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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, 2022

☐ **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)
18 W. 18th St. **New York, New York** (Address of principal executive offices)	**10011** (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 $131,540,173.

As of March 6, 2023, the registrant had outstanding 25,871,889 shares of common stock, $0.0001 par value per share.

Documents Incorporated By Reference: None.

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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;
- the impact of the COVID-19 pandemic on our manufacturing, sales, business plan and the global economy;
- 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, 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.

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.

We continue to generate a significant number of clinical publications. In that regard, we the have published 38 real world data studies with total of 10 generated in 2022, and several more already planned for 2023.

Recent Developments

Integration of Dexcom CGM Data

We collaborated with Dexcom to integrate the data from its market-leading Continuous Glucose Monitoring ("CGMs)" technology, which uses a small, wearable sensor to continuously measure and send glucose levels to a receiver or smart device to enable better real-time decision making for people living with diabetes, into our multi-chronic condition platform. This partnership, signed in early 2023, enables the integration of data from Dexcom CGMs directly into our metabolic solution, making it easy for people using the wearable device to benefit from our highly personalized support.

Sanofi

Our 2022 agreement with Sanofi continues to evolve after the first year of our agreement across all three pillars of the agreement. First, our co-promotion efforts are yielding a healthy pipeline of health plans and Pharmacy Benefit Managers ("PBMs"), and we have several opportunities in or close to contracting. Second, our product development has yielded several new features currently in beta testing with our consumer membership. We expect that these features will be released more broadly to the market in the spring of 2023. Third and finally, we are preparing our first two research studies with Sanofi with the release of data expected in the summer of 2023.

Director and Officers

In January 2023, we announced that we executed a Termination of Employment and Separation with Dror Bacher, our prior Chief Operating Officer, pursuant to which Mr. Bacher's position as Chief Operating Officer was terminated with immediate effect. We have retained Mr. Bacher as a member of our advisory board.

In February 2023, on the recommendation of the Nominating Committee of the Board of Directors, we expanded the Board by one seat and appointed Jon Kaplan as a member of the Board.

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.

Two years post-shift from our business-to-consumer into a B2B2C business model, we believe that the financial impacts are validating our growth and DTaaS theses. Our pro-forma gross profit for the quarter ended December 31, 2022, excluding acquisition related amortizations, has improved to 50% of revenues in 2022 compared to 39% of revenues in 2021. In 2022, our commercial revenue exceeded our consumer revenue.

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 in a study in mid-2023.

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 250,000 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 80 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 in 2023 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.

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*

Method*: 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*

Method: *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

- *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 of 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.

Method*: 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 on 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

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

Method: *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

Method*: 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

Method: *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 February 2020, we presented an additional clinical study at the Advanced Technologies & Treatments for Diabetes (“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

***Method*:** 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 year 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.

***Method*:** 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.

***Method*:** 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. Post-meal readings ratio of <180 mg/dL per entire post-meal measurements increased by 5% (73.75% vs. 70.42%) on average over a year.

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.

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:
  - 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:
  - 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.

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 by 13% 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.

***Method*:** 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.

Method: 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.

***Method*:** 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 55. The group also included 173 users whose starting average blood glucose was <180 mg/dL with average age 59. 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±40.6 vs. 204±42.7) 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 *"Journal of Diabetes Science and Technology"* the article:

"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 T2DM. Future research should replicate our findings using a larger sample.

***Method*:** 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 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.

***Method*:** 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.

***Method*:** 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.

Method: 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 article 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.

Method**:** 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 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™ 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.

***Method*:** A retrospective data evaluation was performed on the Dario data base. 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.

Method: 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 1000 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 were 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, 6^{th} and 12^{th} 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, 6^{th} and 12^{th} 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).

On 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.

Method: 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.

In December 2022, a first manuscript was published in a peer-reviewed journal 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).

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, devices are subject to varying levels of regulatory control, the most comprehensive of which requires that a clinical evaluation is conducted before a device receives clearance for commercial distribution. Under Section 201(h) of the Food, Drug, and Cosmetic Act, a medical device is an article, which, among other things, is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man or other animals. The 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 product design and development, pre-clinical and clinical testing, manufacturing, labeling, storage, pre-market clearance or approval, advertising and promotion, and sales and distribution. Specifically, the FDA classifies medical devices into one of three classes. Class I devices are relatively simple and can be manufactured and distributed with general controls. Class II devices are somewhat more complex and require greater scrutiny. Class III devices are new and frequently help sustain life.

Unless an exemption applies, each medical device commercially distributed in the United States will require a 510(k) clearance, 510(k)+ “de-novo” clearance, or pre-market approval (or PMA) from the FDA.

510(k) Clearance Process. 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. If the FDA denies 510(k) clearance of a device because it is novel and an adequate predicate device does not exist, the “de novo classification” procedure can be invoked based upon a reasonable assurance that the device is safe and effective for its intended use. This procedure approximates the level of scrutiny in the 510(k)

process but may add several months to the clearance process. If the FDA grants the request, the device is permitted to enter commercial distribution in the same manner as if 510(k) clearance had been granted.

Premarket Application Approval Process. After approval of a premarket application, a new premarket application or premarket application supplement is required in the event of a modification to the device, its labeling or its manufacturing process. The premarket application approval pathway is much more costly, lengthy and uncertain. It generally takes from one to three years or longer.

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.

The commercialization of medical devices in Europe is regulated by the European Union. The European Union presently requires that all medical products bore the CE mark, an international symbol of adherence to quality assurance standards and demonstrated clinical effectiveness. Compliance with the Medical Device Directive (MDD) or the Active Implantable Medical Device Directive (AIMD) or the In Vitro Diagnostic Medical Device Directive (IVDD) as audited by a notified body and certified by a recognized European Competent Authority, permits the manufacturer to affix the CE mark on its products.

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 may be tedious. 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.

Clinical Studies

Even when a clinical study has an approved Investigational Device Exemption (IDE) from the FDA under significant risk (SR) determination, has been approved by an Institutional Review Board (IRB) under non-significant risk (NSR) determination and/or has been approved by local or regional Ethics Committee, the study is subject to factors beyond a manufacturer’s control, including, but not limited to the fact that the institutional review board at a given clinical site might not approve the study, might decline to renew approval which is required annually, or might suspend or terminate the study before the study has been completed. 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.

Mobile Medical Applications Guidance

On September 23, 2013, the FDA issued final guidance for developers of mobile medical applications, or apps, which are software programs that run on mobile communication devices and perform the same functions as traditional medical devices. The guidance outlines the FDA's tailored approach to mobile apps. The FDA plans to exercise enforcement discretion (meaning it will not enforce requirements under the Federal Food, Drug & Cosmetic Act) for the majority of mobile apps as they pose minimal risk to consumers. The FDA plans to focus its regulatory oversight on a subset of mobile medical apps that present a greater risk to patients if they do not work as intended. The FDA is focusing its oversight on mobile medical apps that:

- are intended to be used as an accessory to a regulated medical device – for example, an application that allows a health care professional to make a specific diagnosis by viewing a medical image from a picture archiving and communication system (PACS) on a smart mobile device or a mobile tablet; or

- transform a mobile platform into a regulated medical device – for example, an application that turns a smart mobile device into an electrocardiography (ECG) machine to detect abnormal heart rhythms or determine if a patient is experiencing a heart attack.

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;

- quality system regulation, which requires 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 and removals 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 Federal Food, Drug and Cosmetic Act that may present a risk to health; 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.

Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, 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 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, an annual surveillance audit in the company premises and, if needed, at major subcontractors' premises needs to be carried out by the notified body. Additionally, European Directives dictate the following requirements:

- Vigilance system, which requires the manufacturer to immediately notify the relevant Competent Authority when a company product has been involved in an incident that led to a death; led to a serious injury or serious deterioration in the state of health of a patient, user or another person; or might have led to death, serious injury or serious deterioration in health; and

- Post-market surveillance including a documented procedure to review experience gained from devices on the market and to implement any necessary corrective action, commensurate with nature and risks involved with the product.

Failure to comply with applicable regulatory requirements can result in enforcement action by the regulatory agency, 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 clearance and/or registration of our products or granting clearance/registration for new products.

State Licensure Requirements

Several 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. 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.

Federal Anti-Kickback and Self-Referral Laws

The Federal Anti-Kickback Statute prohibits the knowing and willful offer, payment, solicitation or receipt of any form of remuneration in return for, or to induce the:

- referral of a person;

- furnishing or arranging for the furnishing of items or services reimbursable under Medicare, Medicaid or other governmental programs; or

- purchase, lease, or order of, or the arrangement or recommendation of the purchasing, leasing, or ordering of any item or service reimbursable under Medicare, Medicaid or other governmental programs.

To the extent we are required to comply with these regulations, it is possible that regulatory authorities could allege that we have not complied, which could subject us to sanction. Noncompliance with the federal anti-kickback legislation can result in exclusion from Medicare, Medicaid or other governmental programs, restrictions on our ability to operate in certain jurisdictions, as well as civil and criminal penalties, any of which could have an adverse effect on our business and results of operations.

Federal law also includes a provision commonly known as the "Stark Law," which prohibits a physician from referring Medicare or Medicaid patients to an entity providing "designated health services," including a company that furnishes durable medical equipment, in which the physician has an ownership or investment interest or with which the physician has entered into a compensation arrangement. Violation of the Stark Law could result in denial of payment, disgorgement of reimbursements received under a noncompliant arrangement, civil penalties, and exclusion from Medicare, Medicaid or other governmental programs.

Federal False Claims Act

The Federal False Claims Act provides, in part, that the federal government may bring a lawsuit against any person whom it believes has knowingly presented, or caused to be presented, a false or fraudulent request for payment from the federal government, or who has made a false statement or used a false record to get a claim approved. In addition, amendments in 1986 to the Federal False Claims Act have made it easier for private parties to bring "qui tam" whistleblower lawsuits against companies. Penalties include fines ranging from $5,500 to $11,000 for each false claim, plus three times the number of damages that the federal government sustained because of the act of that person.

Civil Monetary Penalties Law

The Federal Civil Monetary Penalties Law prohibits the offering or transferring of remuneration to a Medicare or Medicaid beneficiary that the person knows or should know likely to influence the beneficiary's selection of a particular supplier of Medicare or Medicaid payable items or services. Noncompliance can result in civil money penalties of up to $10,000 for each wrongful act, assessment of three times the amount claimed for each item or service and exclusion from the Federal healthcare programs.

State Fraud and Abuse Provisions

Many states have also adopted some form of anti-kickback and anti-referral laws and false claims acts. A determination of liability under such laws could result in fines and penalties and restrictions on our ability to operate in these jurisdictions.

Administrative Simplification of the Health Insurance Portability and Accountability Act of 1996

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, mandated the adoption of standards for the exchange of electronic health information in an effort to encourage overall administrative simplification and enhance the effectiveness and efficiency of the healthcare industry. Ensuring the privacy and security of patient information is one of the key factors driving the legislation.

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. In February 2016 we were granted U.S. patent No. 9,257,038, which is a further Continuation application connected to the U.S. patent No. 8,797,180, this new patent enhanced the way the Dario Blood Glucose Monitoring System communicates with the end user's smartphone devices.

In 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 Brazil, Canada, China, 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 the Australia, Canada, China, Costa Rica, United States, Israel, China, Canada, Hong Kong, South Africa, Japan, Costa Rica, Europe, Israel, Japan, Korea, Mexico, New Zealand, Panama, Russia, South Africa, and the USA. 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 PRO, UPRIGHT POSTURE IS WITHING REACH – registered in the US.

Utility Models

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

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.

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 February 28, 2023, we had 241 full-time employees and 11 part-time employees. We have employment agreements with our five 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 2023.

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 OrbiMed Royalty and Credit Opportunities III, LP, of which $25 million was made available in June 2022. 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 $62,193,000 and $76,761,000 in 2022 and 2021, respectively. Our accumulated deficit at December 31, 2022 was approximately $285,850,000. 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.

A pandemic, epidemic or outbreak of an infectious disease in the United States, Israel or elsewhere may adversely affect our business.

A regional or global health pandemic, including COVID-19, could severely affect our business, results of operations and financial condition. A regional or global health pandemic, depending upon its duration and severity, could have a material adverse effect on our business. For example, the COVID-19 pandemic has had numerous effects on the

global economy and governmental authorities around the world have implemented measures to reduce the spread of COVID-19. In addition, the COVID-19 pandemic has negatively impacted the global economy, disrupted consumer spending and global supply chains, and created significant volatility of financial markets. The COVID-19 pandemic may also impact our supply chain partners, including third-party manufacturers, logistics providers and other vendors. Current vessel, container and other transportation shortages, labor shortages and port congestion globally have delayed and may continue to delay inventory orders and, in turn, it may delay the delivery of our products to customers. In addition, the impact of COVID-19 on macroeconomic conditions may impact the proper functioning of financial and capital markets, foreign currency exchange rates, commodity prices, and interest rates. Even after the COVID-19 global pandemic has subsided, we may continue to experience adverse impacts to our business as a result of any economic recession that has occurred or may occur in the future.

Following the COVID-19 pandemic, many of our personnel continue to work remotely, it is possible that this could have a negative impact on the execution of our business plans and operations. If a natural disaster, power outage, connectivity issue, or other event occurred that impacted our employees' ability to work remotely, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The increase in remote working may also result in consumer privacy, IT security and fraud concerns as well as increase our exposure to potential wage and hour issues.

We are unable to accurately predict the impact that COVID-19 will have on our operations going forward due to uncertainties that will be dictated by the length of time that the pandemic and related disruptions continue, the impact of governmental regulations that might be imposed in response to the pandemic and overall changes in consumer behavior.

The extent to which COVID-19 will impact our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus, including the actions to contain COVID-19 or treat its impact, the efficacy and scale of the various vaccines currently deployed across the world, among others. Moreover, COVID-19 has had indeterminable adverse effects on general commercial activity and the world economy, and our business and results of operations could be adversely affected to the extent that COVID-19 or any other epidemic continues to harm the global economy generally. To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this "Risk factors" section.

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 Smart Diabetes Management 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 Smart Diabetes Management 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 Smart Diabetes Management 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 Smart Diabetes 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 Smart Diabetes Management 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 Smart Diabetes Management 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 Smart Diabetes 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 Upright and PsyInnovations, and the integration of these businesses could disrupt our ongoing business, distract our management and increase our expenses.

Through our acquisitions of Upright and PsyInnovations, we expanded our product offering to include solutions for MSK as well as behavioral conditions. We believe that the successful integration of Upright and PsyInnovations businesses 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 Upright and PsyInnovations 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 Upright and PsyInnovations 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 until we receive regulatory clearance. To date, we have received regulatory clearance 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. 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.

We are also subject to numerous post-marketing regulatory requirements, which include labeling regulations and medical device reporting regulations, which may 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. 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 510(k) clearance or pre-market approval of new products, new intended uses or modifications to Dario or future products;
- rescinding 510(k) clearance or suspending or withdrawing pre-market approvals 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.

In addition, on September 23, 2013, the FDA issued final guidance (which we refer to herein as the Guidance) for developers of mobile medical applications, or apps, which are software programs that run on mobile communication devices and perform the same functions as traditional medical devices. The Guidance outlines the FDA's tailored approach to mobile apps. The FDA plans to exercise enforcement discretion (meaning it will not enforce requirements under the Federal Food, Drug and Cosmetic Act) for the majority of mobile apps as they pose minimal risk to consumers. The FDA plans to focus its regulatory oversight on a subset of mobile medical apps that present a greater risk to patients if they do not work as intended. We anticipate that the Dario Smart Diabetes Management application will be subject to FDA regulation as a "mobile medical app."

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

To date, we have conducted limited clinical studies on Dario. There can be no assurance that we will successfully complete additional clinical studies 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 pre-clinical studies and clinical studies do not necessarily predict the results that will be obtained from later pre-clinical studies and clinical studies. Moreover, pre-clinical 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 studies, even after promising results in earlier studies. The failure to adequately demonstrate the safety and effectiveness of an intended product under development could delay or prevent regulatory clearance 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 approval for other potential applications of our principal technology, or that we will receive regulatory clearances 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:

- our 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;
- delays that we may experience in enrollment, or completion of certain trials, as a result of COVID-19;
- 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.

If our clinical trial is 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 Quality System Regulation (“QSR”) and are also subject to the regulations of foreign jurisdictions regarding the manufacturing process. If 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 QSR inspectional findings, the FDA 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. If independent investigators 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 standards, commonly referred to as good clinical practice, 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 good clinical practice, 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 have 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.

Legislative reforms to the United States healthcare system may adversely affect our revenues and business.

From time to time, legislative reform measures are proposed or adopted that would impact healthcare expenditures for medical services, including the medical devices used to provide those services. For example, in March 2010, U.S. President Barack Obama signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the Affordable Care Act. The Affordable Care Act made a number of substantial changes in the way health care is financed by both governmental and private insurers and the way that Medicare providers are reimbursed. Among other things, the Affordable Care Act requires certain medical device manufacturers and importers to pay an excise tax equal to 2.3% of the price for which such medical devices are sold, beginning January 1, 2013.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. On August 2, 2011, the President signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes reductions to Medicare payments to providers of 2.0% per fiscal year. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which delayed for another two months the budget cuts mandated by these sequestration provisions of the Budget Control Act of 2011. On March 1, 2013, the President signed an executive order implementing sequestration, and on April 1, 2013, the 2% Medicare payment reductions went into effect. The Bipartisan Budget Act of 2013, enacted on December 26, 2013, extends these cuts to 2023. The ATRA also, among other things, reduced Medicare payments to several providers, including hospitals, imaging centers, and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In December 2014, Congress passed an omnibus funding bill (the Consolidated and Further Continuing Appropriations Act, 2015) and a tax extenders bill, both of which may negatively impact coverage and reimbursement of healthcare items and services. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure. For example, former U.S. President Donald Trump publicly indicated an intent to lower healthcare costs through various potential initiatives. In addition, former President Trump and other U.S. lawmakers have made statements about potentially repealing and/or replacing the Affordable Care Act, although specific legislation for such repeal or replacement has not yet been introduced. While we are unable to predict what changes may ultimately be enacted, to the extent that future changes affect how our products are paid for and reimbursed by government and private payers our business could be adversely impacted.

Government and private sector initiatives to limit the growth of health care costs, including price regulation, competitive pricing, coverage and payment policies, comparative effectiveness reviews of therapies, technology assessments, and managed-care arrangements, are continuing. Government programs, including Medicare and Medicaid, private health care insurance and managed-care plans have attempted to control costs by limiting the amount of reimbursement they will pay for particular procedures or treatments, tying reimbursement to outcomes, and other mechanisms designed to constrain utilization and contain costs, including delivery reforms such as expanded bundling of services. Hospitals are also seeking to reduce costs through a variety of mechanisms, which may increase price sensitivity among customers for our products, and adversely affect sales, pricing, and utilization of our products. Some third-party payors must also approve coverage for new or innovative devices or therapies before they will reimburse health care

providers who use medical devices or therapies. We cannot predict the potential impact of cost-containment trends on future operating results.

We may be subject to federal, state and foreign healthcare fraud and abuse laws and regulations.

Many federal, state and foreign healthcare laws and regulations apply to the BGMS business and medical devices. We may be subject to certain federal and state regulations, including the federal healthcare programs' Anti-Kickback Law, the federal Health Insurance Portability and Accountability Act of 1996, and other federal and state false claims laws. The medical device industry has been under heightened scrutiny as the subject of government investigations and enforcement actions involving manufacturers who allegedly offered unlawful inducements to potential or existing customers in an attempt to procure their business, including arrangements with physician consultants. If our operations or arrangements are found to be in violation of such governmental regulations, we may be subject to civil and criminal penalties, damages, fines, exclusion from the Medicare and Medicaid programs and the curtailment of our operations. All of these penalties could adversely affect our ability to operate our business and our financial results.

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.

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.

We only recently commenced sales of our products, and most of our competitors have long histories and strong reputations within the industry. They have significantly greater brand recognition, financial and human resources than we do. They also have more experience and capabilities in researching and developing testing devices, obtaining and maintaining regulatory clearances and other requirements, manufacturing and marketing those products than we do. There is a significant risk that we may be unable to overcome the advantages held by our competition, and our inability to do so could lead to the failure of our business and the loss of your investment.

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. In addition, since February 2011, Egypt has experienced political turbulence and an increase in terrorist activity in the Sinai Peninsula. Such political turbulence and violence may damage peaceful and diplomatic relations between Israel and Egypt, and could affect the region as a whole. Similar civil unrest and political turbulence has occurred in other countries in the region, including Syria which shares a common border with Israel, and is affecting the political stability of those countries. This instability and any outside intervention may lead to deterioration of the political and economic relationships that exist between the State of Israel and some of these countries, and may have the potential for causing additional conflicts in the region. In addition, Iran has threatened to attack Israel and is widely believed to be developing nuclear weapons. Iran is also believed to have a strong influence among extremist groups in the region, such as Hamas in Gaza, Hezbollah in Lebanon, and various rebel militia groups in Syria. Additionally, a violent jihadist group named Islamic State of Iraq and Levant (ISIL) is involved in hostilities in Iraq and Syria and have been growing in influence. Although ISIL's activities have not directly affected the political and economic conditions in Israel, ISIL's stated purpose is to take control of the Middle East, including Israel. These situations may potentially escalate in the future to more violent events which may affect Israel and us. Any armed conflicts, terrorist activities or political instability in the region could adversely affect business conditions and could harm our results of operations and could make it more difficult for us to raise capital. Parties with whom we do business may decline to travel to Israel during periods of heightened unrest or tension, forcing us to make alternative arrangements when necessary in order to meet our business partners face to face. In addition, the political and security situation in Israel may result in parties with whom we have agreements involving performance in Israel claiming that they are not obligated to perform their commitments under those agreements pursuant to force majeure provisions in such agreements. Further, in the past, the State of Israel and Israeli companies have been subjected to economic boycotts. Several countries still restrict business with the State of Israel and with Israeli companies. These restrictive laws and policies may have an adverse impact on our operating results, financial condition or the expansion of our business.

Our commercial insurance does not cover losses that may occur as a result of events associated with the security situation in the Middle East. Although the Israeli government currently covers 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. Any losses or damages incurred by us could have a material adverse effect on our business. Any armed conflicts or political instability in the region would likely negatively affect business conditions and could harm our results of operations.

Further, the State of Israel and Israeli companies have been subjected to an economic boycott. Several countries still restrict business with the State of Israel and with Israeli companies. These restrictive laws and policies may have an adverse impact on our operating results, financial condition or the expansion of our business.

Furthermore, the Israeli government is currently pursuing 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 due to reluctance of foreign investors to invest or conduct business in Israel, as well as to increased currency fluctuations, downgrades in credit rating, increased interest rates, increased volatility in securities markets, and other changes in macroeconomic conditions. Such proposed changes may also adversely affect the labor market in Israel or lead to political instability or civil unrest. To the extent that any of these negative developments do occur, they may have an adverse effect on our business, our results of operations and our ability to raise additional funds, if deemed necessary by our management and board of directors.

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 9.5% 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 2. Properties

We do not own any real property. Currently, we maintain offices at 8 HaTokhen St., Caesarea Industrial Park, 3088900, Israel. On September 8, 2016, we signed a lease agreement for these facilities for a period of 5 years commencing upon the completion of construction of the new office building. We moved into these offices during November 2017. 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 $19,140. In December 2017, we signed a lease agreement for our new U.S. headquarters facilities in New York, New York for a monthly rent and management services of approximately $6,557.

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". Our warrants to purchase common stock are quoted on the Nasdaq Capital Market under the symbol "DRIOW".

Record Holders

As of March 1, 2023, we had 375 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, 2022:

The following table provides information as of December 31, 2022, 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 (6)	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	119,905	1,918,566	$ 12.88	202,341
Equity compensation plans not approved by security holders (1)		523	$ 2,644.80	—
Equity compensation plans not approved by security holders (2)		213	$ 2,502.00	—
Equity compensation plans not approved by security holders (3)		135,000	$ 8.41	—
Equity compensation plans not approved by security holders (4)		50,000	$ 5.75	—
Equity compensation plans not approved by security holders (5)		20,000	$ 18.62	
Total	119,905	2,124,302		202,341

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

(2) 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.

(1) 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 and January 1, 2023 as the performance milestones were not met.

(2) 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.

(3) 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.

(4) 119,905 restricted shares of common stock issued to employees of the company 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. As of March

3, 2023, there are 2,061,876 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 2022, we issued an aggregate 41,025 shares of our common stock to certain of our service providers as compensation to them for services rendered.

In addition, in November and December 2022, 6,345 of various classes of our Series A Preferred Stock automatically converted into 2,130,322 shares of Common Stock after completing 36-month anniversary of each the series A. The conversion was including accumulative dividends payable available upon conversion of each Series A Preferred Stock.

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. Presently, we have deployed solutions for diabetes, hypertension, and pre-diabetes, musculoskeletal ("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 commenced a commercial launch of our free application in the United Kingdom in late 2013 and commenced an initial soft launch of the full Dario solution (including the app and the Dario Blood Glucose Monitoring System) in selected jurisdictions in March 2014. We continued to scale up launch during 2014 in the United Kingdom, the Netherlands and New Zealand, and during 2015 in Australia, Israel and Canada, with the goal of collecting customer feedback to refine

our longer-term roll-out strategy. We are consistently adding new additional features and functionality in making Dario the new standard of care in diabetes data management.

Through our Israeli subsidiary, Labstyle, and its subsidiary Upright, our plan of operations is to continue the development of our software and hardware offerings and related technology. During 2015, we successfully launched the Dario Smart Diabetes Management Solution according to plan and are currently expanding the launch to other jurisdictions. In 2016, we established our direct-to-consumer model in the U.S. to achieve higher and faster penetration into the market during the launch phase. We have invested in a robust digital marketing department with in-house platforms, experienced personnel and robust infrastructures to support expected growth of users and online subscribers in this market. During the third quarter of 2016 we expanded these efforts to include Australia as well. In 2017, we expanded our direct-to-consumer marketing efforts in the United Kingdom in cooperation with our local distributor and launched similar marketing efforts in Germany. In support of these goals, we intend to utilize our funds for the following activities:

- ramp up of mass production, marketing and distribution and sales efforts related to the Dario Smart Diabetes Management Solution and the DarioEngage platform;
- develop our customer support and telemarketing services in order to support the expect growth of our revenues and the increase of user, and service provider who will use our platform to better serve people with chronic conditions and improve their clinical outcome;
- continued product and software development, and related activities (including costs associated with application development and data storage capabilities as well as any necessary design modifications to the various elements of the Dario Platform;
- continued work on registration of our patents worldwide;
- Regulatory and quality assurance matters;
- professional fees associated with being a publicly reporting company; and
- general and administrative matters.

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 a wholly owned subsidiary of the Company. As part of the acquisition, Dario issued the Selling Shareholders 1,687,612 shares of the Company's common stock, and agreed to assume options to purchase up to 100,193 shares of the Company's 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. The Company has also agreed to file a registration statement covering the resale of the shares within ninety (90) days following the Closing Date. In addition, 30% of the Consideration Shares issuable to Upright's founder, Mr. Oded Cohen, shall be held in a specific holdback retention mechanism, of which 50% shall be released at the lapse of twelve (12) months of retention following the Closing Date, and the balance of 50% shall be released at the lapse of eighteen (18) months of retention following the Closing Date.

On February 1, 2021, the Company, through Labstyle, has also agreed to enter into an employment agreement with Mr. Cohen, pursuant to which he will serve as General Manager of MSK. In consideration for Mr. Cohen's duties, he will be entitled to (a) a monthly salary of NIS 63,000, (b) an annual bonus of up to four times his monthly salary, and (c) up to 220,980 shares of restricted stock of the Company, subject to meeting certain key performance metrics. See "Management – Employment Agreements." On November 25, 2021, Mr. Oded Cohen was relieved from his role as General Manager of MSK and he was reassigned to serve as Senior Vice President of Strategy M&A and MSK of the Company.

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 only into June 2021 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. As such, we have a significant present need for capital. 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 using the accrual basis of accounting 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

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 assesses 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. Contracts typically have a duration of more than one year.

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.

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, 2022, total inventory write-downs expenses amounted to $88,000.

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, 2022 to Year Ended December 31, 2021

Revenues

Revenues for the year ended December 31, 2022 amounted to $27,656,000 compared to $20,513,000 during the year ended December 31, 2021. The increase in revenues for the year ended December 31, 2022, compared to the year ended December 31, 2021, is due to an increase in revenues from sales through our commercial channel.

Revenues generated during the year ended December 31, 2022 were derived mainly from the sale of services to our strategic partners and commercial customers located in the United States.

Cost of Revenues

During the years ended December 31, 2022 and 2021, we recorded costs related to revenues in the amount of $18,001,000 and $16,550,000, respectively. The increase in cost of revenues was in part due to higher costs related to amortization of acquired technology in the amount of $4,357,000 and $4,106,000 as a result of the acquisitions during 2021 and 2022.

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, 2022, amounted to $9,655,000 (34.9% of revenues) compared to $3,963,000 (19.3% of revenues) for the year ended December 31, 2021. The increase in gross profit as a percentage of revenue for the year ended December 31, 2022, compared to the year ended December 31, 2021, is due to the increase in revenues derived from sales through our commercial channels. Gross profit for the year ended December 31, 2022, excluding amortization of acquired technology were $14,012 (50.7% of revenues) compared to $8,069 (39.3% of revenues) during the year ended December 31, 2021.

Research and Development Expenses

Our research and development expenses increased by $2,430,000 to $19,649,000 for the year ended December 31, 2022 compared to $17,219,000 for the year ended December 31, 2021. This increase was mainly due to the increase in our research and development activities during the year ended December 31, 2022. Our research and development expenses, excluding stock-based compensation and depreciation, for the year ended December 31, 2022, were $15,995,000 compared to $13,272,000 for the year ended December 31, 2021, an increase of $2,723,000. 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 $9,383,000 to $30,323,000 for the year ended December 31, 2022 compared to $39,706,000 for the year ended December 31, 2021. This decrease was mainly due to the decreases in our digital marketing and payroll related expenses during the year ended December 31, 2022. Our sales and marketing expenses, excluding stock-based compensation, depreciation and amortization, for the year ended December 31, 2022 were $23,880,000 compared to $33,555,000 for the year ended December 31, 2021, a decrease of $9,675,000. 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 decreased by $7,039,000 to $16,493,000 for the year ended December 31, 2022 compared to $23,532,000 for the year ended December 31, 2021. The decrease was mainly due to a decrease in our stock-based compensation, investor relations and the costs related with the acquisitions performed during the year ended December 31, 2021. Our general and administrative expenses, excluding stock-based compensation, acquisition costs and depreciation, for the year ended December 31, 2022 were $9,803,000 compared to $8,150,000 for the year ended December 31, 2021, an increase of $1,653,000. This increase was due to an increase in payroll, insurance, consulting services, legal and accounting expenses 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 income (expenses), net

Our finance expenses, net, increased by $5,144,000 to $5,379,000 for the year ended December 31, 2022 compared to $235,000 financing expenses for the year ended December 31, 2021. The changes in our financial expenses were mainly due to the long-term loan we have received.

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

Income tax

Income tax expenses were $4,000 for the year ended December 31, 2022 as compared to $32,000 for the year ended December 31, 2021.

Net loss

Net loss for the year ended December 31, 2022 was $62,193,000. Net loss for the year ended December 31, 2021 was $76,761,000. The decrease from 2021 was mainly due to the increase in our gross profit and the decrease in our operating expenses.

Net operating loss carryforwards

As of December 31, 2022, we and WayForward had a U.S. federal net operating loss carryforward of approximately $53,511, 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 - 2022, we generated additional $46,020,000 of net operating losses carryforwards which are not subject to the annual limitation described above.

Our Israeli subsidiary, Labstyle, have accumulated net operating losses for Israeli income tax purposes as of December 31, 2022 in the amount of approximately $150,228,000. 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 $63,836,000 and $78,766,000 for the year ended December 31, 2022 and 2021, 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) unaudited 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)		
	2022	2021	$ Change
Net Loss Reconciliation			
Net loss - as reported	$ (62,193)	$ (76,761)	$ 14,568
Adjustments			
Depreciation expense	356	282	74
Inventory step up amortization	—	1,140	(1,140)
Amortization of acquired technology and brand	4,481	3,035	1,446
Other financial expenses, net	5,379	235	5,144
Income Tax	4	32	(28)
EBITDA	(51,973)	(72,037)	20,064
Acquisition costs	—	880	(880)
Earn-out remeasurement	(497)	(503)	6
Stock-based compensation expenses	16,975	24,971	(7,996)
Non-GAAP adjusted loss	$ (35,495)	$ (46,689)	$ 11,194

Liquidity and Capital Resources

Our primary source of liquidity is cash generated from equity offerings, implanting a debt facility and from cash flows from our operations. We believe our current level of cash and short-term financing capabilities along with future cash flows from operations are sufficient to meet the needs of the business. Under ASC Subtopic 205-40, Presentation of Financial Statements—Going Concern ("ASC 205-40"), we have the responsibility to evaluate whether conditions and/or events raise substantial doubt about our ability to meet our future financial obligations as they become due within one year after the date that the financial statements are issued. The following conditions raised substantial doubt about our ability to continue as a going concern: a history of net losses, net operating cash outflows, significant cash payments for interest on our loan facility and a requirement in our loan facility that we must maintain a minimum of $10 million in liquidity at all times to not be in default of the loan facility. We have approved a plan, to improve our available cash balances, liquidity and cash flows generated from operations. In that regard, we are prepared to implement the following actions as required by business and market conditions: reducing non-essential expenses to conserve cash and improve our liquidity position, deferral and reprioritization of certain research and development programs that would involve reduced program spend and total compensation reductions for senior executives to strengthen liquidity and to preserve key research and development, commercial and functional roles. We believe that these plans alleviate the substantial doubt about the entity's ability to continue as a going concern for at least twelve months from the date that the accompanying financial statements included elsewhere in this annual report were issued. Going concern matters are more fully discussed in Note 1e, Basis of Presentation and Summary of Significant Accounting Policies.

As of December 31, 2022, we had approximately $49,357,000 in cash and cash equivalents compared to $35,808,000 at December 31, 2021.

We have experienced cumulative losses of $285,850,000 from inception (August 11, 2011) through December 31, 2022 and have a stockholders' equity of $79,999,000 at December 31, 2022. 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 $227,971,000 and a credit facility of $23,786,000 as of December 31, 2022.

On July 28, 2020, we entered into subscription agreements with accredited investors relating to an offering with respect to the sale of an aggregate of (i) 2,969,266 shares of our common stock, at a purchase price of $7.47 per share, and (ii) pre-funded warrants to purchase 824,689 shares of common stock, at a purchase price of $7.4699 per pre-funded warrant. In addition, on July 30, 2020, we entered into a subscription agreement with an accredited investor for the purchase of 31,486 shares of our common stock at a purchase price per share of $7.94 per share. The aggregate gross proceeds were approximately $28,591,000.

In September 2020, we and an existing warrant holder entered into an agreement pursuant to which we agreed to lower the exercise price of certain warrants issued in September 2018, from $25.00 to $13.00 per share. As a result, the warrant holder exercised warrants to purchase 88,889 shares of our common stock, resulting in aggregate gross proceeds of approximately $1,156,000.

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, 2022, we sold 73,037 shares of our common stock under the Sales Agreement for aggregate net proceeds of approximately $260,000.

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, as the lender (the "Lender"). The Credit Agreement provides 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 (the "Initial Commitment Amount") and up to $25 million will be made available on or prior to June 30, 2023, subject to certain revenue requirements (the "Delayed Draw Commitment Amount"). On June 9, 2022, we closed on the Initial Commitment Amount, less certain fees and expenses payable to or on behalf of the Lender. All obligations under the Credit Agreement are guaranteed by all of our wholly owned subsidiaries other than Dario Health Services Private Limited. All obligations under the Credit Agreement, and the guarantees of those obligations, are secured by substantially all of our and each guarantor's assets. If, until the maturity date of the Loan Facility, our net revenue does not equal or exceed the applicable amount for such period as set forth in the Credit Agreement, then we shall repay in equal monthly installments the outstanding principal amount of the Loan Facility, together with a repayment premium and other fees. We 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 Credit Agreement, together with a repayment premium and other fees.

During the term of the Loan Facility, interest payable in cash by us shall accrue on any outstanding balance due under the Loan Facility at a rate per annum equal to the higher of (x) the adjusted SOFR rate (which is the forward-looking term rate for a one-month tenor based on the secured overnight financing rate administered by the CME Group Benchmark Administration Limited) and (y) 0.50% plus, in either case, 9.50%. 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. We agreed to pay certain fees with respect to the Loan Facility, including an upfront fee, an unused fee on the undrawn portion of the Loan Facility, an administration fee, a repayment premium and an exit fee, as well as certain other fees and expenses of the Lender. We also agreed to issue the Lender, with respect to the Initial Commitment Amount only, a warrant (to purchase up to 226,586 shares of our common stock, at an exercise price of $6.62 per share, which shall have a term of 7 years from the issuance date. The 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. In the event we are eligible to draw the Delayed Draw Commitment Amount, we agreed to issue the Lender an additional warrant, with a term of 7 years from the issuance date, to purchase up to 6% of the Delayed Draw Commitment Amount based on a 10 day volume weighted average price of our common stock (the "Volume Weighted Average Price") with an exercise price equal to the Volume Weighted Average Price.

Pursuant to the terms of the Credit Agreement, and based on our net revenues for the fiscal year ended December 31, 2022, we started repayment of the outstanding principal amount of the Initial Commitment Amount of $25 million issued as part of the Loan Facility, together with a repayment premium and other fees in monthly installments of up to $518,500 beginning as of January 31, 2023, and continuing through the maturity date, or June 9, 2027.

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,	
	2022	2021
	$	$
Cash used in operating activities:	(47,845,000)	(50,409,000)
Cash used in investing activities:	(573,000)	(8,134,000)
Cash provided by financing activities:	61,940,000	65,766,000
	13,522,000	7,223,000

Net cash used in operating activities

Net cash used in operating activities was $47,845,000 for the year ended December 31, 2022 compared to $50,409,000 used in operations for the same period in 2021. Cash used in operations increased mainly due to the decrease in our marketing activities.

Net cash used in investing activities

Net cash used for investing activities was $573,000 for the year ended December 31, 2022 compared to cash used in investing activities of $8,134,000 for the year ended December 31, 2021. Cash used in investing activities decreased mainly due to the lack of acquisition related cash required in 2022 compared to 2021.

Net cash provided by financing activities

Net cash provided by financing activities was $61,940,000 for the year ended December 31, 2022 compared to $65,766,000 for the year ended December 31, 2021. During the year ended December 31, 2022, we raised net proceeds in an amount of approximately $38,288,000 through our March 2022 offering and a net proceeds in an amount of approximately $23,786,000 through our June 2022 Credit Agreement.

Contractual Obligations

Set forth below is a summary of our current obligations as of December 31, 2022 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	$ 1,204	$ 690	$ 514	$ —
Purchasing Obligations	8,551	8,551	—	—
Total contractual cash obligations	$ 9,756	$ 9,241	$ 514	$ —

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 September 2016, the Financial Accounting Standards Board (the "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 changes the impairment model for most financial assets and certain other instruments. For trade and other receivables, held-to-maturity debt securities, loans, and other instruments, entities will be required to use a new forward-looking "expected loss" model that generally will result in the earlier recognition of allowances for losses. The guidance also requires increased disclosures. For the Company, the amendments in the update were originally effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. 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 U.S. Securities and Exchange Commission) and other non-SEC reporting entities to fiscal years beginning after December 15, 2022, including interim periods within those fiscal periods. Early adoption is permitted. The Company is currently assessing the impact the guidance will have on its consolidated financial statements.

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, 2022, 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, 2022 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, 2022. 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, 2022.

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	49	Chief Executive Officer and Director
Zvi Ben David	62	Chief Financial Officer, Treasurer and Secretary
Richard Anderson	53	President
Yoav Shaked	51	Chairman of the Board of Directors
Dennis Matheis	62	Director
Hila Karah	54	Director
Dennis M. McGrath	66	Director
Jon Kaplan	55	Director
Adam Stern	58	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.

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.

Eric Miledge - ***Chairman of our Advisory Board***, has worked in the healthcare field for his entire career, with a focus on pharmaceuticals and medical devices. With more than 34 years at Johnson & Johnson (JNJ) in roles of increasing responsibility, he built a vast network of relationships across the healthcare landscape. As president of Ortho McNeil Pharmaceutical, Eric led in the licensing and successful introduction of levofloxacin (antibiotic), tramadol (analgesic) and the commercialization of Topamax (anticonvulsant), building a multi-billion dollar U.S. pharmaceutical business. Eric also served as Company Group Chairman for Johnson & Johnson Healthcare Systems which oversaw the negotiation and management of JNJ's medical device, diagnostic and pharmaceutical U.S. hospital contracts. Eric also served as Company Group Chairman of LifeScan Inc., the blood glucose division of JNJ. Under Eric's leadership, LifeScan Global Diabetes franchise experienced rapid organic and inorganic growth, including the acquisition of Inverness Medical Technology's Diabetes Care Products business. His leadership helped transform LifeScan into a global organization with thousands of employees and billions in annual revenues. After retiring from JNJ, Eric served as chairman for a number of medical

device startup companies including chairman of Nfocus Neuromedical, Symetis SA and CeQur SA. Eric also served as an operating partner for Geneva based Endeavour Vision Growth, a medical device growth fund.

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.

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 www.mydario.com under the Investors / 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 www.mydario.com under the Investors / Governance section.

The Compensation Committee has the authority to directly engage, at our expense, any compensation 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, 2022 and 2021.

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	2022	$ 489,848 (1)	$ 306,263 (2)	$ 1,977,250 (3)	$ —	—	—	$ 182,651 (4)	$ 2,956,012
(Chief Executive Officer)	2021	$ 460,787 (1)	$ 345,906 (2)	$ 7,450,399 (3)	$ —	—	—	$ 179,475 (4)	$ 8,436,567
Zvi Ben David	2022	$ 268,022 (5)	87,504 (6)	$ 683,050 (7)	$ —	—	—	$ 73,522 (8)	$ 1,112,098
(Chief Financial Officer)	2021	$ 248,026 (5)	118,596	$ 2,020,474 (7)	$ —	—	—	$ 70,988 (8)	$ 2,458,084
Dror Bacher	2022	$ 251,314 (9)	$ 87,504 (10)	$ 683,050 (11)	$ —	—	—	$ 81,565 (12)	$ 1,103,433
(Chief Operating Officer) (20)	2021	$ 226,060 (9)	$ 118,596 (10)	$ 1,827,964 (11)	$ —	—	—	$ 84,559 (12)	$ 2,257,179
Richard Anderson	2022	$ 689,955 (13)	250,000 (14)	$ (15)	$ 732,510 (16)	—	—	$ 58,467 (17)	$ 1,730,932
(President)	2021	$ 335,000 (13)	212,500 (14)	$ 1,960,853 (15)	$ 1,244,726 (16)	—	—	$ 35,172 (17)	$ 3,788,251

* 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, 2022 and December 31, 2021, computed in accordance with the provisions of ASC 718 “Compensation-Stock Compensation,” or 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 $23,687 per month). On June 1, 2018, his monthly salary was increased to NIS 134,167 (approximately $39,725) and on April 1, 2021 his monthly salary was increased to NIS 137,466 (approximately $40,702 per month). During 2021 and 2022, Mr. Raphael agreed to a waiver of 9.4% and 0% of his cash salary according to our salary program (see further details in “Employment and Related Agreements” below).

(2) On March 2021, Mr. Raphael was paid a bonus of $345,906 for his performance during 2020. On March 2022, Mr. Raphael was paid a bonus of $306,263 for his performance during 2021.

(3) On January 19, 2021, Mr. Raphael was granted 2,268 shares of our common stock under our 2012 Equity Incentive plan against waiver of cash salary for the period from January to March 2021. On May 3, 2021, Mr. Raphael was granted 673 shares of our common stock under our 2020 Equity Incentive plan against waiver of cash salary for the period from April to June 2021. On July 18, 2021, Mr. Raphael was granted 688 shares of our common stock under our 2012 Equity Incentive plan against waiver of cash salary for the period from July to September 2021. On October 10, 2021, Mr. Raphael was granted 695 shares of our common stock under our 2012 Equity Incentive plan against waiver of cash salary for the period from October to December 2021. On January 19, 2021, Mr. Raphael was granted 413,158 restricted shares of our common stock under our 2020 Equity Incentive Plan.

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 $9,238) 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 $11,457 per month, commencing April 1, 2016, his monthly salary was updated to NIS 60,000 (approximately $17,765). Commencing June 1, 2018, his monthly salary was updated to NIS 67,200 (approximately $19,897), and commencing April 1, 2021, his monthly salary was updated to NIS 74,620 (approximately $22,094). During 2021 and 2022, Mr. Ben David agreed to a waiver of 9.3% and 0% of his cash salary according to our salary program (see further details in "Employment and Related Agreements" below).

(6) In March 2021, Mr. Ben David was paid a bonus of $118,596 for his performance during 2020. In March 2022, Mr. Ben David was paid a bonus of $87,504 for his performance during 2021.

(7) On January 19, 2021, Mr. Ben David was granted 1,152 shares of our common stock under our 2012 Equity Incentive plan against waiver of cash salary for the period from January to March 2021. On May 3, 2021, Mr. Ben David was granted 357 shares of our common stock under our 2020 Equity Incentive plan against waiver of cash salary for the period from April to June 2021. On July 18, 2021, Mr. Ben David was granted 365 shares of our common stock under our 2012 Equity Incentive plan against waiver of cash salary for the period from July to September 2021. On October 10, 2021 Mr. Ben David was granted 369 shares of our common stock under our 2012 Equity Incentive plan against waiver of cash salary for the period from October to December 2021. On January 19, 2021, Mr. Ben David was granted 111,228 restricted shares of our common stock under our 2020 Equity Incentive Plan.

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 second amendment to the employment agreement with our company effective April 2016, Mr. Bacher was entitled to a monthly salary of NIS 48,000 (approximately $14,815 per month), commencing July 1, 2017, Mr. Dror was appointed as our Chief Operating Officer and his monthly salary was increased to NIS 55,000 (approximately $16,975 per month). Commencing June 1, 2018 his monthly salary was increased to NIS 61,490 (approximately $18,978 per month), and. commencing April 1, 2021 his monthly salary was increased to NIS 68,910 (approximately $21,269 per month). During 2020 and 2021, Mr. Bacher agreed to a waiver of 10.6% and 9.6% of his cash salary respectively, according to our salary program (see further details in "Employment and Related Agreements" below).

(10) In March 2021, Mr. Bacher was paid a bonus of $118,596 for his performance during 2020. In March 2022, Mr. Bacher was paid a bonus of $87,504 for his performance during 2021.

(11) On January 19, 2021, Mr. Bacher was granted 1,039 shares of our common stock under our 2012 Equity Incentive plan against waiver of cash salary for the period from January to March 2021. On May 3, 2021, Mr. Bacher was granted 346 shares of our common stock under our 2020 Equity Incentive plan against waiver of cash salary for the period from April to June 2021. On July 18, 2021, Mr. Bacher was granted 353 shares of our common stock under our 2012 Equity Incentive plan against waiver of cash salary for the period from July to September 2021. On October 10, 2021, Mr. Bacher was granted 357 shares of our common stock under our 2012 Equity Incentive plan against waiver of cash salary for the period from October to December 2021. On January 19, 2021, Mr. Bacher was granted 100,580 restricted shares of our common stock under our 2020 Equity Incentive Plan. On May 18, 2022, Mr. Bacher was granted 95,000 restricted shares of our common stock under our 2020 Equity Incentive Plan.

(12) In addition to his salary, Mr. Bacher 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."

(13) 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.

(14) In March 2021, Mr. Anderson was paid a bonus of $212,500 for his performance during 2020. In April 2022, Mr. Anderson was paid a bonus of $250,000 for his performance during 2021.

(15) On January 19, 2021, Mr. Anderson was granted 91,652 restricted shares of our common stock under our 2020 Equity Incentive Plan, and on July 18, 2021, Mr. Anderson was granted 20,000 restricted shares of our common stock under our 2020 Equity Incentive Plan following the closing of the acquisition of wayForward. In June 2022 17,957 of the vested shares were redeemed by the Company for aggregate proceeds of $170.275, to satisfy certain withholding tax obligations ox existing vested restricted stock awards. The redemption of the securities was approved by the Compensation Committee of the issuer and was exempt pursuant to Rule 16b-3.

(16) On January 19, 2021, Mr. Anderson was granted 91,652 options to purchase shares of our common stock under our 2020 Equity Incentive Plan, at an exercise price of $17.89 per share.

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.

(17) 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."

(18) On January 23, 2023, we executed a Termination of Employment and Separation Agreement with Mr. Bacher, pursuant to which Mr. Bacher's position as Chief Operating Officer was terminated with immediate effect.

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 $40,702 per month). During 2021 and 2022, Mr. Raphael agreed to a waiver of 9.4% and 0% of his cash salary according to our salary program pursuant to which Mr. Raphael received compensation shares of restricted common stock as consideration for cash salary waived.

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 January 19, 2021, the Compensation Committee of our Board of Directors approved the issuance to Mr. Raphael of 2,268 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $16,942 of salary otherwise payable to Mr. Raphael from January to March 2021.

On May 3, 2021, the Compensation Committee of our Board of Directors approved the issuance to Mr. Raphael of 673 shares of our common stock under our 2020 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $14,380 of salary otherwise payable to Mr. Raphael from April to June 2021.

On July 20, 2021, the Compensation Committee of our Board of Directors approved the issuance to Mr. Raphael of 688 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $14,698 of salary otherwise payable to Mr. Raphael from July to September 2021.

On October 10, 2021, the Compensation Committee of our Board of Directors approved the issuance to Mr. Raphael of 695 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $14,853 of salary otherwise payable to Mr. Raphael from October to December 2021.

On April 7, 2021, the Compensation Committee of our Board of Directors approved an increase of Mr. Raphael's annual salary by $12,000 in the aggregate and increased his 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 $9,238) 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 $11,547). Commencing April 1, 2016, Mr. Ben David's Salary was updated to NIS 60,000 (approximately $17,765) per month. Commencing June 1, 2018, his monthly salary was updated to NIS 67,200 (approximately $19,897), and commencing April 1, 2021, his monthly salary was updated to NIS 74,620 (approximately $22,094). During 2021 and 2022, Mr. Ben David agreed to a waiver of 9.3% and 0% respectively of his cash salary according to our salary program pursuant to which Mr. Ben David received compensation shares of restricted common stock as consideration for cash salary waived.

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 January 19, 2021, the Compensation Committee of our Board of Directors approved the issuance to Mr. Ben David of 1,152 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $8,610 of salary otherwise payable to Mr. Ben David from January to March 2021.

On May 3, 2021, the Compensation Committee of our Board of Directors approved the issuance to Mr. Ben David of 357 shares of our common stock under our 2020 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $7,637 of salary otherwise payable to Mr. Ben David from April to June 2021.

On July 18, 2021, the Compensation Committee of our Board of Directors approved the issuance to Mr. Ben David of 365 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $7,805 of salary otherwise payable to Mr. Ben David from July to September 2021.

On October 10, 2021, the Compensation Committee of our Board of Directors approved the issuance to Mr. Ben David of 369 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $7,887 of salary otherwise payable to Mr. Ben David from October to December 2021.

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.

Dror Bacher, Chief Operating Officer – On August 30, 2013, LabStyle Innovation Ltd., our Israeli subsidiary, entered into an employment agreement with Mr. Bacher, pursuant to which Mr. Bacher receives an annual base salary of NIS 55,000 (approximately $16,975), effective as of July 2017. Commencing June 1, 2018 his monthly salary was increased to NIS 61,490 (approximately $18,978 per month), and commencing April 1, 2021 his monthly salary was increased to NIS 68,910 (approximately $21,269 per month). Pursuant to Mr. Bacher's existing personal employment agreement as amended, either Mr. Bacher or we may terminate his employment agreement upon four months' notice, provided, however, that in the event of a termination for cause, Mr. Bacher's employment may be terminated immediately. Mr. Bacher's employment agreement also includes a twelve (12) month non-competition and non-solicitation provision, certain confidentiality covenants and assignment of any of his company-related inventions. Under the terms of Mr. Bacher's employment agreement, Mr. Bacher is entitled to certain expense reimbursements and other standard benefits, including vacation, sick leave, life, and disability insurance and car and mobile phone allowances. In addition, in conjunction with his appointment as Chief Operating Officer, we issued Mr. Bacher 500 shares of common stock, and 500 options that will vest in 12 equal quarterly installments over a three-year period with an exercise price of $49.20 per share, all issued pursuant to the Registrant's Amended and Restated 2012 Equity Incentive Plan.

On January 19, 2021, the Compensation Committee of our Board of Directors approved the issuance to Mr. Bacher of 1,039 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $7,761 of salary otherwise payable to Mr. Bacher from January to March 2021.

On April 3, 2021, the Compensation Committee of our Board of Directors approved the issuance to Mr. Bacher of 346 shares of our common stock under our 2020 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $7,394 of salary otherwise payable to Mr. Bacher from April to June 2021.

On July 20, 2021, the Compensation Committee of our Board of Directors approved the issuance to Mr. Bacher of 353 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $7,558 of salary otherwise payable to Mr. Bacher from July to September 2021.

On October 16, 2021, the Compensation Committee of our Board of Directors approved the issuance to Mr. Bacher of 357 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $7,635 of salary otherwise payable to Mr. Bacher from October to December 2021.

On April 7, 2021, the Compensation Committee of our Board of Directors approved an increase of Mr. Bacher's annual salary by $27,000 in the aggregate and increased his target bonus to 40% of his annual base salary.

On January 23, 2023, we executed a Termination of Employment and Separation Agreement with Mr. Bacher, pursuant to which Mr. Bacher's position as Chief Operating Officer was terminated with immediate effect.

Pursuant to the terms of the Separation Agreement, we agreed to retain Mr. Bacher as a member of our advisory board. We also agreed to pay Mr. Bacher, in lieu of his notice period and accrued vacation, a reduced monthly salary of 42,137 NIS ($12,504) for the period from February 1, 2023 through May 31, 2025. In addition, we agreed, subject to the approval of our Compensation Committee, to issue Mr. Bacher 75,000 shares of restricted stock which shall vest on a quarterly basis from the date of grant through December 31, 2024.

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 and 2022 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.

Outstanding Equity Awards at December 31, 2022

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	101	—	—	$ 2,430	March 14, 2023
(Chief Executive Officer)	12	—	—	$ 5,400	June 5, 2023
	167	—	—	$ 4,806	August 28, 2023
	45	—	—	$ 3,330	January 6, 2024
	234	—	—	$ 1,764	July 6, 2024
	7,159	—	—	$ 64.04	January 30, 2023
Zvi Ben David	1,592	—	—	$ 64.04	January 30, 2023
(Chief Financial Officer, Secretary and Treasurer)	25,509	2,318 (1)		$ 7.736	February 12, 2026
Dror Bacher	67	—	—	$ 3,330	January 6, 2024
(Chief Operating Officer)	67	—	—	$ 1,764	July 6, 2024
	1,375	—	—	$ 64.04	January 30, 2023
	500	—	—	$ 49.20	July 25, 2023
	26,276	2,388 (1)		$ 7.736	February 12, 2026
Richard Anderson	82,500	7,500 (2)		$ 8.41	January 30, 2026
(President and General Manager of North America)	53,465	38,187 (1)		$ 17.89	January 19, 2031
	22,500	112,500 (1)		$ 7.19	May 18, 2032
Total Option Shares	**221,569**	**162,893**		$	

(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 January 19, 2021, the Compensation Committee of our Board of Directors approved the following issuances, each was done under our 2020 Equity Incentive Plan: (i) 16,609 restricted shares of our common stock to Mr. Shaked; (ii) 20,147 restricted shares of our common stock to Ms. Karah; (iii) 17,620 restricted shares of our common stock to Mr. Matheis; (iv) 43,850 restricted shares of our common stock to Mr. Stern; (v) 20,000 restricted shares of our common stock to Prof. Stone; and (vi) 29,616 restricted shares of our common stock to Mr. McGrath.

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	2022	$ 70,000	$ 395,450 (1)	$ — (2)	$ —	$ —	$ —	$ 465,450
Prof. Richard B. Stone **	2022	$ 17,500	$ — (3)	$ 189,910 (4)	$ —	$ —	$ —	$ 207,410
Dennis Matheis	2022	$ 61,667	$ — (5)	$ 189,910 (6)	$ —	$ —	$ —	$ 251,577
Hila Karah	2022	$ 70,000	$ 575,200 (7)	$ — (8)	$ —	$ —	$ —	$ 645,200
Yoav Shaked	2022	$ 70,000	$ 431,400 (9)	$ — (10)	$ —	$ —	$ —	$ 501,400
Adam Stern	2022	$ 50,000	$ 395,450 (11)	$ — (12)	$ —	$ —	$ —	$ 445,450

* 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, 2022, 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.

** Passed away on May 30, 2022 and ceased serving on the Board of Directors on such date.

(1) 74,744 stock awards are outstanding as of December 31, 2022.

(2) 899 option awards are outstanding as of December 31, 2022.

(3) 49,999 stock awards are outstanding as of December 31, 2022.

(4) No option awards are outstanding as of December 31, 2022.

(5) 32,620 stock awards are outstanding as of December 31, 2022.

(6) 55,000 option awards are outstanding as of December 31, 2022.

(7) 148,751 stock awards are outstanding as of December 31, 2022.

(8) 801 option awards are outstanding as of December 31, 2022.

(9) 163,896 stock awards are outstanding as of December 31, 2022.

(10) No option awards are outstanding as of December 31, 2022.

(11) 108,341 stock awards are outstanding as of December 31, 2022.

(12) No option awards are outstanding as of December 31, 2022.

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 3, 2023 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]	848,115	3.3 %
Zvi Ben David [3]	278,184	1.1 %
Dror Bacher [4]	200,206	* %
Richard Anderson [5]	225,267	* %
Dennis M. McGrath [6]	10,771	* %
Jon Kaplan	—	— %
Hila Karah [7]	85,056	* %
Yoav Shaked [8]	120,042	* %
Adam Stern [9]	587,169	2.2 %
Dennis Mathies [10]	102,166	* %
All Executive Officers and Directors as a group (10 persons) **	**2,456,976**	**9.5 %**
5% Stockholders		
Nantahala Capital Management, LLC. [11]	2,673,914	9.9 %
Y.D More Investments Ltd. [12]	1,518,026	5.9 %
The Phoenix Holdings Ltd. [13]	1,341,027	5.2 %

* less than 1%.

(1) Percentage ownership is based on 25,871,889 shares of our common stock outstanding as of March 6, 2023 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 7,718 vested options to purchase common stock and 378,620 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 29,419 vested options to purchase common stock and 107,172 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 30,673 vested options to purchase common stock and 108,562 vested restricted shares.

(5) Includes 192,490 vested options to purchase common stock and 17,595 vested restricted shares. Excludes 124,162 options which are not vested.

(6) Includes 899 vested options to purchase common stock and 19,744 vested restricted shares.

(7) Includes 801 vested options to purchase common stock and 35,112 vested restricted shares.

(8) Includes 27,457 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.

(9) Includes 29,234 vested restricted shares. Includes warrants exercisable into 409,535 shares of common stock, subject to a contractual beneficial ownership limitation of 4.99%.

(10) Includes 25,419 vested options to purchase common stock and 11,747 vested restricted shares. Excludes 29,581 options which have not vested.

(11) Based solely on information contained in Form 13G/A filed with the SEC on February 14, 2023, and data provided by the holder. Includes 277,546 pre-funded warrants to purchase common stock issued in May 2019 and preferred shares convertible into 859,800 shares of common stock, subject to a contractual beneficial ownership limitation of 9.99% and excludes preferred shares convertible into 18,779 shares of common stock and 824,689 pre-funded warrants issued on July 31, 2020, and 667,559 pre-funded warrants issued on February 28, 2022.

(12) Based solely on information contained in Form 13G filed with the SEC on February 14, 2023. The address for Y.D More Investments Ltd. is 2 Ben-Gurion Street, Ramat Gan, Israel.

(13) Based solely on information contained in Form 13G filed with the SEC on February 14, 2023. The address of the Phoenix Holdings Ltd. is Derech Hashalom 53, Givataim, 53454, Israel.

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 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, 2022	December 31, 2021
Audit Fees	$ 236,443	$ 196,289
Audited Related Fees	$ —	$ —
Tax Fees (1)	$ 55,980	$ 77,000
All Other Fees (2)	$ 16,750	$ 179,155
Total	$ 309,173	$ 452,444

(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).
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).
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.
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.
101*	The following financial statements from the Company's annual report on Form 10-K for the year ended December 31, 2022, 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 9, 2023

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 9, 2023
/s/ Zvi Ben David Zvi Ben David	Chief Financial Officer, Secretary and Treasurer (Principal Financial and Accounting Officer)	March 9, 2023
/s/ Yoav Shaked Yoav Shaked	Chairman of the Board	March 9, 2023
/s/ Dennis Matheis Dennis Matheis	Director	March 9, 2023
/s/ Hila Karah Hila Karah	Director	March 9, 2023
/s/ Dennis M. McGrath Dennis M. McGrath	Director	March 9, 2023
/s/ Jon Kaplan Jon Kaplan	Director	March 9, 2023
/s/ Adam Stern Adam Stern	Director	March 9, 2023

DARIOHEALTH CORP. AND ITS SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

AS OF DECEMBER 31, 2022

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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, 2022 and 2021, 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, 2022, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, 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, management identified there were conditions that raised substantial doubt about the Company's ability to continue as a going concern for a period of one year from the date the financial statements were issued. The conditions that resulted in the substantial doubt being raised included a history of net losses, net operating cash outflows, significant interest payments, a requirement through its Credit Agreement to maintain a minimum liquidity of $10 million, and an accumulated deficit. However, based on management's operating plan and resulting available liquidity, management believes the Company's liquidity is sufficient to fund operations and satisfy their financial obligations as they become due for at least one year from the financial statement issuance date. Therefore, the Company concluded these plans alleviate the substantial doubt that was raised about the Company's ability to continue as a going concern for at least twelve months from the date that the financial statements were issued.

We identified the evaluation of going concern as a critical audit matter. There was significant auditor judgment required in evaluating the Company's forecasted cash flows, and resulting available liquidity, throughout the 12 months from the date of the issuance of the consolidated financial statements.

How We Addressed the Matter in Our Audit

In addressing the matter our audit procedures included, among others, , assessing the reasonableness of the forecasted revenue, operating expenses, and uses and sources of cash used in management's assessment of 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, consideration of positive and negative evidence impacting management's forecasts and liquidity and evaluated management's analysis of their impact on the forecasted cash flows. We performed sensitivity analyses to assess the impact of changes in the key assumptions included in management's liquidity forecast models. We also assessed the probability and timing of forecasted cash outflows related to the settlement of current liabilities included in management's assessment and evaluated the reasonableness of management's cost reduction initiatives. 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 9, 2023

DARIOHEALTH CORP. AND ITS SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS
U.S. dollars in thousands

	December 31,	
	2022	2021
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 49,357	$ 35,808
Short-term restricted bank deposits	165	192
Trade receivables	6,416	1,310
Inventories	7,956	6,228
Other accounts receivable and prepaid expenses	1,630	2,067
Total current assets	65,524	45,605
NON-CURRENT ASSETS:		
Deposits	6	20
Operating lease right of use assets	1,206	287
Long-term assets	111	57
Property and equipment, net	788	702
Intangible assets, net	9,916	12,460
Goodwill	41,640	41,640
Total non-current assets	53,667	55,166
Total assets	$ 119,191	$ 100,771

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,	
	2022	2021
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 2,322	$ 5,109
Deferred revenues	1,320	1,195
Operating lease liabilities	293	266
Other accounts payable and accrued expenses	6,592	7,806
Loan, current	8,823	-
Total current liabilities	19,350	14,376
NON-CURRENT LIABILITIES		
Operating lease liabilities	827	21
Earn-out liability	—	825
Long-term loan	18,105	—
Warrant liability	910	—
Total non-current liabilities	19,842	846
STOCKHOLDERS' EQUITY		
Common stock of $0.0001 par value - Authorized: 160,000,000 shares at December 31, 2022 and December 31, 2021; Issued and Outstanding: 25,724,470 and 16,573,420 shares at December 31, 2022 and December 31, 2021, respectively	3	2
Preferred stock of $0.0001 par value - Authorized: 5,000,000 shares at December 31, 2022 and December 31, 2021; Issued and Outstanding: 3,567 and 11,927 shares at December 31, 2022 and December 31, 2021, respectively	*) -	*) -
Additional paid-in capital	365,846	307,561
Accumulated deficit	(285,850)	(222,014)
Total stockholders' equity	79,999	85,549
Total liabilities and stockholders' equity	$ 119,191	$ 100,771

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,	
	2022	2021
Revenues:		
Services	$ 17,859	$ 2,085
Hardware and consumable products	9,797	18,428
Total revenues	27,656	20,513
Cost of revenues:		
Services	5,324	338
Hardware and consumable products	8,320	12,106
Amortization of acquired intangible assets	4,357	4,106
Total cost of revenues	18,001	16,550
Gross profit	9,655	3,963
Operating expenses:		
Research and development	$ 19,649	$ 17,219
Sales and marketing	30,323	39,706
General and administrative	16,493	23,532
Total operating expenses	66,465	80,457
Operating loss	56,810	76,494
Total financial expenses, net	5,379	235
Loss before taxes	62,189	76,729
Income Tax	4	32
Net loss	$ 62,193	$ 76,761
Other comprehensive loss:		
Deemed dividend	$ 1,643	$ 2,005
Net loss attributable to shareholders	$ 63,836	$ 78,766
Net loss per share:		
Basic and diluted loss per share	$ 2.54	$ 4.07
Weighted average number of common stock used in computing basic and diluted net loss per share	23,635,038	16,591,718

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, 2021	8,119,493	$ *) -	15,823	$ *) -	$171,399	$ (143,248)	$ 28,151
Payment for executives and directors under stock for salary program	10,934	*) -	—	—	152	—	152
Exercise of Options	40,545	*) -	—	—	256	—	256
Exercise of agent warrants	111,061	*) -	—	—	—	—	*) -
Exercise of warrants	219,992	*) -	—	—	633	—	633
Issuance of common stock to consultants and service provider	342,947	*) -	—	—	4,626	—	4,626
Issuance of common stock to directors and employees	18,885	*) -	—	—	303	—	303
Deemed dividend related to issuance of Preferred Stock	—	—	—	—	2,005	(2,005)	—
Conversion of preferred stock to common stock	918,237	*) -	(3,896)	*) -	—	—	*) -
Issuance of warrants to service providers	—	—	—	—	6,817	—	6,817
Issuance of common stock, net of issuance cost	3,278,688	1	—	—	64,876	—	64,877
Issuance of Common Stock, net of issuance cost upon Acquisitions	2,418,011	1	—	—	43,421	—	43,422
Stock-based compensation	1,094,627	—	—	—	13,073	—	13,073
Net loss	—	—	—	—	—	(76,761)	(76,761)
Balance as of December 31, 2021	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

*) 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,	
	2022	2021
Cash flows from operating activities:		
Net loss	$ (62,193)	$ (76,761)
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	16,975	24,971
Depreciation	356	282
Change in operating lease right of use assets	(919)	211
Amortization of acquired intangible assets	4,361	4,175
Increase in trade receivables	(5,106)	(351)
Decrease (Increase) in other accounts receivable, prepaid expense and long-term assets	(3)	(16)
Increase in inventories	(1,728)	(2,230)
Increase (decrease) in trade payables	(2,787)	1,080
Decrease in other accounts payable and accrued expenses	(1,314)	(865)
Increase (decrease) in deferred revenues	125	(157)
Change in operating lease liabilities	833	(245)
Remeasurement of earn-out	(497)	(503)
Non-Cash financial expenses	4,052	—
Net cash used in operating activities	(47,845)	(50,409)
Cash flows from investing activities:		
Purchase of property and equipment	(442)	(261)
Cash paid as part of PsyInnovations Inc. (dba WayForward) acquisition	—	(4,997)
Cash paid as part of Upright Technologies Ltd. acquisition	—	(2,476)
Investment in a loan	—	(400)
Purchase of intangible assets	(131)	—
Net cash used in investing activities	(573)	(8,134)
Cash flows from financing activities:		
Proceeds from issuance of common stock and prefunded warrants (net of issuance costs)	38,288	64,877
Proceeds from exercise of warrants	—	633
Proceeds from exercise of options	—	256
Proceeds from borrowings on credit agreement	23,786	—
Repurchase and retirement of common stock	(134)	—
Net cash provided by financing activities	61,940	65,766
Increase in cash, cash equivalents and restricted cash and cash equivalents	13,522	7,223
Cash, cash equivalents and restricted cash and cash equivalents at beginning of period	35,948	28,725
Cash, cash equivalents and restricted cash and cash equivalents at end of period	49,470	35,948
Supplemental disclosure of cash flow information:		
Cash paid during the period for interest on long-term loan	1,876	—
Non-cash activities:		
Right-of-use assets obtained in exchange for lease liabilities	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") was incorporated in 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 diabetes solution, its user-centric approach is used by tens of thousands of customers around the globe. DarioHealth is rapidly expanding its solutions for additional chronic conditions such as hypertension and moving into new geographic markets.

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. On January 26, 2021, the Company entered into a share purchase agreement (the "Share Purchase Agreement") pursuant to which the Company, through LabStyle, acquired all of the outstanding securities of Upright Technologies Ltd. and its wholly owned subsidiary Upright Technologies Inc. ("Upright"). Upright is a digital musculoskeletal ("MSK") health company focused on preventing and treating the most common MSK conditions through behavioral science, biofeedback, coaching, and wearable tech. See note 4.

d. On May 15, 2021, the Company entered into an agreement and plan of merger (the "Agreement and Plan of Merger") pursuant to which the Company, through its fully owned subsidiary WF Merger Sub, Inc. ("Merger Sub") merged with PsyInnovations Inc. ("WayForward"), pursuant to which the Merger Sub was the surviving company. PsyInnovations Inc. (dba WayForward) is a mental health company who develops the WayForward behavioral digital health platform with artificial intelligence (AI) enabled screening to triage and navigate members to specific interventions, digital cognitive behavioral therapy (CBT), self-directed care, expert coaching and access to in-person and telehealth provider visits. See note 4.

e. Under Accounting Standard Codification ("ASC") Subtopic 205-40, Presentation of Financial Statements—Going Concern ("ASC 205-40"), the Company has the responsibility to evaluate whether conditions and/or events raise substantial doubt about its ability to meet its obligations as they become due within one year after the date that the financial statements are issued. As required under ASC 205-40, management's evaluation should initially not take into consideration the potential mitigating effects of management's plans that have not been fully implemented as of the date the financial statements are issued. The accompanying financial statements have been prepared assuming that the Company will continue as a going concern.

NOTE 1:- GENERAL (Cont.)

Evaluation of Substantial Doubt Raised

In performing the first step of the evaluation, the Company concluded that the following conditions raised substantial doubt about its ability to continue as a going concern:

- History of net losses of $62,193 and $76,761 for the years ended December 31, 2022, and 2021, respectively.
- Net operating cash outflow of $47,845 and $50,409 in 2022 and 2021, respectively.
- Significant cash payments for interest on our Loan Facility (as hereinafter defined) of $1,876 in 2022 and significant cash payments for interest and principal of $8,823 expected in 2023.
- A requirement that the Company maintain a minimum of $10,000 in liquidity, at all times, to not be in default of the Loan Facility. If the Company will be in default of the Loan Facility, the lender could require the immediate payment of all the outstanding loan amount.

Consideration of Management's Plans

In performing the second step of this assessment, the Company is required to evaluate whether it is probable that the Company's plans will be effectively implemented within one year after the financial statements are issued and whether it is probable those plans will alleviate the substantial doubt raised about the Company's ability to continue as a going concern.

As of December 31, 2022, the Company had $49,357 in available cash and cash equivalents.

The Company has approved a plan, to improve its available cash balances, liquidity and cash flows generated from operations. The Company is prepared to implement the following actions as required by business and market conditions : reducing non-essential expenses to conserve cash and improve its liquidity position, deferral and reprioritization of certain research and development programs that would involve reduced program spend and total compensation reductions for senior executives to strengthen liquidity and to preserve key research and development, commercial and functional roles.

Management Assessment of Ability to Continue as a Going Concern

The Company has a history of operating losses and negative cash flows from operations. However, despite these conditions, the Company believes management's plans, as described more fully above, will provide sufficient liquidity to meet its financial obligations and maintain levels of liquidity as specifically required under the Loan Facility.

Therefore, management concluded these plans alleviate the substantial doubt that was raised about the Company's ability to continue as a going concern for at least twelve months from the date that the consolidated financial statements were issued.

DARIOHEALTH CORP. AND ITS SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
U.S. dollars in thousands

NOTE 1:- GENERAL (Cont.)

Future Plans and Considerations

Although not considered for purposes of the Company's assessment of whether substantial doubt was alleviated, the Company has plans to improve operating cash flows by entering into strategic partnerships with other companies that can provide access to additional customers and new markets. The Company may also seek to raise additional funds through the issuance of debt and/or equity securities or otherwise.

The Company's plans are subject to inherent risks and uncertainties. Accordingly, there can be no assurance that the Company's plans can be effectively implemented and, therefore, that the conditions can be effectively mitigated.

Until such time, if ever, that the Company can generate revenue sufficient to achieve profitability, the Company expects to finance its operations through equity or debt financings, which may not be available to the Company on the timing needed or on terms that the Company deems to be favorable. To the extent that the Company raises additional capital through the sale of equity or debt securities, the ownership interest of its stockholders will be diluted. If the Company is unable to maintain sufficient financial resources, its business, financial condition and results of operations will be materially and adversely affected.

f. In December 2015, the United States Food and Drug Administration granted LabStyle 510(k) clearance for the Dario Blood Glucose Monitoring System, including its components, the Dario Blood Glucose Meter, Dario Blood Glucose Test Strips, Dario Glucose Control Solutions and the Dario app on the Apple iOS 6.1 platform and higher.

g. On March 4, 2016, the Company's Common Stock, par value $0.0001 per share (the "Common Stock") and warrants to purchase shares of Common Stock were approved for listing on the Nasdaq Capital Market under the symbols "DRIO" and "DRIOW," respectively. Our listed warrants expired in March 2021 and ceased trading on the Nasdaq Capital Market as a result.

h. The Company has been carefully monitoring the COVID-19 pandemic and its impact on its business. In that regard, the Company has continued to sell its Dario™ Blood Sugar Monitor and has not experienced disruptions in its supply chains. With respect to the Company's DTx platform, it has observed that some of its business-to-business prospective partners have been addressing their business needs as a result of the COVID-19 pandemic, which has resulted in a slowdown of negotiations and discussions with some of these potential partners. In addition, the Company has also seen an increase in interest from other business-to-business prospective partners in its DTx platform, as certain parties are seeking tele-health products. While the Company is not able at this time to estimate future impacts of the COVID-19 pandemic on its financial and operational results, such impacts could be material.

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.

Management believes the Company's critical accounting policies and estimates are reasonable based upon information available at the time they are made. 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 and Upright 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.

DARIOHEALTH CORP. AND ITS SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
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 0.61% and 0.01% as of December 31, 2022 and 2021, respectively. The short-term restricted bank deposits are presented at their cost, including accrued interest.

As of December 31, 2022, and 2021, the Company had a short-term restricted bank deposit which are used as collateral for rent in the amount of $113 and $127, respectively.

As of December 31, 2022, and 2021, the Company had short-term restricted bank deposits which are used as collateral for credit payments in amounts of $52 and $65, 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,	
	2022	2021
Cash, and cash equivalents as reported on the balance sheets	$ 49,357	$ 35,808
Short-term restricted bank deposits, as reported on the balance sheets	$ 113	$ 140
Cash, restricted cash, cash equivalents and restricted cash and cash equivalents as reported in the statements of cash flows	$ 49,470	$ 35,948

g. 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 and ramp up of manufacturing 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, 2022, and 2021 amounted to $88 and $73, respectively.

DARIOHEALTH CORP. AND ITS SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
U.S. dollars in thousands

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

h. 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

i. 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. As of December 31, 2022, and 2021, no impairment was recorded.

j. 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.

Consumers revenue

The Company considers customer and distributers purchase orders to be the 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. As the Company’s standard payment terms are less than one year, the contracts have no significant financing component. The Company allocates 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 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 and the costs associated with these contracts are recognized as incurred.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

Commercial revenue

The Company provide a 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 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. Revenue is recognized either on a per engaged member per month (PEMPM) or a per employee per month (PEPM) basis. Contracts typically have a duration of more than one year.

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 rate. 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. 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.

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.

k. 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.

l. Concentrations of credit risk:

Financial instruments that potentially subject the Company to credit risk primarily consist of cash and cash equivalents, short-term restricted bank 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 of the 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 performs ongoing credit evaluations of its customers. An allowance for doubtful accounts is determined with respect to those specific amounts that the Company has determined to be doubtful of collection. 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, 2022, the Company's major customer accounted for 80.9% of the Company's accounts receivable balance.

The Company's major customer accounted for 39.8%, for the year ended December 31, 2022, of the Company's revenue in the relevant period.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

m. 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. As of December 31, 2022, and 2021 a full valuation allowance was provided by the Company.

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, 2022, and 2021, no liability for unrecognized tax benefits was recorded.

n. Research and development costs:

Research and development costs are charged to the consolidated statements of comprehensive loss, as incurred.

o. 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.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

p. 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.

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 less observable or unobservable in the market, the determination of fair value requires more judgment, and the investments 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, warrants liability and earn-out liability were measured at fair value using Level 3 unobservable inputs (see note 4b) until the resolution date of December 31, 2022. The Company utilized a Monte Carlo simulation model for the initial and subsequent valuations of the earn-out liability.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

q. 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.

r. 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 considers its Convertible Preferred shares to be participating securities as the holders of the Convertible Preferred shares would be entitled to dividends that would be distributed to the holders of Common Stock, on a pro-rata basis 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 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.

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 5,744,428 and 6,812,285 for the year ended December 31, 2022 and 2021, respectively.

s. 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, 2022 and 2021 amounted to $1,136 and $870, respectively.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

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 92%, but generally not greater than $21 per year (for certain employees over 50 years of age the maximum contribution is $27 per year), of their annual compensation to the plan through salary deferrals, subject to Internal Revenue Service limits.

t. 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, 2022 and 2021, 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.

u. 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.

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.

v. 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.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

Significant estimates in valuing certain intangible assets include, but are not limited to future expected cash flows from acquired technology and acquired brand from a market participant perspective, useful lives and discount rates. Management's estimates of fair value are based upon assumptions believed to be reasonable, but which are inherently uncertain and unpredictable and, as a result, actual results may differ from estimates. Acquisition-related expenses are recognized separately from the business combination and are expensed as incurred.

The Company accounts for a transaction as an asset 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.

w. 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, in accordance with the guidance in FASB Accounting Standards Update (“ASU”) No. 2017-04,

Intangibles - Goodwill and Other (Topic 350), Simplifying the Test for Goodwill Impairment, which was adopted as of January 1, 2020.

For the years ended December 31, 2022 and 2021, no impairment of goodwill has been recorded.

x. Recently issued accounting pronouncements, not yet adopted:

1. In September 2016, the Financial Accounting Standards Board (the "FASB") issued ASU 2016-13, “Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments” (“ASU 2016-13”). ASU 2016-13 changes the impairment model for most financial assets and certain other instruments. For trade and other receivables, held-to-maturity debt securities, loans, and other instruments, entities will be required to use a new forward-looking “expected loss” model that generally will result in the earlier recognition of allowances for losses.

   The guidance also requires increased disclosures. For the Company, the amendments in the update were originally effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. 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 U.S. Securities and Exchange Commission) and other non-SEC reporting entities to fiscal years beginning after December 15, 2022, including interim periods within those fiscal periods. Early adoption is permitted. The Company does not expect this standard to have a material effect on its consolidated financial statements.

DARIOHEALTH CORP. AND ITS SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
U.S. dollars in thousands

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

2. In August 2020, the FASB issued ASU 2020-06, which simplifies the guidance on the issuer's accounting for convertible debt instruments by removing the separation models for (1) convertible debt with a cash conversion feature and (2) convertible instruments with a beneficial conversion feature. As a result, entities will not separately present in equity an embedded conversion feature in such debt. Instead, they will account for a convertible debt instrument wholly as debt, unless certain other conditions are met. The elimination of these models will reduce reported interest expense and increase reported net income for entities that have issued a convertible instrument that was within the scope of those models before the adoption of ASU 2020-06. ASU 2020-06 also requires that the effect of potential share settlement be included in the diluted earnings per share calculation when an instrument may be settled in cash or share. This amendment removes current guidance that allows an entity to rebut this presumption if it has a history or policy of cash settlement. Furthermore, ASU 2020-06 requires the application of the if-converted method for calculating diluted earnings per share, the treasury stock method will be no longer available. The provisions of ASU 2020-06 are applicable for fiscal years beginning after December 15, 2023, with early adoption permitted for fiscal years beginning after December 15, 2020. The Company is currently evaluating the impact of ASU 2020-06 on its consolidated financial statements.

3. 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 does not expect this standard to have a material effect on its consolidated financial statements.

NOTE 3:- OTHER ACCOUNTS RECEIVABLE AND PREPAID EXPENSES

	December 31,	
	2022	2021
Prepaid expenses	$ 908	$ 1,591
Costs to fulfill a contract	483	—
Government authorities	239	76
Loan receivables	—	400
	$ 1,630	$ 2,067

NOTE 4:- ACQUISITIONS

2022 Acquisition

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

Prior Year Acquisitions

Acquisition of Upright

On February 1, 2021 (the "Acquisition Date"), the Company completed the acquisition, through its subsidiary LabStyle, of Upright. The acquisition was accounted as a business combination.

The consideration transferred included 1,649,887 shares of Common Stock, the repayment of Upright's outstanding debt in the amount of $3,020, a settlement of a loan previously granted by the Company to Upright in the amount of $1,500 and an issuance of a replacement share based compensation awards in the amount of $712. The total consideration transferred in the acquisition of Upright was $33,578.

Goodwill is primarily attributable to expected synergies arising from technology integration and expanded product availability to the Company's existing and new customers. Goodwill is not deductible for income tax purpose.

In addition, the Company incurred acquisition-related costs in a total amount of $378. Acquisition-related costs include legal and accounting services which were included in general and administrative expenses in the Consolidated Statements of Comprehensive loss.

Purchase price allocation:

Under business combination accounting principles, the total purchase price was allocated to Upright's net tangible and intangible assets based on their estimated fair values as set forth below. The excess of the purchase price over the net tangible and identifiable intangible assets was recorded as goodwill.

The allocation of the purchase price to the assets acquired and liabilities assumed based on management's estimate of fair values at the date of acquisition as follows:

		Amortization period (Years)
Tangible assets acquired (including cash of $544)	$ 1,405	
Inventory	2,845	
Liabilities assumed	(6,001)	
Net liabilities assumed	(1,751)	
Technology	9,599	4
Goodwill	25,730	Infinite
Total purchase price	$ 33,578	

U.S. dollars in thousands

NOTE 4:- ACQUISITIONS (Cont.)

Acquisition of WayForward

On June 7, 2021, the Company through the Merger Sub, completed the acquisition of WayForward through the merger of WayForward into Merger Sub, which changed its name to PsyInnovations, Inc. The acquisition was accounted for as a business combination.

The consideration transferred included 889,956 restricted shares of Common Stock (including 121,832 hold-back shares that were issued in December 2022), cash consideration of $5,387 and an earn-out consideration payable of 76,856 restricted shares of Common Stock, subject to certain revenue thresholds that will be resolved in 2022. The fair value total consideration transferred in the acquisition of WayForward was $21,079.

The fair value, as of the closing date, of the earn-out consideration was $1,328 and was included as part of the consideration transferred. Since the earn-out arrangement is not indexed to the Company's own stock, the earn-out arrangement was accounted for as a liability, subsequently measured at fair value through earnings until resolution. Goodwill is primarily attributable to expected synergies arising from technology integration and expanded product availability to the Company’s existing and new customers. Goodwill is not deductible for income tax purpose.

As of December 31, 2022, the earnout conditions have been satisfied. Pursuant to the settlement agreement, the Company remeasured the earn-out liability measured at fair value through earnings until the resolution date. The Company is to issue 76,856 shares of Common Stock with a fair value of $328 as of December 31, 2022. For the year ended December 31, 2022, the Company recorded remeasurement income in the amount of $497.

In addition, the Company incurred acquisition-related costs in a total amount of $502 acquisition-related costs which include legal and accounting acquisition-related costs include legal and accounting services which were included in general and administrative expenses in the Consolidated Statements of Comprehensive loss.

Purchase price allocation:

Under business combination accounting principles, the total purchase price was allocated to WayForward’s net tangible and intangible assets based on their estimated fair values as set forth below. The excess of the purchase price over the net tangible and identifiable intangible assets was recorded as goodwill.

The allocation of the purchase price to the assets acquired and liabilities assumed based on management’s estimate of fair values at the date of acquisition as follows:

		Amortization period (years)
Tangible assets acquired (including cash of $139)	$ 349	
Liabilities assumed	(1,076)	
Net liabilities assumed	(727)	
Technology	5,520	4
Brand	376	3
Goodwill	15,910	Infinite
Total purchase price	$ 21,079	

DARIOHEALTH CORP. AND ITS SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
U.S. dollars in thousands

NOTE 5:- INVENTORIES

Inventory consists of the following:

	December 31,	
	2022	2021
Raw materials	$ 1,346	$ 714
Finished products	6,610	5,514
	$ 7,956	$ 6,228

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.

Since the contract consideration includes variable consideration, as of December 31, 2022, 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.

During 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 revenues for the completion of the first development plan.

On December 13, 2022, the second development plan was approved. 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 revenues with respect to the second development plan, with additional revenues from the second development plan of $2,494 expected to be recognized by the end of June 2023.

U.S. dollars in thousands

NOTE 6: - REVENUES (Cont.)

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.

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.

As of December 31, 2022, the Company has recognized revenues of $1,778 with additional revenues of $872 expected to be recognized by June of 2023.

Revenue Source:

The following tables represent the Company total revenues for the year ended December 31, 2022 and 2021 disaggregated by revenue source:

	December 31,	
	2022	2021
Commercial	$ 16,377	$ 851
Consumers	11,279	19,662
	$ 27,656	$ 20,513

U.S. dollars in thousands

NOTE 6:- REVENUE (Cont.)

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 reporting period.

The following table presents the significant changes in the deferred revenue balance during the year ended December 31, 2022:

Balance, beginning of the period	$ 1,195
New performance obligations	27,781
Reclassification to revenue as a result of satisfying performance obligations	(27,656)
Balance, end of the period	$ 1,320

Costs to fulfill a contract

The Company defer costs incurred to fulfill contracts that: (1) relate directly to the contract; (2) are expected to generate resources that will be used to satisfy our performance obligation under the contract; and (3) are expected to be recovered through revenue generated under the contract. Contract fulfillment costs are expensed as we satisfy our performance obligations and recorded in cost of revenue.

Costs to fulfill a contract are recorded to other accounts receivable and prepaid expenses and long term assets.

Costs to fulfill a contract consist of (1) deferred hardware cost incurred in connection with delivery of services that are deferred. (2) deferred costs incurred, related to future performance obligations which are capitalized.

Costs to fulfill a contract as of December 31, 2022, consisted of the following:

	December 31, 2022
Costs to fulfill a contract, current	$ 483
Costs to fulfill a contract, noncurrent	41
Total Costs to fulfill a contract	$ 524

DARIOHEALTH CORP. AND ITS SUBSIDIARIES

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U.S. dollars in thousands

NOTE 7:- FAIR VALUE MEASUREMENTS

The carrying amounts of cash and cash equivalents, short-term and restricted bank deposits, trade receivables, trade payables, other receivables and prepaid expenses and other payables and accrued expenses approximate their fair value due to the short-term maturity of such instruments.

The following tables present information about the Company's financial assets and liabilities measured at fair value on a recurring basis and indicate the level of the fair value hierarchy used to determine such fair values:

	Year ended December 31, 2022			
	Fair Value	Level 1	Level 2	Level 3
	(in thousands)			
Financial Liabilities:				
Long Term Loan	26,928	—	—	26,928
Warrant liability	910	—	—	910
Total Financial Liabilities	$ 27,838	$ —	$ —	$ 27,838

	December 31, 2021			
	Fair Value	Level 1	Level 2	Level 3
	(in thousands)			
Financial Liabilities:				
Earn out liability	$ 825	$ —	$ —	$ 825
Total Financial Liabilities	$ 825	$ —	$ —	$ 825

FCA

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 "Lender"). The Credit Agreement provides for a five-year senior secured credit facility in an aggregate principal amount of up to $50 million (the "Loan Facility" or "Loan"), of which $25 million was made available on the Closing Date (the "Initial Commitment Amount" or "First Tranche") and up to $25 million may be made available on or prior to June 30, 2023, subject to certain revenue requirements (the "Delayed Draw Commitment Amount" or "Second Tranche"). On June 9, 2022, the Company closed on the Initial Commitment Amount, less certain fees and expenses payable to or on behalf of the Lender.

The FCA instrument was recognized in connection with the Delayed Draw Commitment Amount (Note 8). The fair value of the FCA is estimated by the Company at each reporting date, which are prepared based on significant inputs that are generally determined based on relative value analyses. The FCA fair value was estimated using a discount rate of 15.6% which reflects the internal rate of return of the Loan at closing of the transactions contemplated by the Credit Agreement as of June 9, 2022 and represents the $25 million Delayed Draw Commitment Amount that may be made available on or prior to June 30, 2023 on similar terms to the Initial Commitment Amount. Therefore, the value of the FCA for the Delayed Draw Commitment Amount of the Loan was initially estimated as 50% of the sum of the commitment fee paid upfront and the lender expenses in relation to the Loan origination.

As of December 31, 2022, the Company will not be eligible to the Delayed Draw Commitment Amount. Based on that, the fair value of the FCA was de-recognized.

U.S. dollars in thousands

NOTE 7:- FAIR VALUE MEASUREMENTS (Cont.)

Loan Facility

The fair value of the Loan Facility is recognized in connection with the Company's Credit Agreement with respect to the Initial Commitment Amount only (Note 8). The fair value of the 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 Loan, which is reported within non-current liabilities and current liabilities (Maturity Date - June 9, 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 Loan incorporates comparisons to instruments with similar covenants, collateral, and risk profiles and was obtained using a discounted cash flow technique. On the date of Loan origination, or June 9, 2022, the discount rate was arrived at by calibrating the loan amount of $25 million with the fair value of the warrants of $910 and the loan terms interest rate of secured overnight financing rate ("SOFR") + 9.5%. The implied internal rate of return of the loan was 15.6%. The fair value of the Loan, as of December 31, 2022, was estimated using a discount rate of 15.6% which reflects the internal rate of return of the Loan at closing, as of June 9, 2022. The change in the fair value of the loan was recorded in earnings since the Company has concluded that no adjustment 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 Loan agreement with the 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):

	June 9, 2022	December 31, 2022
Stock price	$ 7.45	$ 4.28
Exercise price	6.62	6.62
Expected term (in years)	7.00	6.44
Volatility	148.8%	148.1%
Dividend rate	-	-
Risk-free interest rate	3.13%	4.05%

U.S. dollars in thousands

NOTE 7:- FAIR VALUE MEASUREMENTS (Cont.)

The following tables present the summary of the changes in the fair value of our Level 3 financial instruments:

	Year ended December 31, 2022		
	Long-Term Loan	Warrant Liability	FCA
Balance as of January 1, 2022	$ —	$ —	$ —
Issuance	23,070	1,930	—
Initial measurement of the FCA	—	—	607
Change in fair value	3,858	(1,020)	(607)
Balance as of December 31, 2022	$ 26,928	$ 910	$ 0

Earn out Liability

As part of the acquisition of wayForward on June 7, 2021, the consideration transferred included earn-out payable in up to 237,076 restricted shares of Common Stock. The earn-out arrangement is not indexed to the Company's own stock and was accounted as a liability and subsequently measured at fair value through earnings until resolution of the earn-out.

In determining the earn-out fair value, the Company used the Monte-Carlo simulation valuation technique, in order to predict the probability of different outcomes that rely on repeated random variables.

On July 7, 2022, the Company entered into an Amendment to Agreement and Plan of Merger (the “Amendment”) with representatives of the former equity holders of PsyInnovations, Inc. Pursuant to the terms of the Amendment, the Company agreed to reduce the earn-out threshold of revenue derived from wayForward products from $5 million to $3 million.

As of December 31, 2022, the earnout conditions have been satisfied. As a result, the Company will issue 76,856 shares of Common Stock with fair value of $328.

NOTE 8:- DEBT

Loan Facility

On June 9, 2022 the Company entered into the Credit Agreement with the Lender. The Credit Agreement provides for a five-year senior secured credit facility in an aggregate principal amount of up to $50 million, of which $25 million, representing the Initial Commitment Amount, was made available on the closing date and up to $25 million, representing the Delayed Draw Commitment Amount, may be made available on or prior to June 30, 2023, subject to certain revenue requirements. On June 9, 2022, the Company closed on the Initial Commitment Amount, less certain fees and expenses payable to or on behalf of the Lender.

All obligations under the Credit Agreement are guaranteed by all of the Company’s wholly owned subsidiaries other than Dario Health Services Private Limited. All obligations under the Credit Agreement, and the guarantees of those obligations, are secured by substantially all of the Company's and each guarantor's assets by a Pledge and Security Agreement, dated June 9, 2022 (the “Pledge and Security Agreement”). The Credit Agreement contains a revenue covenant effective to the maturity date, of which if the Company’s net revenue does not equal or exceed the applicable amount for such period as set in the Credit Agreement, then the Company shall repay in equal monthly installments the outstanding principal amount of the Loan Facility. The Company 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 Credit Agreement.

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NOTE 8: - DEBT (Cont.)

During the term of the Loan Facility, interest payable in cash by the Company shall accrue on any outstanding balance due under the Loan Facility at a rate per annum equal to the higher of (x) the adjusted SOFR rate (which is the forward-looking term rate for a one-month tenor based on the secured overnight financing rate administered by the CME Group Benchmark Administration Limited) and (y) 0.50% plus, in either case, 9.50%.

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 Credit Agreement contains customary events of default, including with respect to non-payment of principal, interest, fees or other amounts; material inaccuracy of a representation or warranty; failure to perform or observe covenants; bankruptcy and insolvency events; material monetary judgment defaults; impairment of any material definitive loan documentation; other material adverse effects; key person events and change of control.

Each of the Credit Agreement and a Pledge and Security Agreement also contain a number of customary representations, warranties and covenants that, among other things, will limit or restrict the ability of the Company and its subsidiaries to (subject to certain qualifications and exceptions): create liens and encumbrances; incur additional indebtedness; merge, dissolve, liquidate or consolidate; make acquisitions, investments, advances or loans; dispose of or transfer assets; pay dividends or make other payments in respect of their capital stock;

amend certain material documents; redeem or repurchase certain debt; engage in certain transactions with affiliates; and enter into certain restrictive agreements. In addition, the Company will be required to maintain at least $10 million of unrestricted cash and cash-equivalents at all times.

On the closing date of the Credit Agreement, and with respect to the Initial Commitment Amount only, the Company agreed to issue the Lender a warrant (the “Warrant”) to purchase up to 226,586 shares of the Company’s common stock, at an exercise price of $6.62 per share, which shall have a term of 7 years from the issuance date. In the event the Company is eligible to draw the Delayed Draw Commitment Amount, the Company agreed to issue the Lender an additional warrant (the “Additional Warrant”), with a term of 7 years from the issuance date, to purchase up to 6% of the Delayed Draw Commitment Amount based on a 10-day volume weighted average price of the Company’s common stock (the “Volume Weighted Average Price”) with an exercise price equal to the Volume Weighted Average Price.

The Company concluded that the Credit Agreement includes three legally detachable and separately exercisable freestanding financial instruments: the Initial Commitment Amount, the warrants, and the right to receive the Delayed Draw Commitment Amount, which we refer to as the "Financial Commitment Asset" or "FCA".

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.

The Company has also concluded that the FCA is not indexed to the Company's own stock and should be recorded as an asset, measured at fair value with changes in fair value recognized in earnings. The FCA is presented within other accounts receivable on the interim consolidated balance sheets.

The Company elected to account for the Initial Commitment Amount 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.

DARIOHEALTH CORP. AND ITS SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
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NOTE 8: - DEBT (Cont.)

During the year ended December 31, 2022, the Company recognized $2,838 of remeasurement expenses related to the Initial Commitment Amount, which were included as part of financial expenses (income) in the Company's statements comprehensive loss. During the year ended December 31, 2022, the Company did not recognize any instrument specific credit risk fair value adjustment.

Pursuant to the terms of the Credit Agreement the Company started repayment of the outstanding principal amount of the initial commitment Amount of $25 million issued as part of the Loan Facility, together with a repayment premium and other fees in monthly installments of up to $518 beginning as of January 31, 2023, and continuing through the maturity date, or June 9, 2027.

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 2021 and 2023. 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 the practical expedient for short term leases.

The components of lease costs, lease term and discount rate are as follows:

	Twelve Months Ended December 31, 2022
Lease cost	
Operating lease cost	$ 333
Short term lease cost	314
Variable lease cost	15
Total lease cost	$ 662
Weighted Average Remaining Lease Term	
Operating leases	4.62 years
Weighted Average Discount Rate	
Operating leases	6.26 %

DARIOHEALTH CORP. AND ITS SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
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NOTE 9:- LEASES

The following is a schedule, by years, of maturities of lease liabilities as of December 31, 2022:

	Operating Leases
2023	$ 303
2024	287
2025	250
2026	230
2027	231
Total undiscounted cash flows	1,301
Less imputed interest	(181)
Present value of lease liabilities	$ 1,120

Supplemental cash flow information related to leases are as follows:

	Year ended December 31, 2022
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows from operating leases	$ 333
Lease liabilities arising from obtaining right-of-use assets:	
Operating leases	$ 150

DARIOHEALTH CORP. AND ITS SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
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NOTE 10:- PROPERTY AND EQUIPMENT, NET

Composition of assets, grouped by major classification, is as follows:

	December 31,	
	2022	2021
Cost:		
Computers and peripheral equipment	$ 944	$ 805
Office furniture and equipment	154	161
Production lines	988	812
Leasehold improvement	141	150
	2,227	1,928
Accumulated depreciation:		
Computers and peripheral equipment	534	460
Office furniture and equipment	60	57
Production lines	773	647
Leasehold improvement	72	62
	1,439	1,226
Property and equipment, net	$ 788	$ 702

Depreciation expenses for the year ended December 31, 2022 and 2021 amounted to $356 and $282, respectively.

During the year ended December 31, 2022, the Company recorded a decrease of computers equipment amounted to $143.

DARIOHEALTH CORP. AND ITS SUBSIDIARIES

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NOTE 11:- OTHER INTANGIBLE ASSETS, NET

a. Definite-lived other intangible assets:

	Year ended December 31,		Weighted Average
	2022	2021	Remaining Life
Original amounts:			
Technology	$ 16,936	$ 15,119	2.2
Brand	376	376	1.4
	17,312	15,495	
Accumulated amortization:			
Technology	7,199	2,964	
Brand	197	71	
	7,396	3,035	
Other intangible assets, net	$ 9,916	$ 12,460	

b. Amortization expense amounted to $4,361 and $3,035 for the year ended December 31, 2022 and 2021, respectively.

c. Estimated amortization expense:

For the year ended December 31,	
2023	$ 4,512
2024	4,452
2025	952
	$ 9,916

NOTE 12:- GOODWILL

Following the Company's acquisitions in 2021 as described in Note 4, the changes in the carrying amount of goodwill for the year ended December 31, 2022 and 2021 are as follows:

	December 31, 2022
As of December 31, 2020	$ —
Additions	41,640
As of December 31, 2021	41,640
Additions	—
As of December 31, 2022	$ 41,640

DARIOHEALTH CORP. AND ITS SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
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NOTE 13:- OTHER ACCOUNTS PAYABLE AND ACCRUED EXPENSES

	December 31,	
	2022	2021
Employees and payroll accruals	$ 4,407	$ 3,408
Accrued expenses	2,185	4,398
	$ 6,592	$ 7,806

NOTE 14:- 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.

During the Year ended the company recorded IIA royalties related to the acquisition of Physimax Technology in amount of $120.

NOTE 15:- LONG-LIVED ASSETS

As of December 31, 2022, substantially all of the Company long live assets are located in Israel.

NOTE 16:- 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.

NOTE 16:- TAXES ON INCOME (Cont.)

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.

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 2021 and 2022 was 23%.

Net operating loss carryforward:

Labstyle has accumulated net operating losses for Israeli income tax purposes as of December 31, 2022, in the amount of approximately $150,228. The net operating losses may be carried forward and offset against taxable income in the future for an indefinite period.

As of December 31, 2022, the Company and WayForward had a U.S. federal net operating loss carryforward of approximately $45,427 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 $38,307 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 2018-2022 are excluded from the limitation and can be carried forward indefinitely to offset 100% of future net income.

U.S. dollars in thousands

NOTE 16:- 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,	
	2022	2021
Deferred tax assets:		
Net operating loss and capital losses carry forward	$ 45,790	$ 39,328
Temporary differences - Research and development expenses	4,058	2,654
Temporary differences - Accrued employees costs	366	320
Temporary differences - Stock-based compensation	3,734	1,426
Temporary differences - Credit Facility	723	—
Temporary differences - Intangible Assets	65	—
Temporary differences - Lease	253	—
Deferred tax assets:	54,989	43,728
Less: Valuation allowance	(52,504)	(41,520)
Deferred tax assets	2,485	2,208
Deferred tax liability:		
Temporary differences - Intangible Assets	(2,208)	(2,208)
Temporary differences - Lease	(277)	—
Deferred tax liability	(2,485)	(2,208)
Net deferred tax asset	$ —	$ —

The deferred tax balances included in the consolidated financial statements as of December 31, 2022, 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, 2022, was an increase of $10,984 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 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 16:- TAXES ON INCOME (Cont.)

a. Loss before taxes on income consists of the following:

	Year ended December 31,	
	2022	2021
Domestic	$ 22,902	$ 21,065
Foreign	39,287	55,664
	$ 62,189	$ 76,729

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 17:- 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 April 3, 2015, the Company's Board of Directors approved stock for salary program pursuant to which the Company will issue compensation shares of restricted Common Stock ("Compensation Shares") to directors, officers, and employees of the Company as consideration for a reduction in or waiver of cash salary, bonus or fees owed to such individuals. The waiver of cash salary will be done upon the average closing price of the Common Stock for the 30 trading days prior to the date the Compensation Shares are granted or as otherwise defined by the Compensation Committee of the Board of Directors.

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, 2022 and 2021, a total of 32,926 and 16,126 restricted unregistered shares of Common Stock, respectively, were issued to certain service providers under this approval. During the year ended December 31, 2022 and 2021, the Company recorded compensation expense for service providers in the amount of $172 and $159, respectively.

In April 2020, the Audit and Compensation Committee of the Board of Directors approved monthly grants of 1,500 shares of the Company's Common Stock, of which 639 shares were issued to a board member under the 2012 Plan, and 861 restricted shares to certain service providers to be granted monthly during the 12-month period that the certain consulting agreement with said service providers is in effect.

During the year ended December 31, 2021, a total of 4,500 shares of Common Stock were issued under the said approval of which 1,857 shares were issued to a board member and 2,643 shares were issued to certain service providers under the 2012 and 2020 Plans. The Company recorded compensation expense for service providers in the amount of $21.

During the year ended December 31, 2021, the Company's Compensation Committee of the Board of Directors approved an aggregate of 10,934 shares of Common Stock to certain officers and employees of the Company as consideration for a reduction in, or waiver, of cash salary, or fees owed to such individuals and the grant of 5,000 restricted shares of Common Stock to employee. 14,180 shares were issued under the Company's 2012 Plan and 1,754 shares were issued under the 2020 Plan.

During the year ended December 31, 2021, the Board of Directors approved the grant of an aggregate of 18,885 shares of Common Stock, to officers, employees, and consultants of Upright. The shares were issued under the Company's 2020 Plan.

During the year ended December 31, 2021, the Board of Directors approved the grant of 319,914 unregistered shares of Common Stock to certain consultants and service providers of the Company, and the grant of 7,500 shares of Common Stock that were issued under the 2012 Plan.

NOTE 17:- STOCKHOLDERS' EQUITY (Cont.)

During the year ended December 31, 2021, the Company's Compensation Committee approved the grant of an aggregate of 1,102,243 restricted shares of Common Stock, subject to time vesting to directors, officers, employees and consultants of the Company. The time vesting restricted shares vest over a period of three years commencing on the respective grant dates. The shares were issued under the 2020 Plan.

On April 23, 2022, the Company released 56,788 holdback shares of the Company's common stock to 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 65,000 shares of which 35,000 shell vest over a three-year period, to certain consultants 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 1,233,050 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.

c. In February 2021, the Board of Directors authorized the Company to issue warrants to purchase up to 400,000, shares of Common Stock, to a certain consultant of the Company, at a purchase price of $25.00. As such, during the year ended December 31, 2022 and 2021 the Company recorded compensation a warrant expense for service providers in the amount of $863 and $5,700, respectively.

In April 2021, the Compensation Committee authorized the Company to issue warrants to purchase 30,000 shares of Common Stock, to a certain consultant of the Company, with an exercise price of $30.00 per share, and warrants to purchase 12,500 shares of Common Stock with an exercise price of $18.57 per share. As such, during the year ended December 31, 2021, the Company recorded a warrant compensation expense for service providers in the amount of $387.

In July 2021, the Compensation Committee authorized the Company to issue warrants to purchase 30,000 shares of Common Stock, to certain consultants of the Company, with an exercise price of $23.30 per share, and warrants to purchase 83,948 shares of Common Stock with an exercise price of $16.06 per share. Of these warrants, warrants to purchase 35,000 shares of Common Stock shall vest over a 48-month period and warrants to purchase 48,948 shares of Common Stock are subjected to certain performance terms. As of December 31, 2021, the terms of 3,000 performance-based warrants were met. As such, during the year ended December 31, 2022 and 2021 the Company recorded a warrant compensation expense for service providers in the amount of $131 and $312, respectively.

In September 2021, the Compensation Committee authorized the Company to issue warrants to purchase 25,000 shares of Common Stock, to certain consultant of the Company, with an exercise price of $13.88 per share. As such, during the year ended December 31, 2021, the Company recorded a warrant compensation expense for service providers in the amount of $194.

NOTE 17:- STOCKHOLDERS' EQUITY (Cont.)

In October and December 2021, the Compensation Committee authorized the Company to issue 8,000 shares which shell vest over a six-month period, and warrants to purchase up to 40,000, and 208,000 shares of Common Stock, to certain consultants of the Company, at a purchase price of $25.10 and $13.60, respectively. As such, during the year ended December 31, 2022 and 2021 the Company recorded compensation expense for service providers in the amount of $1,806 and $214, respectively.

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.

In May and June 2022, the Compensation Committee authorized the Company to grant warrants to purchase up to 70,000, and 175,000 shares of the Company's common stock which shall vest over 12 months and 24 months period, respectively, to certain consultants of the Company, at a purchase price of $6.45 and $7.20, respectively. During the year ended December 31, 2022, the Company recorded a warrant compensation expense for service providers in the amount of $375.

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. As such, during the year ended December 31, 2022 the Company recorded compensation a warrant expense for service providers in the amount of $29.

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.

The holders of series A Preferred Stock (excluding Series A-1 Preferred Stock, which do not possess any voting rights) shall be entitled to cast the number of votes equal to the number of whole shares of Common Stock into which the shares of Series A Preferred Stock held by such holder are convertible as of the record date for determining stockholders entitled to vote on such matter. Except as provided by law or by the other provisions of the Certificate of Incorporation, Holders of Series A Preferred Stock shall vote together with the holders of Common Stock as a single class. Upon any liquidation, dissolution or winding-up of the Company, after the satisfaction in full of the debts of the Company and payment of the liquidation preference to the Senior Securities, holders of Series A Preferred Stock shall be entitled to be paid, on a pari passu basis with the payment of any liquidation preference afforded to holders of any Parity Securities, the remaining assets of the Company available for distribution to its stockholders. For these purposes, (i) "Parity Securities" means the Common Stock, Series A Preferred Stock and any other class or series of capital stock of the Company hereinafter created that expressly ranks pari passu with the Series A Preferred Stock; and (ii) "Senior Securities" shall mean any class or series of capital stock of the Company hereafter created which expressly ranks senior to the Parity Securities. Each share of Series A Preferred Stock is convertible at the option of the holder, subject to certain beneficial ownership limitations as set forth in the Series A Certificate of Designation into such number of shares of Company's Common Stock equal to the number of Series A Preferred Shares to be converted, multiplied by the Stated Value, divided by the conversion price in effect at the time of the conversion.

NOTE 17:- STOCKHOLDERS' EQUITY (Cont.)

The Series A Preferred Stock was to automatically convert into shares of Common Stock, subject to certain beneficial ownership limitations, on the earliest to occur of (i) upon the approval of the holders at least 50.1% of the outstanding shares of Series A Preferred with respect to the Series A Preferred Stock; or (ii) the 36-month anniversary of each of the Series A Effective Date. The holders of Series A Preferred Stock will also be entitled dividends payable as follows: (i) 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 Series A Preferred Stock then held by such holder on the 12-month anniversary of the Series A Effective Date, (ii) a number of shares of Common Stock equal to fifteen percent (15%) of the number of shares of Common Stock issuable upon conversion of the Series A Preferred then held by such holder on the 24-month anniversary of the Series A Effective Date, and (iii) a number of shares of Common Stock equal to twenty percent (20%) of the shares of Common Stock issuable upon conversion of the Series A Preferred Stock then held by such holder on the 36-month anniversary of the Series A Effective Date. During the year ended December 31, 2022 and 2021, the Company accounted for the dividend as a deemed dividend in a total amount of $1,580 and 2,005, respectively.

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, 2022, 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 nine months ended 30, 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 and 2021, a total of 1,130 and 3,896 of certain Series A Convertible Preferred Stock, were converted into 339,417 and 918,237 shares of Common Stock, respectively, including issuance of dividend shares.

In November and December 2022, 6,345 Series A Preferred Stock automatically converted into 2,130,322 shares of Common Stock after completing 36-month anniversary of each the Series A Preferred Stock. The conversion was including accumulative dividends payable available upon conversion of each Series A Preferred Stock.

e. On February 1, 2021, the Company 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 Common Stock, at a purchase price of $21.35 per share. The aggregate gross proceeds were approximately $70,000 ($64,877, net of issuance expenses).

f. During the year ended December 31, 2021, options were exercised into 40,545 shares of Common Stock, with aggregate gross proceeds of approximately $256.

DARIOHEALTH CORP. AND ITS SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
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NOTE 17:- STOCKHOLDERS' EQUITY (Cont.)

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 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 fee paid to the sales agent. For the year ended December 31, 2022, the Company received net proceeds of $260 from the sale of 73,037 shares of the Company's common stock. As of December 31, 2022, there were $49,600 remaining funds available under the ATM.

i. The table below summarizes the outstanding warrants as of December 31, 2022:

	Warrants outstanding as of December 31, 2022	Exercise price $	Expiration date
Consultants	400,000	25.00	February 16, 2024
Consultants	10,000	7.50	April 6, 2024
Consultants	12,500	18.57	April 13, 2024
Consultants	10,000	8.00	June 17, 2024
Consultants	10,000	9.00	September 9, 2024
Consultants	20,000	10.00	November 9, 2024
Consultants	35,000	16.06	December 1, 2024
Consultants	3,000	16.06	December 1, 2024
Placement Agent Warrants A-1 December 2019	233,347	4.05	December 19, 2024
Placement Agent Warrants A-2 December 2019	25,034	4.28	December 19, 2024
Placement Agent Warrants A-3 December 2019	47,527	4.98	December 19, 2024
Placement Agent Warrants A-4 December 2019	5,839	5.90	December 19, 2024
Consultants	60,000	6.39	February 12, 2025
Consultants	30,000	30.00	April 1, 2025
Consultants	30,000	23.30	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	25.10	October 1, 2025
Consultants	8,000	13.60	December 31, 2025
Consultants	70,000	6.45	May 19, 2026
Consultants	100,000	13.60	December 31, 2026
Consultants	100,000	13.60	December 31, 2026
Consultants	43,750	7.20	June 8, 2027
Lender of loan facility	226,586	6.62	June 9, 2029
Consultants	13,750	12.00	August 1, 2029
Total outstanding	1,711,796		

NOTE 17:- STOCKHOLDERS' EQUITY (Cont.)

During the year ended December 31, 2022 and 2021, certain Company warrant holders have exercised and exchanged Company warrants as detailed here below:

During the year ended December 31, 2021, certain Company warrants holders have exercised warrants into 219,992 shares for total proceeds of $633.

j. 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.

k. The following shares, restricted shares and, options were issued under the 2012 Plan during 2021 and 2022:

In May 2021, the Compensation Committee of the Board of Directors approved an inducement grant of a non-qualified performance-based stock option award to purchase 60,000 shares of the Company's Common Stock, as well as an additional inducement grant consisting of a non-qualified performance-based stock option award to purchase an additional 15,000 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 one employee as part of the acquisition of WayForward (see note 4), the options were granted on June 7, 2021 as part of the closing of the Merger. As of December 31, 2021, the terms of the performance-based stock options were met.

In July 2021, the Compensation Committee of the Board of Directors approved the grant of a non-qualified stock option award to purchase 20,000 shares of the Company's Common Stock outside of the Company's existing equity incentive plans, pursuant to Nasdaq Listing Rule 5635(c)(4), in connection with the employment of its Special Vice President of Market Access.

On November 9, 2021, the Compensation Committee of the Board of Directors approved the grant of a non-qualified stock option award to purchase 140,000 shares of the Company's Common Stock outside of the Company's existing equity incentive plans, pursuant to Nasdaq Listing Rule 5635(c)(4), in connection with the employment of a Chief Commercial Officer.

DARIOHEALTH CORP. AND ITS SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
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NOTE 17:- 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, 2022 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	1,878,168	18.13	6.96	3,861
Options granted	1,009,550	6.50	—	—
Options exercised		—	—	—
Options expired	(225,568)	18.25	—	—
Options forfeited	(537,848)	15.05	—	—
Options outstanding at end of period	2,124,302	13.38	6.98	121
Options vested and expected to vest at end of period	1,989,466	13.57	6.93	121
Exercisable at end of period	995,513	17.77	5.19	121

Weighted average grant date fair value of options granted during the year ended December 31, 2022 and 2021 is $4.43 and $13.59, respectively.

DARIOHEALTH CORP. AND ITS SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
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NOTE 17:- STOCKHOLDERS' EQUITY (Cont.)

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 2022 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, 2022. 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, 2022 were as follows

	Number of Restricted shares
Restricted shares outstanding at beginning of period	1,094,627
Restricted shares granted	1,233,050
Restricted shares forfeited	(119,905)
Restricted shares outstanding at end of period	2,207,772

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,	
	2022	2021
Volatility	91.11-92.60 %	93.34-111.82 %
Risk-free interest rate	1.89-3.62 %	0.11-1.37 %
Dividend yield	0 %	0 %
Expected life (years)	5.81-6.00	2.09-5.86

As of December 31, 2022, the total unrecognized estimated compensation cost related to non-vested stock options and restricted shares granted prior to that date was $19,651, which is expected to be recognized over a weighted average period of approximately 1.11 year.

The total compensation cost related to all the Company's equity-based awards, recognized during year ended December 31, 2022 and 2021 were comprised as follows:

	Year ended December 31,	
	2022	2021
Cost of revenues	$ 66	$ 97
Research and development	3,608	3,872
Sales and marketing	6,042	6,039
General and administrative	7,259	14,963
Total stock-based compensation expenses	$ 16,975	$ 24,971

DARIOHEALTH CORP. AND ITS SUBSIDIARIES

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NOTE 18:- SELECTED STATEMENTS OF OPERATIONS DATA

Financial losses, net:

	Year ended December 31,	
	2022	2021
Bank charges	$ 83	$ 84
Foreign currency adjustments expenses, net	(243)	195
Interest income	(506)	(44)
Loan Interest Expenses	1,876	—
Remeasurement of long-term loan	3,858	—
Remeasurement of warrant liability	(1,020)	—
Debt issuance cost	724	—
Remeasurement of FCA	607	—
Total Financial expenses, net	$ 5,379	$ 235

NOTE 19: - BASIC AND DILUTED NET LOSS PER COMMON STOCK

We compute net loss per share of common stock using the two-class method. Basic net loss per share is computed using the weighted-average number of shares outstanding during the period. Diluted net loss per share is computed using the weighted-average number of shares and the effect of potentially dilutive securities outstanding during the period.

The following table sets forth the computation of the Company's basic and diluted net loss per common stock:

	Year ended December 31,	
	2022	2021
Net loss attributable to common stock shareholders used in computing basic net loss per share	$ 59,957	$ 67,521
Weighted average number of common stock used in computing basic loss per share	23,635,038	16,591,718
Basic net loss per common stock	$ 2.54	$ 4.07

NOTE 20:- SUBSEQUENT EVENTS

a. In April 2020, the Compensation Committee of the Board of Directors approved a monthly grant of shares of the Company's Common Stock equal up to $18 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 first quarter of 2023, the Company issued a total of 7,030 restricted shares of the Company's Common Stock to certain service providers.

b. 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.

c. In January 2023, the Compensation Committee of the Board of Directors approved the grant of 280,000 warrants 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. In addition, the Compensation Committee approved to change the exercise price of 350,000 warrants 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.

d. In January 2023, the Compensation Committee of the Board of Directors approved the grant of a non-qualified stock option award to purchase 100,000 shares of the Company's Common Stock, as well as an additional non-qualified performance-based stock option award to purchase an additional 100,000 shares of the Company's Common Stock outside of the Company's existing equity compensation plans, pursuant to Nasdaq Listing Rule 5635(c)(4), in connection with the employment of its Senior Vice President of Growth'.

e. In February 2023, the Compensation Committee of the Board of Directors approved the grant of 105,000 restricted shares subject to time vesting to employees and consultant of the Company and approved the grant of 50,000 options to purchase Common Stock, and 100,000 performance-based options to purchase Common Stock to employee of the Company, at exercise price $4.48 per share. The time vesting restricted shares and stock options vest over a period of three years commencing on the respective grant dates. The options have a ten-year term. 75,000 shares and the options were issued under the 2020 Plan.

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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 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

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. 333-269092, 333-265992, 333-260439 and 333-254968) of DarioHealth Corp., and

(2) Registration Statement (Form S-8 Nos. 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 9, 2023, with respect to the consolidated financial statements of DarioHealth Corp. included in this Annual Report (Form 10-K) for the year ended December 31, 2022.

Tel-Aviv, Israel
March 9, 2023

/s/Kost Forer Gabbay & Kasierer
A Member of Ernst & Young 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 9, 2023

/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 9, 2023

/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, 2022 (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 9, 2023

/s/ Erez Raphael
Erez Raphael
Chief Executive Officer
(Principal Executive Officer)

Date: March 9, 2023

/s/ Zvi Ben David
Zvi Ben David
Chief Financial Officer, Secretary and Treasurer
(Principal Financial Officer)