Execution of Documents.

The undersigned agrees to assist the Company, upon request and at its expense, during and after the undersigned's service the Company in every reasonable way, to obtain for its own benefit patents, trademarks, copyrights, mask work rights or other proprietary rights for Inventions in any and all countries. The undersigned agrees to execute such papers and perform such lawful acts as the Company deems to be necessary to allow it to exercise all rights, title and interest in such patents, trademarks copyrights, and mask work rights, including executing, acknowledging, and/or delivering to the Company upon request and at its expense, applications.

In the event the Company is unable to secure the undersigned's signature on any document needed to apply for or prosecute any patent, copyright, or other right or protection relating to an Invention, the undersigned hereby irrevocably designates and appoints the Company and its duly authorized officers and agents as the undersigned's agent and attorney-in-fact to act for and on the undersigned's behalf to execute, verify and file any such document and to do all other lawfully permitted acts to further the prosecution thereon with the same legal force and effect as if executed by the undersigned.

If, in the course of the undersigned's engagement with the Company, the undersigned incorporates a preexisting work into a Company product, process or machine, the Company is hereby granted and shall have a nonexclusive, royalty-free, irrevocable, perpetual, worldwide license (with rights to sublicense through multiple tiers of sublicenses) to make, have made, modify, use, execute, reproduce, display, perform, distribute internally or externally, sell copies of, and prepare derivative works based upon such preexisting works, and authorize or sublicense others from time to time to do any or all of the foregoing . Notwithstanding the foregoing, the undersigned agrees that: (i) the undersigned will not incorporate, or permit to be incorporated, preexisting work in any Invention without the Company's prior written consent, (ii) the undersigned's failure to obtain such prior consent shall not affect the grant of the license relating to the preexisting work.

4. Maintenance of Records.

The undersigned agrees to keep and maintain adequate and current written records of all Inventions made by the undersigned as provided in Section 3 above (in the form of notes, sketches, drawings, and as may be specified by the Company) which records shall be available to and remain the sole property of the Company at all times.

5. Competitive Activity.

a. Non-Solicitation of Clients. The undersigned agrees with and for the benefit of the Company that during the undersigned's employment by the Company and for a period of twelve (12) months from the date of the termination of employment, however caused, the undersigned shall not at any time, directly or indirectly, without the prior written consent of the Company, in any capacity whatsoever (including as an employer, employee, principal, agent, joint venturer, partner, shareholder or other equity holder, independent contractor, licensor, licensee, franchiser, franchisee, distributor, lender, director, officer, consultant, supplier, trustee or by and through any corporation, company, co-operative, partnership, trust, entity with juridical personality, unincorporated association or otherwise), solicit, attempt to solicit, divert or attempt to divert, with respect to business activities, operations or opportunities that are similar to, or competitive with the Company as it is carried on at the date of termination of this Agreement, any of the clients or customers of the Company or wherever situated. For the purposes of this Section, the expression "clients, and customers of the Company" shall mean any client or potential client business partner of the Company, which the Company provided services or products or which the undersigned had contacts with, for which the undersigned performed services, concerning which the undersigned obtained unique or confidential knowledge as a result of his position, or in respect of which the undersigned was engaged in on behalf of the Company within the twelve (12) months immediately preceding the termination of employment with the Company.

b. Non-Solicitation of Employees. The undersigned further agrees that, during his employment by the Company and for a period of twelve (12) months following the termination of his employment, however caused, the undersigned will not at any time, directly or indirectly, without the prior written consent of the Company, in any capacity whatsoever (including as an employer, employee, principal, agent, joint venturer, partner, shareholder or other equity holder, independent contractor, licensor, licensee, franchiser, franchisee, distributor, lender, director, officer, consultant, supplier, trustee or by and through any corporation, company, co-operative, partnership, trust, entity with juridical personality, unincorporated association or otherwise), solicit, attempt to solicit, take away or cause to be hired or taken away any employee of the Company or, following the termination of the undersigned's employment, however caused, hire any employee who was in the employment of the Company during the 12 months preceding the date of the termination of the undersigned's employment with the Company.

6. No Conflicting Obligations.

The undersigned confirms that it is not a party to or bound by any employment agreement, consulting agreement, agreement not to compete, or other contract that would prohibit the undersigned engagement with the Company or that would conflict with the undersigned obligation to use her/his/its best efforts to promote the interests of the Company, or that would conflict with the business conducted and/or proposed to be conducted by the Company.

7. Third Party Confidential information.

The undersigned will not disclose or make available to the Company or use or induce the Company to use any trade secret, confidential or proprietary information or material belonging to any previous employer, client or other person. The undersigned represents that her/his/its performance of this Agreement and as a consultant of the Company does not and will not breach any agreement to keep in confidence any information, knowledge or data acquired by the undersigned in confidence or in trust prior to the undersigned engagement with the Company. The undersigned agrees not to enter into any agreement either written or oral in conflict herewith.

8. Modification.

This Agreement may not be supplemented, modified, released, discharged, abandoned, or otherwise amended, in whole or in part, except by an instrument in writing, signed by the undersigned and an officer of the Company. The undersigned agrees that any subsequent change or changes in the undersigned duties, salary, or compensation shall not affect the validity or scope of this Agreement. The undersigned further agrees that either the Company or the undersigned can terminate the undersigned's service at any time and for any reason and nothing in this Agreement changes or restricts that right.

9. Entire Agreement.

The undersigned acknowledges receipt of this Agreement as part of the Company's offer of employment and agrees that with respect to the subject matter hereof, it is the entire agreement with the Company, superseding any previous oral or written communications, representations, understandings, or agreements with the Company or any officer or representative thereof.

10. Severability.

In the event that any paragraph or provision of this Agreement shall be held to be illegal or unenforceable, such paragraph or provision shall be severed from this Agreement, and the entire Agreement shall not fail on account thereof but shall otherwise remain in full force and effect, and shall be interpreted as if such provision were so excluded and shall be enforceable in accordance with its terms; provided, however, that in such event this Agreement shall be interpreted so as to give effect, to the greatest extent consistent with and permitted by applicable law, to the meaning and intention of the excluded provision as determined by such court of competent jurisdiction.

11. Successors and Assigns.

This Agreement shall be binding upon the undersigned heirs, executors, administrators, or other legal representatives and is for the benefit of the Company, its affiliates, successors and assignees.

_____

Tomer Ben Kiki

Date: February 16, 2024

PERSONAL EMPLOYMENT AGREEMENT

THIS PERSONAL EMPLOYMENT AGREEMENT (the "Agreement") is made and entered into this **February 16, 2024** by and between LabStyle Innovation Ltd., a company incorporated under the laws of the State of Israel, with its offices at HaTochen 8, Cesarea Industrial Park, 3088900, Israel (the "**Company**"), and Employee **Tomer Ben Kiki** (Israeli I.D. **024956120**) residing at **2 Levi Eshkol St. Tel Aviv, Israel** (the "**Employee**").

WHEREAS, the Company wishes to employ the Employee, and the Employee wishes to be employed by the Company, as of the Commencement Date (as such term is defined hereunder); and

WHEREAS, the parties hereto desire to state the terms and conditions of the Employee's employment by the Company, as set forth below.

NOW, THEREFORE, in consideration of the mutual premises, covenants and other agreements contained herein, the parties hereby agree as follows:

General

1. Position. The Employee shall serve in the position described in **Exhibit A** attached hereto. In such position the Employee shall report regularly and shall be subject to the direction and control of the Company's management and specifically under the direction of the person specified in **Exhibit A**. The Employee shall perform his duties diligently, conscientiously and in furtherance of the Company's best interests. The Employee agrees and undertakes to inform the Company, immediately after becoming aware of any matter that may in any way raise a conflict of interest between the Employee and the Company. During his employment by the Company, the Employee shall not receive any payment, compensation or benefit from any third party in connection, directly or indirectly, with his position in the Company. For purposes of this Agreement, references to "third party" shall not include a parent company, subsidiaries and affiliates of the Company.

3. Location. The Employee shall perform his duties hereunder at the Company's facilities in Israel, but he understands and agrees that his position may involve significant domestic and international travel or working from home where required.

4. Employee's Representations and Warranties. The Employee represents and warrants that the execution and delivery of this Agreement and the fulfillment of its terms: (i) will not constitute a default under or conflict with any agreement or other instrument to which he is a party or by which he is bound; and (ii) do not require the consent of any person or entity. Further, with respect to any past engagement of the Employee with third parties and with respect to any permitted engagement of the Employee with any third party during the term of his engagement with the Company (for purposes hereof, such third parties shall be referred to as "**Other Employers**"), the Employee represents, warrants and undertakes that: (a) his engagement with the Company is and/or will not be in breach of any of his undertakings toward Other Employers, and (b) he will not disclose to the Company, nor use, in provision of any services to the Company, any proprietary or confidential information belonging to any Other Employer.

Term of Employment

5. Term. The Employee's employment by the Company shall commence on the date set forth in **Exhibit A** (the "**Commencement Date**"), and shall continue until it is terminated pursuant to the terms set forth herein.

6. Termination at Will. Either party may terminate the employment relationship hereunder at any time, without the obligation to provide any reason, by giving the other party a prior written notice as set forth in **Exhibit A** (the "**Notice Period**"). The Employee acknowledges and agrees that he has been given ample opportunity to consider the aforesaid waiver and further acknowledges that the Base Salary includes due consideration for such waiver. Notwithstanding the foregoing, the Company is entitled to terminate this Agreement and related employment with immediate effect upon a written notice to Employee and to pay the Employee a one time amount equal to the Salary and all other benefits that would have been paid to the Employee during the Notice Period, in lieu of such prior notice.

The Company and Employee agree and acknowledge that the Company's Severance Contribution to the Insurance Scheme in accordance with Section 11 below, shall, provided contribution is made in full, be instead of severance payment to which the Employee (or his beneficiaries) is entitled with respect to the Salary upon which such contributions were made and for the period in which they were made (the "**Exempt Salary**"), pursuant to Section 14 of the Severance Pay Law 5723 – 1963 (the "**Severance Law**"). The parties hereby adopt the General Approval of the Minister of Labor and Welfare, which is attached hereto as **Exhibit C**. The Company hereby forfeits any right it may have in the reimbursement of sums paid by Company into the Insurance Scheme, except: (i) in the event that Employee withdraws such sums from the Insurance Scheme, other than in the event of death, disability or retirement at the age of 60 or more; or (ii) upon the occurrence of any of the events provided for in Sections 16 and 17 of the Severance Law. Nothing in this Agreement shall derogate from the Employee's rights to severance payment in accordance with the Severance Law or agreement or applicable ministerial order including the General Approval of the Minister of Labor and Welfare, as set forth in this Section 6, in the event contributions to the Insurance Scheme in accordance with Section 11 below have not been made in full.

7. Termination for Cause. The Company may immediately terminate the employment relationship for Cause, and such termination shall be effective as of the time of notice of the same. "**Cause**" means herein (a) conviction of any felony by the Employee involving moral turpitude affecting the Company or its affiliates or any crime involving fraud; (b) action taken by the Employee intentionally to materially harm the Company or its affiliates; (c) embezzlement of funds of the Company or its affiliates by the Employee; (d) falsification of Company's or its affiliates' records or reports by the Employee; (e) ownership by the Employee, direct or indirect, of an interest in a person or entity (other than a minority interest in a publicly traded company) in competition with the products or services of the Company or its affiliates, including those products or services contemplated in a plan adopted by the Company or its affiliates; (f) any material breach of the Employee's fiduciary duties or duties of care to the Company (except for conduct taken in good faith) which, to the extent such breach is curable, has not been cured by Employee within fifteen (15) days after its receipt of notice thereof from Company containing a description of the breach or breaches alleged to have occurred; (g) any material breach of the Proprietary Information, Assignment of Inventions and Non-Competition Agreement attached as **Exhibit B** by the Employee; and (i) any other act or omission that constitutes "cause" under the laws of the State of Israel. In the event of termination for Cause, the Employee's entitlement to severance pay will be subject to Sections 16 and 17 of the Severance Law.

8. Notice Period; End of Relations. During the Notice Period and unless otherwise determined by the Company in a written notice to the Employee, the employment relationship hereunder shall remain in full force and effect, the Employee shall be obligated to continue to discharge and perform all of his duties and obligations with Company, and the Employee shall cooperate with the Company and assist the Company with the integration into the Company of the person who will assume the Employee's responsibilities.

Covenants

9. Proprietary Information; Assignment of Inventions and Non-Competition. Upon the execution of this Agreement, the Employee will execute the Company's Proprietary Information, Assignment of Inventions and Non-Competition Agreement attached hereto as **Exhibit B**. Exhibit B hereto shall survive the expiration or other termination of this Agreement.

Salary and Additional Compensation; Insurance

10. (a) Salary. The Company shall pay to the Employee as compensation for the employment services an aggregate monthly base salary in the amount set forth in **Exhibit A** (the "**Base Salary**"). In addition, since the Employee may, from time to time, work overtime hours and since the Company cannot keep specific track of all of the Employee's overtime hours, the Company shall pay to the Employee an additional monthly gross amount, as set forth in **Exhibit A** paid for all of the Employee's overtime hours, as they may be from time to time (the "**Additional Compensation**" the Additional Compensation and Base Salary together shall constitute the "**Salary**" for purposes of this Agreement). Except as specifically set forth herein, the Salary includes any and all payments to which the Employee is entitled from the Company hereunder and under any applicable law, regulation or agreement and the Employee shall not be entitled to any additional payment, including, for avoidance of doubt, any payment for overtime hours of work or reimbursement for travel expenses to and from his home to the workplace (which are paid on global basis through the payment of the Additional Compensation). The Employee's Salary and other terms of employment may be reviewed and updated by the Company's management, from time to time, at the Company's discretion. The Salary is to be paid to the Employee no later than the 9th day of each calendar month after the month for which the Salary is paid, after deduction of applicable taxes and like payments.

You hereby agree and acknowledge that other than the compensation set forth herein you shall not be entitled to any additional compensation irrespective of the number of hours and/or scope of employment actually worked by you.

(b) Special Compensation for Non-Competition Obligations. The Employee acknowledges that 20% of the Salary is paid as special supplementary monthly compensation in consideration for the Employee's non-competition undertakings and obligations set forth in **Exhibit B** hereto (the "**Special Non-Competition Monthly Compensation**"). The Employee warrants and represents that the Special Non-Competition Monthly Compensation constitutes a real, appropriate and full consideration to any prejudice he may suffer due to his non-competition undertakings and obligations set forth in **Exhibit B** hereto, including but not limited to restriction of his freedom of employment.

11. Insurance and Social Benefits.

11.1. The Company will insure the Employee under a "Manager's Insurance Policy" ("*Bituach Menahalim*") ("**Policy**") or a Pension Fund ("**Pension Fund**"), to be selected by the Employee. The employee shall be entitled to contributions to a pension arrangement of his choice (the "**Pension Arrangement**"), at the following monthly rates:

(a) The Company shall contribute:

(i) 8.33% of the Salary towards the severance pay component; and

(ii) 6.5% of the Salary towards the pension component. In case you are insured in a mangers insurance policy or a provident fund (which is not a pension fund), the said rate shall include the rate of contributions towards the disability insurance, ensuring loss of earning payment of 75% of the Salary but no less than 5% towards the pension component, all subject to the terms of the Extension Order regarding the Increase of Pension Contributions - 2016 (the "**Pension Order 2016**"). In accordance with the terms of the Pension Order 2016, if the said rate shall not be sufficient to insure you in disability insurance, the total rate of contributions shall increase up to 7.5% of the Salary.

(b) The Company shall also deduct 6% of the Salary to be paid on your account towards the Pension Arrangement.

11.2. By signing this Agreement, you acknowledge that in accordance with the terms of the General Order, if you choose to be insured in a Pension Arrangement, which is not a pension fund, you must also be insured in disability insurance, ensuring loss of earning payment of 75% of the Salary (or the relevant portion of the Salary which the you choose to insure in such an arrangement).

11.3. Additionally, the Company together with the Employee will maintain an advanced study fund ("**Keren Hishtalmut**") and the Employee and the Company shall contribute to such fund an amount equal to 2.5% (two percent and one half of a percent) of the Salary and 7.5% (seven percent and one half of a percent) of the Salary, respectively. All of the Employee's aforementioned contributions shall be transferred to the above referred to plans and funds by the Company by deducting such amounts from each monthly Salary payment. Any tax results for payments made for amounts greater than the maximum amount exempt from tax under applicable laws will bear upon the employee.

Additional Benefits

12. Expenses. The Company will reimburse the Employee for traveling expenses in **Exhibit A**.

13. Vacation. The Employee shall be entitled to the number of vacation days per year as set forth in **Exhibit A**, as coordinated with the Company (with unused days to be accumulated up to the limit set pursuant to applicable law).

14. Sick Leave; Convalescence Pay. The Employee shall be entitled to that number of paid sick leave per year as set forth in **Exhibit A** (with unused days to be accumulated up to the limit set pursuant to applicable law), and also to Convalescence Pay ("Dmei Havra'a") pursuant to applicable law.

15. Taxes. The Employee agrees that he is solely responsible for all United States income and employment tax obligations arising out of the performance of services under this Agreement, including, without limitation, any obligations arising under Internal Revenue Code Section 409A and/or 4999. Any payments to be made under this Agreement upon a termination of employment will only be made upon a "separation from service" under Internal Revenue Code Section 409A. Notwithstanding anything in the Agreement to the contrary, if the Employee is a "specified employee" within the meaning of Internal Revenue Code Section 409A(a)(2)(B)(i), no payments that are "deferred compensation" subject to Internal Revenue Code Section 409A that would otherwise be payable upon the Employee's "separation from service" (as defined in Internal Revenue Code Section 409A) shall be made to the Employee prior to the date that is six (6) months after the date of the Employee's "separation from service" or, if earlier, the Employee's date of death. Following any applicable six (6) month delay, all such delayed payments will be paid in a single lump sum on the earliest date permitted under Internal Revenue Code Section 409A that is also a business day.

16. Stock Options. You will be entitled to a stock option grant to purchase up to **358,974** shares of the Company's common stock, subject to the approval of the Company's Board of Directors. **145,871** of these options will vest on the grant date and the remining **213,103** options will vest over two years in eight equal quarterly amounts elapsed from the grant date. This Option grant is subject, in all respects, to the approval of the Company's Board of Directors. The options " will serve as an inducement grant pursuant to Nasdaq Listing Rule 5635(c)(4) and will be issued outside of the Company's 2020 Equity Incentive Plan (the "Plan") but will otherwise follow the material terms of similar grants issuable pursuant to the Plan. The vesting period shall immediately end, and all shares shall immediately vest, in the event a Change in Control (as defined in the Plan) occurs prior to, or within 180 days of, the termination of a grantee's employment or retention with the Company.

a. Performance options. You will be granted options to purchase up to **150,000** performance options which will vest upon achieving personal objectives as follows:

Area	Milestone	Grants
Commercial Transition Support	Achieve GAAP revenues at $18M from Twill products for the year ending December 31, 2024 as reported in the Company's form 10K for that year.	• 22,500 options will vest upon achievement of 100% of this milestone. Employee shall be entitled to a pro-rated vesting upon reaching at least 70% of this milestone.
OPEX targets 2024	2024 OPEX – not higher than $56M for the year ending December 31, 2024	• 22,500 options will vest upon achievement of 100% of this milestone. Employee shall be entitled to 50% vesting upon maintaining expense level below 105% of goal.
OPEX targets 2025	Q1-2025 OPEX run rate enabling $50M of OPEX in 2025, and not higher than $13M.	• 20,000 options will vest upon achievement of 100% of this milestone. Employee shall be entitled to 50% vesting upon maintaining expense level below 105% of goal
Product Development and Life Cycle and Delivery	Generate software value from funds invested and meet product roadmap	• 42,500 options will vest upon achievement of 100% of this milestone. Employee shall be entitled to a pro-rated vesting upon reaching at least 70% of this milestone.
Key talent retention	Retain 15 key Twill/Dario employees according to a list to be agreed between the Employee and the Chief of Stuff.	• 42,500 options will vest upon achievement of 100% of this milestone. Employee shall be entitled to a pro-rated vesting upon reaching at least 70% of this milestone.

b. This Option grant is subject, in all respects, to the approval of the Company's Board of Directors. The options will serve as an inducement grant pursuant to Nasdaq Listing Rule 5635(c)(4) and will be issued outside of the Company's 2020 Equity Incentive Plan (the "Plan") but will otherwise follow the material terms of similar grants issuable pursuant to the Plan. The options grant is subject, in all respects, to the approval of the Company's Board of Directors.

You also hereby acknowledge that all equity based grants are subject to the Company's Clawback Policy, which provides for the recoupment (or clawback) of certain executive compensation in the event of an accounting restatement resulting from material noncompliance with financial reporting requirements under the federal securities laws of the United States.

Miscellaneous

16. The laws of the State of Israel shall apply to this Agreement and the sole and exclusive place of jurisdiction in any matter arising out of or in connection with this Agreement shall be the Tel-Aviv Regional Labor Court. The provisions of this Agreement are in lieu of the provisions of any collective bargaining agreement, and therefore, no collective bargaining agreement shall apply with respect to the relationship between the parties hereto (subject to the applicable provisions of law). No failure, delay or

forbearance of either party in exercising any power or right hereunder shall in any way restrict or diminish such party's rights and powers under this Agreement, or operate as a waiver of any breach or nonperformance by either party of any terms or conditions hereof. In the event it shall be determined under any applicable law that a certain provision set forth in this Agreement is invalid or unenforceable, such determination shall not affect the remaining provisions of this Agreement, unless the business purpose of this Agreement is substantially frustrated thereby. The preface and exhibits to this Agreement constitute an integral and indivisible part hereof. This Agreement constitutes the entire understanding and agreement between the parties hereto, supersedes any and all prior discussions, agreements and correspondence with regard to the subject matter hereof, and may not be amended, modified or supplemented in any respect, except by a subsequent writing executed by both parties hereto. The Employee acknowledges and confirms that all terms of the Employee's employment are personal and confidential, and undertake to keep such terms in confidence and refrain from disclosing such terms to any third party. All references to applicable law are deemed to include all applicable and relevant laws and ordinances and all regulations and orders promulgated there under, unless the context otherwise requires. The parties agree that this Agreement constitutes, among others, notification in accordance with the Notice to Employees (Employment Terms) Law, 2002. Nothing in this Agreement shall derogate from the Employee's rights according to any applicable law, extension order, collective agreement or other agreement with respect to the terms of Employee's employment.

IN WITNESS WHEREOF the parties hereto have signed this Agreement as of the date first hereinabove set forth.

LabStyle Innovation Ltd.	**Tomer Ben Kiki**

Exhibit A

To the Personal Employment Agreement by and between
LabStyle Innovation Ltd. and the Employee whose name is set forth herein

1. Name of Employee:	Tomer Ben Kiki
2. I.D. No. of Employee:	024956120
3. Address of Employee:	2 Levi Eshkol St. Tel Aviv, Israel
4. Position in the Company:	Head of Innovation
5. Under the Direct Direction of:	Erez Raphael
6. Commencement Date:	February 16,2024
7. Notice Period:	90 Days
8. Monthly Base Salary:	NIS 52,000
9. Additional Compensation:	NIS 13,000
10. Vacation Days Per Year:	11
11. Travel Allowance	NIS250
12. Sick Leave Days Per Year:	The Employee should be entitled to fully paid sick leave pursuant to applicable sick law.
13. Parking:	Employee shall be entitled to subscription to a parking space at the Company's premises.
14. Bonus	Employee will be eligible for an individual bonus of up to 20% of the Salary based upon Company performance, individual performance and subject to continued employment through the payment date and the other terms and conditions established by the CEO from time to time.

Exhibit B

To the Personal Employment Agreement by and between
LabStyle Innovation Ltd. and the Employee whose name is set forth herein

Name of Employee: **Tomer Ben Kiki**
I.D. No. of Employee: 024956120
Date: February 16, 2024 _____(the "**Commencement Date**")

General

1. Capitalized terms herein shall have the meanings ascribed to them in the Agreement to which this Exhibit is attached (the "**Agreement**"). For purposes of any undertaking of the Employee toward the Company, the term "Company" shall include any parent company, subsidiaries and affiliates of the Company. The Employee's obligations and representations and the Company's rights under this Exhibit shall apply as of the Commencement Date, regardless of the date of execution of the Agreement.

Confidentiality; Proprietary Information

2. "**Proprietary Information**" means confidential and proprietary information concerning the business and financial activities of the Company, including, without limitation, patents, patent applications, trademarks, copyrights and other intellectual property, and information relating to the same, technologies and products (actual or planned), know how, inventions, research and development activities, inventions, trade secrets and industrial secrets, and also confidential commercial information such as investments, investors, employees, customers, suppliers, marketing plans, etc., all the above - whether documentary, written, oral or computer generated. Proprietary Information shall also include information of the same nature which the Company may obtain or receive from third parties.
3. Proprietary Information shall be deemed to include any and all proprietary information disclosed by or on behalf of the Company and irrespective of form but excluding information that (i) was known to Employee prior to Employee's association with the Company, as evidenced by written records; (ii) is or shall become part of the public knowledge except as a result of the breach of the Agreement or this Exhibit by Employee; (iii) reflects general skills and experience; or (iv) reflects information and data generally known in the industries or trades in which the Company operates.
4. Employee recognizes that the Company received and will receive confidential or proprietary information from third parties, subject to a duty on the Company's part to maintain the confidentiality of such information and to use it only for certain limited purposes. In connection with such duties, such information shall be deemed Proprietary Information hereunder, *mutatis mutandis*.
5. Employee agrees that all Proprietary Information, and patents, trademarks, copyrights and other intellectual property and ownership rights in connection therewith shall be the sole property of the Company and its assigns. At all times, both during the employment relationship and after the termination of the engagement between the parties, Employee will keep in confidence and trust all Proprietary Information, and will not use or disclose any Proprietary Information or anything relating to it without the written consent of the Company, except as may be necessary in the ordinary course of performing Employee's duties under the Agreement.
6. Upon termination of Employee's engagement with the Company, Employee will promptly deliver to the Company all documents and materials of any nature pertaining

to Employee's engagement with the Company, and will not take with him any documents or materials or copies thereof containing any Proprietary Information.

7. Employee's undertakings set forth in Section 1 through Section 6 shall remain in full force and effect after termination of the Agreement or any renewal thereof.

Disclosure and Assignment of Inventions

8. "**Inventions**" means any and all inventions, improvements, designs, concepts, techniques, methods, systems, processes, know how, computer software programs, databases, mask works and trade secrets, whether or not patentable, copyrightable or protectable as trade secrets; "**Company Inventions**" means any Inventions that are made or conceived or first reduced to practice or created by Employee, whether alone or jointly with others, during the period of Employee's engagement with the Company, and which are: (i) developed using equipment, supplies, facilities or Proprietary Information of the Company, (ii) result from work performed by Employee for the Company, or (iii) related to the field of business of the Company, or to current or anticipated research and development.

9. Employee hereby confirms that all rights that he may have had at any time in any and all Company's Inventions, are and have been from inception in the sole ownership of the Company, including during the process of its incorporation. If ever any doubt shall arise as to the Company's rights or title in any Invention and it shall be asserted that the Employee, allegedly, is the owner of any such rights or title, then Employee hereby irrevocably transfer and assign in whole to the Company without any further royalty or payment any and all rights, title and interest in any and all Inventions. Employee has listed below in this Section 9 a complete list of all Inventions to which he claim ownerships (the "**Prior Inventions**") and that he desires to remove from the operation of this Agreement, and acknowledges and agrees that such list is complete. If no such list is attached to this Agreement, Employee represents that he has no such Inventions at the time of signing this Agreements. The Prior Inventions, if any, patented or unpatented, are excluded from the scope of this Agreement. If, in the course of employment with the Company, Employee incorporates a Prior Invention into a Company product, process or machine, the Company is hereby granted and shall have a nonexclusive, royalty-free, irrevocable, perpetual, worldwide license (with rights to sublicense through multiple tiers of sublicensees) to make, have made, modify, use and sell such Prior Invention. Notwithstanding the foregoing, Employee agrees that he will not incorporate, or permit to be incorporated, Prior Inventions in any Company Inventions without the Company's prior written consent. Employee hereby represents and undertakes that none of his previous employers or any entity with whom he was engaged, has any rights in the Inventions or Prior Inventions and such employment with the Company will not grant any of them any right in the results of the Employee's work.

Prior Inventions: ***[fill-in, if any.]***

None.

10. Employee undertakes and covenants he will promptly disclose in confidence to the Company all Inventions deemed as Company Inventions. The Employee agrees and undertakes not to disclose to the Company any confidential information of any third party and, in the framework of his employment by the Company, not to make any use of any intellectual property rights of any third party.

11. Employee hereby irrevocably transfers and assigns to the Company all worldwide patents, patent applications, copyrights, mask works, trade secrets and other intellectual property rights in any Company Invention, and any and all moral rights that he may have in or with respect to any Company Invention. For the removal of any doubt, it is hereby

clarified that the provisions concerning assignment of Inventions contained in Section 8 and this Section 11 will apply also to any "Service Inventions" as defined in the Israeli Patent Law, 1967 (the "**Patent Law**"). However, in no event will such Service Invention become the property of the Employee and the provisions contained in Section 132(b) of the Patent Law shall not apply unless the Company provides in writing otherwise. The Employee will not be entitled to royalties or other payment with regard to any Prior Inventions, Company Inventions, Service Inventions or any of the intellectual property rights set forth above, including any commercialization of such Prior Inventions, Company Inventions, Service Inventions or other intellectual property rights. The Employee irrevocably confirms that the consideration explicitly set forth in the employment agreement is in lieu of any rights for compensation that may arise in connection with the Inventions under applicable law and the employee hereby expressly and irrevocably confirms that the provisions contained in Section 134 of the Patent Law shall not apply and he waives any right to claim royalties or other consideration with respect to any Invention.

12. Employee agrees to assist the Company, at the Company's expense, in every proper way to obtain for the Company and enforce patents, copyrights, mask work rights, and other legal protections for the Company Inventions in any and all countries. Employee will execute any documents that the Company may reasonably request for use in obtaining or enforcing such patents, copyrights, mask work rights, trade secrets and other legal protections. Such obligation shall continue beyond the termination of Employee's engagement with the Company. Employee hereby irrevocably designates and appoints the Company and its authorized officers and agents as Employee's agent and attorney in fact, coupled with an interest to act for and on Employee's behalf and in Employee's stead to execute and file any document needed to apply for or prosecute any patent, copyright, trademark, trade secret, any applications regarding same or any other right or protection relating to any Proprietary Information (including Company Inventions), and to do all other lawfully permitted acts to further the prosecution and issuance of patents, copyrights, trademarks, trade secrets or any other right or protection relating to any Proprietary Information (including Company Inventions), with the same legal force and effect as if executed by Employee himself.

Non-Competition

13. In consideration of Employee's terms of employment hereunder, which include special compensation for his undertakings under this Section 13 and the following Section 14, and in order to enable the Company to effectively protect its Proprietary Information, Employee agrees and undertakes that he will not, so long as the Agreement is in effect and for a period of twelve (12) months following termination of the Agreement, for any reason whatsoever, directly or indirectly, in any capacity whatsoever, engage in, become financially interested in, be employed by, or have any connection with any business or venture that is engaged in any activities competing with the activities of the Company. Employee hereby acknowledges and agrees that the Salary and social benefits to which the Employee is or shall be entitled to, if any, as set forth in the Agreement, is set to a level which reflects adequate compensation sufficient to reimburse prejudice, if any, including but not limited to any of Employee's legitimate rights and interests. Employee further warrants and represents that the Special Non-Competition Monthly Compensation (as defined in the Agreement) constitutes a real, appropriate and full consideration to any prejudice Employee may suffer due to his non-competition undertakings and obligations set forth in this Exhibit, including but not limited to restriction of his freedom of employment.

14. Employee agrees and undertakes that during the employment relationship and for a period of twelve (12) months following termination of this engagement for whatever reason, Employee will not, directly or indirectly, including personally or in any business

in which Employee may be an officer, director or shareholder, solicit for employment any person who is employed by the Company, or any person retained by the Company as a consultant, advisor or the like who is subject to an undertaking towards the Company to refrain from engagement in activities competing with the activities of the Company (for purposes hereof, a "**Consultant**"), or was retained as an employee or a Consultant during the six months preceding termination of Employee's employment with the Company.

Reasonableness of Protective Covenants

15. Insofar as the protective covenants set forth in this Exhibit are concerned, Employee specifically acknowledges, stipulates and agrees as follows: (i) the protective covenants are reasonable and necessary to protect the goodwill, property and Proprietary Information of the Company, and the operations and business of the Company; and (ii) the time duration of the protective covenants is reasonable and necessary to protect the goodwill and the operations and business of Company, and does not impose a greater restrain than is necessary to protect the goodwill or other business interests of the Company. Nevertheless, if any of the restrictions set forth in this Exhibit is found by a court having jurisdiction to be unreasonable or overly-broad as to geographic area, scope or time or to be otherwise unenforceable, the parties hereto intend for the restrictions set forth in this Exhibit to be reformed, modified and redefined by such court so as to be reasonable and enforceable and, as so modified by such court, to be fully enforced.

Remedies for Breach

16. Employee acknowledges that the legal remedies for breach of the provisions of this Exhibit may be found inadequate and therefore agrees that, in addition to all of the remedies available to Company in the event of a breach or a threatened breach of any of such provisions, the Company may also, in addition to any other remedies which may be available under applicable law, obtain temporary, preliminary and permanent injunctions against any and all such actions.

Intent of Parties

17. Employee recognizes and agrees: (i) that this Exhibit is necessary and essential to protect the business of Company and to realize and derive all the benefits, rights and expectations of conducting Company's business; (ii) that the area and duration of the protective covenants contained herein are in all things reasonable; and (iii) that good and valuable consideration exists under the Agreement, for Employee's agreement to be bound by the provisions of this Exhibit.

IN WITNESS WHEREOF the Employee has signed this Agreement as of the date first hereinabove set forth.

_____

Tomer Ben Kiki

Exhibit C

GENERAL APPROVAL REGARDING PAYMENTS BY EMPLOYERS TO A PENSION FUND AND INSURANCE FUND IN LIEU OF SEVERANCE PAY UNDER THE SEVERANCE PAY LAW, 5723-1963

אישור כללי בדבר תשלומי מעבידים לקרן פנסיה ולקופת ביטוח במקום פיצויי פיטורים (י"פ 4659 התשנ"ח; י"פ 4803 התש"ס,5; י"פ 4970 התשס"א, 1949)

בתוקף סמכותי לפי סעיף 14 לחוק פיצויי פיטורים, התשכ"ג- 1963 (להלן - החוק), אני מאשר כי תשלומים ששילם מעביד החל ביום פרסומו של אישור זה, בעד עובדו לפנסיה מקיפה בקופת גמל לקצבה שאינה קופת ביטוח כמשמעותה בתקנות מס הכנסה (כללים לאישור ולניהול קופות גמל), התשכ"ד- 1964 (להלן - קרן פנסיה), או לביטוח מנהלים הכולל אפשרות לקצבה או שילוב של תשלומים לתוכנית קיצבה ולתוכנית שאינה לקיצבה בקופת ביטוח כאמור (להלן - קופת ביטוח), לרבות תשלומים ששילם תוך שילוב של תשלומים לקרן פנסיה ולקופת ביטוח בין אם יש בקופת ביטוח תוכנית לקיצבה ובין אם לאו, (להלן - תשלומי המעביד), יבואו במקום פיצויי הפיטורים המגיעים לעובד האמור בגין השכר שממנו שולמו התשלומים האמורים ולתקופה ששולמו (להלן - השכר המופטר), ובלבד שנתקיימו כל אלה:

(1) תשלומי המעביד

(א) לקרן פנסיה אינם פחותים מ- 14.33% מן השכר המופטר או 12% מן השכר המופטר אם משלם המעביד בעד עובדו בנוסף לכך גם תשלומים להשלמת פיצויי פיטורים לקופת גמל לפיצויים או לקופת ביטוח על שם העובד בשיעור של 2.33% מן השכר המופטר. לא שילם המעביד בנוסף ל- 12% גם 2.33% כאמור, יבואו תשלומיו במקום 72% מפיצויי הפיטורים של העובד, בלבד;

(ב) לקופת ביטוח אינם פחותים מאחד מאלה:

(1) 13.33% מן השכר המופטר, אם משלם המעביד בעד עובדו. בנוסף לכך גם תשלומים להבטחת הכנסה חודשית במקרה אובדן כושר עבודה, בתכנית שאישר הממונה על שוק ההון ביטוח וחסכון במשרד האוצר, בשיעור הדרוש להבטחת 75% מן השכר המופטר לפחות או בשיעור של 2.5% מן השכר המופטר, לפי הנמוך מביניהם (להלן - תשלום לביטוח אובדן כושר עבודה);

(2) 11% מן השכר המופטר, אם שילם המעביד בנוסף גם תשלום לביטוח אובדן כושר עבודה, ובמקרה זה יבואו תשלומי המעביד במקום 72% מפיצויי הפיטורים של העובד, בלבד; שילם המעביד נוסף על אלה גם תשלומים להשלמת פיצויי פיטורים לקופת גמל לפיצויים או לקופת ביטוח על שם העובד בשיעור של 2.33% מן השכר המופטר, יבואו תשלומי המעביד במקום 100% פיצויי הפיטורים של העובד.

(2) לא יאוחר משלושה חודשים מתחילת ביצוע תשלומי המעביד נערך הסכם בכתב בין המעביד לבין העובד ובו -

(א) הסכמת העובד להסדר לפי אישור זה בנוסח המפרט את תשלומי המעביד ואת קרן הפנסיה וקופת הביטוח, לפי הענין; בהסכם האמור ייכלל גם נוסחו של אישור זה;

(ב) ויתור המעביד מראש על כל זכות שיכולה להיות לו להחזר כספים מתוך תשלומיו, אלא אם כן נשללה זכות העובד לפיצויי פיטורים בפסק דין מכח סעיפים 16 או 17 לחוק ובמידה שנשללה או שהעובד משך כספים מקרן הפנסיה או מקופת הביטוח שלא בשל אירוע מזכה; לעניין זה, "אירוע מזכה" - מוות, נכות או פרישה בגיל שישים או יותר.

(3) אין באישור זה כדי לגרוע מזכותו של עובד לפיצויי פיטורים לפי החוק, הסכם קיבוצי, צו הרחבה או חוזה עבודה, בגין שכר שמעבר לשכר המופטר.

*הנוסח של האישור הכללי עשוי להתעדכן בתקופה הקרובה, וכל מקרה של סטירה בין שיעורי הפרשות באישור הכללי לבין הסכם העבודה, יש להתייחס לשיעורי ההפרשות בהסכם העבודה.

Exhibit 21.1

Subsidiaries of the Registrant

Labstyle Innovation Ltd., an Israeli company
PsyInnovations Inc., a Delaware company
DarioHealth India Services Pvt. Ltd., an Indian company
Twill, Inc., a Delaware company

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statements:

(1) Registration Statement (Form S-3 Nos. 333-273019, 333-269092, 333-265992, 333-260439 and 333-254968) of DarioHealth Corp., and

(2) Registration Statement (Form S-8 Nos. 333-277215, 333-276617, 333-269147, 333-262056, 333-256897, 333-251968, 333-249474 and 333-269147) pertaining to 2020 Equity incentive Plan of DarioHealth Corp.

of our report dated March 28, 2024, with respect to the consolidated financial statements of DarioHealth Corp. included in this Annual Report (Form 10-K) for the year ended December 31, 2023.

Tel-Aviv, Israel
March 28, 2024

/s/ Kost Forer Gabbay & Kasierer
A Member of EY Global

Exhibit 31.1

CERTIFICATION
OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO RULE 13A-14(A) AND 15D-14(A)
UNDER THE SECURITIES EXCHANGE ACT OF 1934

I, Erez Raphael, certify that:

1. I have reviewed this Annual Report on Form 10-K of DarioHealth Corp. (the "Registrant");

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

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

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13-a13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: March 28, 2024

/s/ Erez Raphael
Erez Raphael
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION
OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO RULE 13A-14(A) AND 15D-14(A)
UNDER THE SECURITIES EXCHANGE ACT OF 1934

I, Zvi Ben David, certify that:

1. I have reviewed this Annual Report on Form 10-K of DarioHealth Corp. (the "Registrant");

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

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

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13-a13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

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

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

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

Date: March 28, 2024

/s/ Zvi Ben David
Zvi Ben David
Chief Financial Officer, Secretary and Treasurer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION
OF PRINCIPAL EXECUTIVE OFFICER AND
PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U. S. C. SECTION 1350,

In connection with the Annual Report of DarioHealth Corp. (the "Company") on Form 10-K for the period ended December 31, 2023 (the "Report"), I, Erez Raphael, Chief Executive Officer of the Company, and I, Zvi Ben David, Chief Financial Officer of the Company, hereby certify pursuant to 18 U.S.C. Section 1350, that to my knowledge:

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

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

Date: March 28, 2024

/s/ Erez Raphael
Erez Raphael
Chief Executive Officer
(Principal Executive Officer)

Date: March 28, 2024

/s/ Zvi Ben David
Zvi Ben David
Chief Financial Officer, Secretary and Treasurer
(Principal Financial Officer)

DARIOHEALTH CORP. (the "Company")

CLAWBACK POLICY

Effective as of October 30, 2023

Background

The Board of Directors of the Company (the "**Board**") believes that it is in the best interests of the Company and its shareholders to create and maintain a culture that emphasizes integrity and accountability and that reinforces the Company's pay-for-performance compensation philosophy. The Board has therefore adopted this policy, which provides for the recoupment (or clawback) of certain executive compensation in the event of an accounting restatement resulting from material noncompliance with financial reporting requirements under the federal securities laws of the United States (the "**Policy**"). This Policy is designed to comply with Section 10D of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), Rule 10D-1 promulgated under the Exchange Act ("**Rule 10D-1**") and the listing standards of the Nasdaq Stock Market ("**Nasdaq**") under Nasdaq Listing Rule 5608.

Administration

This Policy shall be administered by the Compensation Committee of the Board (the "**Compensation Committee**"). Any determinations made by the Board shall be final and binding on all affected individuals. Subject to any limitation under applicable law, the Board may authorize and empower any officer or employee of the Company to take any and all actions necessary or appropriate to carry out the purpose and intent of this Policy (other than with respect to any recovery under this Policy involving such officer or employee).

Covered Executives

This Policy applies to the Company's current and former executive officers, as determined by the Board in accordance with Section 10D of the Exchange Act and the listing standards of the Nasdaq ("**Covered Executives**").

Recoupment; Accounting Restatement

In the event the Company is required to prepare an accounting restatement of its financial statements due to the Company's material noncompliance with any financial reporting requirement under the securities laws, the Board will require prompt reimbursement or forfeiture of any excess Incentive Compensation (as defined below) received by any Covered Executive during the three completed fiscal years immediately preceding the date on which the Company is required to prepare an accounting restatement. For the sake of clarity, recoupment is required in the event of any restatement that either: (a) corrects an error in previously issued financial statements that is material to the previously issued financial statements; or (b) corrects an error not material to previously issued financial statements, but that would result in a material misstatement if (i) the error was left uncorrected in the then current period; or (ii) the error correction was recognized in the then current period. The Company's obligation to recover

erroneously awarded compensation is not dependent on if or when the restated financial statements are filed. For purposes of determining the relevant recovery period, the date that the Company is required to prepare an accounting restatement as described above is the earlier to occur of: (A) the date the Board, a committee of the Board, or the officer or officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an accounting restatement as described above; or (B) the date a court, regulator, or other legally authorized body directs the Company to prepare an accounting restatement as described above. In accordance with Nasdaq Rule 5608(e), this Policy is applicable to Incentive Compensation received on or after October 2, 2023.

Incentive Compensation

For purposes of this Policy, "Incentive Compensation" means any of the following, provided that such compensation is granted, earned or vested based wholly or in part on the attainment of a financial reporting measure affected by the restated financial statements:

- Annual bonuses and other short- and long-term cash incentives.
- Stock options.
- Stock appreciation rights.
- Restricted stock.
- Restricted stock units.
- Performance shares.
- Performance units.

Financial reporting measures are measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures that are derived wholly or in part from such measures. Stock price and total shareholder return are also financial reporting measures. A financial reporting measure need not be presented within the financial statements or included in a filing with the Securities and Exchange Commission. The Company's financial reporting measures may include, but are not limited to, the following:

- Revenues.
- Net income.
- Earnings before interest, taxes, depreciation and amortization (EBITDA).
- Funds from operations.
- Liquidity measures such as working capital, operating cash flow or Free Cash Flow.

This Policy applies to all Incentive Compensation received by a Covered Person:

- After beginning service as an executive officer;
- Who served as an executive officer at any time during the performance period for that Incentive Compensation;
- While the Company has a class of securities listed on a national securities exchange or a national securities association; and
- During the three completed fiscal years immediately preceding the date that the Company is required to prepare an accounting restatement as described in this Policy. In addition to these last three completed fiscal years, this Policy applies to any transition period (that results from a

change in the Company's fiscal year) within or immediately following those three completed fiscal years. However, a transition period between the last day of the Company's previous fiscal year end and the first day of its new fiscal year that comprises a period of nine to 12 months would be deemed a completed fiscal year.

Incentive Compensation is deemed received in the Company's fiscal period during which the financial reporting measure specified in the Incentive Compensation award is attained, even if the payment or grant of the Incentive Compensation occurs after the end of that period.

Excess Incentive Compensation: Amount Subject to Recovery

The amount to be recovered will be the excess of the Incentive Compensation paid to the Covered Executive based on the erroneous data over the Incentive Compensation that would have been paid to the Covered Executive had it been based on the restated results, as determined by the Board, and without regard to any taxes paid by or withheld from the Covered Executive. If the Board cannot determine the amount of excess Incentive Compensation received by the Covered Executive directly from the information in the accounting restatement, then it will make its determination based on a reasonable estimate of the effect of the accounting restatement. For Incentive Compensation based on stock price or total shareholder return, where the amount of erroneously awarded compensation is not subject to mathematical recalculation directly from the information in an accounting restatement, the amount will be based on a reasonable estimate of the effect of the accounting restatement on the stock price or total shareholder return upon which the Incentive Compensation was received. In such case, the Company shall maintain documentation of the determination of that reasonable estimate and provide such documentation to Nasdaq.

Method of Recoupment

The Board will determine, in its sole discretion, the method for recouping Incentive Compensation hereunder which may include, without limitation:

- Requiring reimbursement of cash Incentive Compensation previously paid;
- Seeking recovery of any gain realized on the vesting, exercise, settlement, sale, transfer, or other disposition of any equity-based awards;
- Offsetting the recouped amount from any compensation otherwise owed by the Company to the Covered Executive in accordance with applicable law;
- Cancelling outstanding vested or unvested equity awards; and/or
- Taking any other remedial and recovery action permitted by law, as determined by the Board.

No Indemnification

The Company shall not indemnify any Covered Executives against the loss of any Incentive Compensation recovered under this Policy or from any consequence arising therefrom.

Interpretation

The Board is authorized to interpret and construe this Policy and to make all determinations necessary, appropriate or advisable for the administration of this Policy. It is intended that this Policy be interpreted in a manner that is consistent with the requirements of Section 10D of the Exchange Act, Rule 10D-1 and any applicable rules or standards adopted by the Securities and Exchange Commission or Nasdaq.

Effective Date

This Policy shall be effective as of the date it is adopted by the Board (the "**Effective Date**") and shall apply to Incentive Compensation that is approved, awarded or granted to Covered Executives on or after that date.

Amendment; Termination

The Board may amend this Policy from time to time in its discretion and shall amend this Policy as it deems necessary to reflect regulations adopted by the Securities and Exchange Commission under Section 10D of the Exchange Act and to comply with any rules or standards adopted by Nasdaq. The Board may terminate this Policy at any time.

Other Recoupment Rights

The Board intends that this Policy will be applied to the fullest extent of the law. The Board may require that any employment agreement, equity award agreement, or similar agreement entered into or amended on or after the Effective Date shall, as a condition to the grant of any benefit thereunder, require a Covered Executive to agree to abide by the terms of this Policy. Any right of recoupment under this Policy is in addition to, and not in lieu of: (a) any other remedies or rights of recoupment that may be available to the Company pursuant to the terms of any similar policy in any employment agreement, equity award agreement or similar agreement and any other legal remedies available to the Company, including termination of employment or institution of legal proceedings; and (b) any statutory recoupment requirement, including Section 304 of the Sarbanes-Oxley Act of 2022. For the avoidance of doubt, any amounts paid to the Company pursuant to Section 304 of the Sarbanes-Oxley Act of 2022 shall be considered (and may be credited) in determining any amounts recovered under this Policy.

Impracticability

The Board shall recover any excess Incentive Compensation in accordance with this Policy unless such recovery would be impracticable, as determined in accordance with Rule 10D-1(b)(1)(iv) under the Exchange Act and the listing standards of Nasdaq. In order for the Company to determine that recovery would be impracticable, the Company's Compensation Committee must conclude the following:

a) The direct expense paid to a third party to assist in enforcing this Policy would exceed the amount to be recovered after making a reasonable attempt to recover such Incentive Compensation. Note that the attempt(s) to recover must be documented by the Company and such documentation provided to Nasdaq;
b) Recovery would violate home country law where that law was adopted prior to November 28, 2022. Note that the Company must obtain a legal opinion of home country counsel that such

recovery would result in a violation of local law and provide such opinion to Nasdaq; or

c) Recovery would likely cause an otherwise tax-qualified retirement plan under which benefits are broadly available to Company employees to fail to meet the requirements for qualified pension, profit-sharing and stock bonus plans under Section 401(a)(13) of the U.S. Internal Revenue Code or the minimum vesting standards under Section 411(a) of the U.S. Internal Revenue Code.

Successors

This Policy shall be binding and enforceable against all Covered Executives and their beneficiaries, heirs, executors, administrators or other legal representatives.

Exhibit Filing

A copy of this Policy shall be filed as an exhibit to the Company's annual report on Form 10-K.

ATTESTATION AND ACKNOWLEDGEMENT OF CLAWBACK POLICY FOR DARIOHEALTH CORP. (the "Company")

By my signature below, I acknowledge and agree that:

- I have received and read the attached Clawback Policy (this "Policy") of the Company.
- I hereby agree to abide by all of the terms of this Policy both during and after my employment with the Company, including, without limitation, by promptly repaying or returning any incorrectly awarded Incentive Compensation to the Company as determined in accordance with this Policy.

Signature: _____

Printed Name: _____

Date: _____