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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2018

☐ **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)

8 HaTokhen Street
Caesarea North Industrial Park
3088900, Israel
(Address of principal executive offices)(Zip Code)

972-4-770-4055
(Registrant's telephone number, including area code)

Securities Registered pursuant to Section 12(b) of the Act

Title of each class	Name of each exchange on which registered:
Common Stock, par value $0.0001 per share	**The Nasdaq Stock Market LLC**
Warrants to purchase Common Stock	**The Nasdaq Stock Market LLC**

Securities Registered pursuant to Section 12(g) of the Act:
None
(Title of class)

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

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 þ

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 þ 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 þ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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

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

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

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

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 $20,786,954.

As of March 22, 2019, the registrant had outstanding 36,821,173 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

This Annual Report on Form 10-K 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 launch and market penetration plans;
- our ability to manufacture, market and generate sales of our Dario Smart Diabetes Management Solution;
- our ability to commercialize DarioEngage;
- our ability to develop, launch and commercialize Dario Intelligence;
- our ability to maintain our relationships with key partners;
- our ability to complete required clinical trials of our product and obtain clearance or approval from the United States Food and Drug Administration, or 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;
- 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 which 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 "DarioHealth," "the Company," "we," "our," and "us" refer to DarioHealth Corp., a Delaware corporation and our subsidiary LabStyle Innovation Ltd., an Israeli 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.

PART I

Item 1. Business

Overview

We are a leading global Digital Therapeutics (DTx) company revolutionizing the way people manage their health across the chronic condition spectrum. By delivering evidence-based interventions that are driven by data, high quality software and coaching, we developed a novel approach that empowers individuals to adjust their lifestyle in a personalized way. Our cross -functional team operates at the intersection of biology, behavioral science and software technology to deliver highly engaging therapeutic interventions. Already the highest rated diabetes solution by more than tens of thousands of consumers who love our user-centered approach, DarioHealth is rapidly moving into new chronic conditions and geographic markets.

Our flagship product, Dario, which we also refer to as our Dario Smart Diabetes Management Solution, is a mobile, real-time, cloud-based, diabetes management solution based on an innovative, multi-feature software application to track and monitor all facets of diabetes, combined with a stylish, 'all-in-one', pocket-sized, blood glucose monitoring device, which we call the Dario Blood Glucose Monitoring System, that essentially turns a smartphone into a glucometer. In addition, our product offerings will focus on the newly launched DarioEngage software platform, where we, or any care giver, can digitally engage with Dario users, assist them in monitoring their chronic conditions and provide them with coaching, support, digital communications, and real-time alerts, trends and pattern analysis. The DarioEngage platform can 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. Finally, we intend to utilize the data we obtain from our Dario Smart Diabetes Management Solution and the DarioEngage platform to develop our upcoming healthcare analytics program, Dario Intelligence, which will provide our users with evidence-based therapeutic intervention to assist them and enhance their diabetes management skills. As such, our solutions will span the full spectrum of disease monitoring, real-time response, user-centric engagement, motivational tools, nutritional data and content, coaching tools, and big data and intelligence solutions. We have obtained regulatory clearance or approval for the Dario Blood Glucose Monitoring System in the U.S., Canada, the E.U., Israel and Australia. We believe that our targeted health platform is a highly personalized preventative and proactive approach to health improvement based on individual behavior and treatment, that provides care independent of a user's schedule and in their private environment, tailored to each person's unique profile.

Our principal operating subsidiary, LabStyle Innovation Ltd., is an Israeli company 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.

Diabetes is a disease where insufficient levels, or a total absence, of the hormone insulin, or if the individual has insulin resistance, produces high levels of glucose in the bloodstream, which can lead to long term adverse effects on a patient's blood vessels, which in turn can lead to heart attack, stroke, high blood pressure, blindness, kidney disease and nerve damage. As part of controlling blood sugar, many patients must self-monitor their blood glucose levels using home testing kits (called glucose meters) and treat high and low blood sugar episodes accordingly to avoid the complications from the disease. We believe that allowing patients to properly monitor the disease, provide actionable insights in real-time and create an online link to healthcare providers, will ultimately improve patient outcomes and reduce healthcare costs - both critical advantages for the healthcare industry.

The latest studies released by the Centers for Disease Control and Prevention (CDC) report that in 2015 over 30.3 million Americans have diabetes. More alarming is that in 2015, an addition 84.1 million Americans age 18 or older have what is known as prediabetes, which when left unmanaged will most likely become diabetes in a matter of a few years. The number of people with diabetes or prediabetes equates to 35% of the adult population in the U.S. In addition, there is a strong correlation between obesity and the development of diabetes. Many believe, including the National Center for Biotechnology Information (NCBI), that diabetes is one of the worst epidemics of the 21st century. The diabetes epidemic is not only felt in terms of its impact on health but also represents a financial burden on the U.S. and global healthcare system.

Importantly, one out of three American adults with prediabetes can, in fact, reverse the condition if they take action, and the health of people with diabetes can be improved through measurement adherence and medication. Furthermore, studies have shown that a 1% reduction in the concentration of glycated hemoglobin (also known as HbA1c or A1c) in human blood goes beyond better diabetes control. That reduction may translate into a 15% to 20% decrease in heart attack and stroke risk and a 25% to 40% lower risk of diabetes-related eye or kidney disease. Better diabetes management may result in substantial savings in the costs related to diabetes and healthcare in general, through the avoidance of health complications and related expense savings. A 2013 NCBI study found that improved A1c levels are associated with healthcare savings.

Based on data we have extracted from our user database, using the Dario Smart Diabetes Management Solution leads to an improvement in glucose level of the users and lowers their A1c levels over time. This data also indicated that higher engagement of users with the Dario Smart Diabetes Management Solution increased the level of A1c improvement. Specifically, we found A1c improvements during a period of 3 months, 6 months, and 9-months for people who began the study with A1c levels of more than 8%, 9%, and 10%. The key finding was that, on average, every segment of the users showed an improvement compared to their A1c level when they started to use the Dario Smart Diabetes Management Solution, while 75% of participants which started to use the Dario Smart Diabetes Management Solution with A1c levels higher than 9% were able to lower their A1cC levels during that period with as little as 3 glucose level measurements per day.

Beginning in September 2013, the Dario Smart Diabetes Management Solution has been reviewed and approved or cleared by various global regulatory authorities. We received the CE Mark in 2013 which allowed the Dario Smart Diabetes Management Solution to be marketed and sold in 32 countries across Europe as well as in certain other countries worldwide. This clearance was followed by approval received from Israel's Ministry of Health in July 2014, and we received Therapeutic Goods Administration (TGA) certification to market the Dario Smart Diabetes Management Solution in Australia in December 2014, followed by approval from Health Canada in May 2015.

In December 2015, we announced that we received 510(k) clearance for the Dario Blood Glucose Monitoring System from the U.S. Food and Drug Administration (FDA), including its components, and the Dario Smart Diabetes Management app on the Apple iOS 6.1 platform and higher. Achieving FDA clearance was a significant milestone and we commenced marketing and commercialization of the Dario Smart Diabetes Management Solution in the United States in the first quarter of 2016. On September 7, 2017, we announced that the FDA granted 510(k) clearance for the Dario Blood Glucose Monitoring System to be used with certain leading Android smart mobile devices. This FDA clearance allowed us to widen our potential customer base in the United States commencing in the last quarter of 2017.

During 2017, we completed the development of a version of the Dario Blood Glucose Monitoring System that connects to an iPhone 7 through the Lightning connector, which we refer to as our Lightning meter, instead of the eliminated 3.5 mm audio jack. On May 18, 2017, we completed the Notice of Change for the CE Mark for the Apple Lightning connector to connect to Apple smart mobile devices that do not come with 3.5 mm audio jack. Additionally, we have registered with the TGA in Australia for the Lightning-enabled Dario Blood Glucose Monitoring System. Sales of this version of the device in Australia commenced during January 2018. In March 2018, we received FDA clearance to market this version of the device in the U.S.

We intend to continue to generate demand through a digital direct-to-consumer marketing campaign. Customers are currently able to purchase the Dario Blood Glucose Monitoring System directly through our proprietary e-store where they can also subscribe to a subscription-based service. In July 2016, we signed an agreement with GEMCO Medical, an established healthcare distributor and a pioneer in the diabetes supply industry, to become the first authorized United States distributor of the Dario Blood Glucose Monitoring System and to complement our direct-to-consumer model to further expand and strengthen its presence in the United States. Also during July 2016, we launched our Australian proprietary e-store where customers may subscribe to a subscription-based service, and in September 2017 we launched our proprietary e-store in Germany offering our product to customers in Germany.

Although we are initially targeting only the large and growing Blood Glucose Monitoring System, or BGMS, market, we believe our invention has the potential to cover dozens of laboratory tests of bodily fluids (including blood, urine, and saliva) that could potentially be undertaken using a smart mobile device, including blood coagulation, cholesterol, HIV and others. Our goal is to develop additional interfaces for other chronic illnesses and health conditions, thereby empowering people around the globe to put themselves in control of managing their medical conditions while leveraging our platform. By doing so, we believe that we will be positioned to make a dramatic impact on the lives of millions of people that face daily lifestyle and medical challenges. Our technology provides a body-fluid testing apparatus for performing metered measurement of samples utilizing: (i) a lancing device to obtain a test sample (blood in the case of the Dario Blood Glucose Monitoring System); and (ii) an adaptor specifically designed to connect a strip devised to absorb the sample, which then produces an electric signal indicating the level of the substance tested for in the sample. The adaptor is then connected to a smart mobile device via the 3.5 mm audio jack or Lightning connector, which allows the test signal to be transmitted to the smart mobile device, which will then utilize our software application to obtain and display the test result on the device. This is coupled with a set of software features available via a smart mobile device application as well as cloud-based services, in real-time. We are presently pursuing patent applications in multiple jurisdictions covering the specific processes related to blood glucose level measurement as well as more general methods of rapid tests of body fluids using mobile devices and cloud-based services. On August 5, 2014, we were issued a U.S. patent (No. 8,797,180) relating to how the Dario Blood Glucose Monitoring System draws power from and transmits data to a smartphone via the audio jack port, on September 8, 2015, we were issued a U.S. patent (No. 9,125,549) that broadens our registered patent No. 8,797,180 to include testing of other bodily fluids through an audio jack connection, and on November 11, 2017, we were issued a U.S. patent (No. 9,832,301) that enhances the way the Dario Blood Glucose Monitoring System communicates with users' smartphone devices. We believe these represent critical intellectual property recognition and a significant initial validation of our intellectual property efforts.

DarioHealth's Solutions

Our DTx products are centered around our users and include the Dario Blood Glucose Monitoring System, the Dario Smart Diabetes Management Solution (provided to our users in the form of a smart phone application that enables the delivery of valuable content and periodical evidence based reports that are intended to be utilized by our users to better control and improve their diabetes), the DarioEngage platform (which provides support and two-way real time connectivity between our users and their care givers) and Dario Intelligence (which utilizes user data and is intended to be an analytics tool that can assist healthcare providers in the treatments and predictability of diseases).

Dario Smart Diabetes Management Solution

The Dario Blood Glucose Monitoring System is the original, all-in-one smart glucose meter. It syncs with the Dario Smart Diabetes Management app to measure, record and track blood glucose levels. In addition, the app records carbohydrate intake, insulin medication, and physical activity.

The flagship brand of DarioHealth, the Dario Smart Diabetes Management Solution, was initially launched in the United Kingdom in the first quarter of 2015 and has since expanded to Canada, Australia, the United States, and Germany. We earn a majority of our revenues in the United States. We manufacture our products using subcontractors and distribute our proprietary device ourselves. We believe this control over end to end production allows us to maintain high standards of quality control. To that end, we are the owner of several patents relating to our technology and processes.

We use our patented technology to enhance the way our Dario Blood Glucose Monitoring System communicates with users' smartphone devices. In the U.S. market, the Dario Blood Glucose Monitoring System connects to a smartphone via a sugar-cube dongle that does not require a battery for operation; rather, it relies on the smartphone's battery as its power source. In the effort to reduce battery-dependence and ensure 100% real-time data capture, the application is able to monitor and adjust power levels on smartphones accordingly to enable sufficient output with minimal reliance.

The benefits and features of our product include:

- **Comfort -** *Sleek, pocket-sized all-in-one smart glucose meter simplifies diabetes management*

- **Record -** *Automatically records every blood glucose measurement without ever having to sync your meter*

- **Share -** *Easily share results with loved ones and your healthcare team takes diabetes management to a new level*

- **Emergency Hypo Alerts -** *Built-in, emergency hypo alert feature with GPS location adds an extra safety measure*

- **Track -** *Tracking activity and counting carbs are made easy with a scanner feature that syncs with a database of over 1 million verified items across more than 50 unique countries.*

Available worldwide in the Apple App Store and Google Play Store, our user-friendly Dario Smart Diabetes Management mobile app is known for its accuracy and ease-of-use. The Dario Smart Diabetes Management Solution is accessible with affordable pricing models, including subscription plans. Our pricing is often in line with current co-payments, and sometimes it may even be less than current out of pocket costs. In addition, many of our customers in the United States get coverage through their flexible spending accounts (FSA) or health savings accounts (HSA) or with our third-party healthcare integrations.

Items for sale in the Dario Shop

Customers can purchase the Dario Blood Glucose Monitoring System through our direct to consumer online shopping experience, where we offer:

Dario Blood Glucose Monitoring System

All-in-one pocket size glucose meter, with 10 Disposable Covers and 10 Lancets.

Dario Blood Glucose Test Strips

Blood Glucose Test strips for use with the Dario Blood Glucose Monitoring System. Test strips come in boxes of 25, 50 and 100. In addition, test strips are available on a pay-as-you-go basis or a subscription plan.

Dario Glucose Control Solutions

Level M and Level H control solutions for use with the Dario Blood Glucose Monitoring System.

Dario Sterile Lancets

Sterile Lancets for use with the Dario Blood Glucose Monitoring System.

Dario Disposable Covers

Protects the mobile device from direct contact with blood while measuring with the Dario Blood Glucose Monitoring System.

Our revenues are derived from sales of Dario's components, including the Dario Blood Glucose Monitoring System itself, and principally from the recurring sale of our disposable cartridges of test strips and other consumables. Our customers receive access to the Dario Smart Diabetes Management application, which incorporates tools to help people with diabetes manage their condition. Importantly, our revenue model is driven by the fact that only our test strips, purchased through us and our partners, can be utilized with the Dario Blood Glucose Monitoring System and software, so we expect that we will be the sole source for Dario Blood Glucose Monitoring System compatible test strips.

During the second half of 2018, we have begun to offer our U.S. users the opportunity to register for our membership programs by purchasing 3 month and 1 year membership plans. In addition to our products, these plans include an unlimited supply of test strips, subject to the user's active measurement of his glucose level, and a weekly digital progress report about the user's measurements, in order to help the users understand the progress made in their diabetes management. Our members are also provided with personalized diabetes programs – including lifestyle changes, healthy eating and advanced tracking, and live coaching seminars.

In addition, we anticipate generating revenues in the future from our second revenue pillar that we call the DarioEngage platform, our software platform for health coaches. We plan to offer this software platform to healthcare providers such as insurers, self-insured employers, diabetes clinics, certified diabetes educators and other third-party providers of coaching and monitoring services for people with diabetes for a monthly service fee. Our third revenue pillar, which we are planning to introduce at a later stage, is the Dario Intelligence platform. The Dario Intelligence platform will take advantage of a large amount of data that will be collected through our servers through the use of our Dario Smart Diabetes Management Solution and the DarioEngage platform, in order to develop predictive models and artificial intelligence algorithms as detailed below.

We believe the following features of our Dario Smart Diabetes Management Solution and the manner in which we plan to market and distribute the product will help position Dario to gain users and drive revenue growth:

- *Look and Feel*. While utilizing the same state of the art electrochemical, blood-based measurement techniques as standard glucose monitors offer familiar usability, the Dario Blood Glucose Monitoring System is easily integrated with the patient's own smart mobile device that offers a distinctive look and feel. Furthermore, unlike the market standards, the Dario Blood Glucose Monitoring System has an integrated lancing device and a disposable strip cartridge. This eliminates the need for a separate glucose monitor, lancing device and strip vial and, we believe, makes the Dario Blood Glucose Monitoring System among the smallest footprint in the market. Furthermore, Dario has novel applications incorporating software tools to help diabetic patients manage their disease.

- *Large Market of Potential Users*. Our reliance on diabetics within the massive smart mobile device market gives us an established potential user-base. According to recently published Mobile Fact Sheet by Pew Research Center, or PRC, 81% of Americans own a smartphone, up just 35% in PRC's first survey of smartphone ownership conducted in 2011. Between the ages of 18 to 34, 95% have a smartphone, and between the age of 34 to 49, 92% own a smartphone. We believe that it is reasonable to assume that the percentage of smart mobile device users with diabetes mirrors that of the general population.

- *Marketing and Distribution*. In the U.S., Germany, and Australia we have our own direct to consumer marketing channel to support our sales efforts. In the U.S. we also plan to contract with partners to provide coaching services to employers and health care providers. In the United Kingdom and Canada, we use distribution partners to market and sell the Dario Blood Glucose Monitoring System. This approach enables a direct communication channel with the market and the diabetic community. This approach is also designed to effectively create brand awareness with a significantly reduced use of our capital resources versus the amounts required via the traditional, offline retail channels.

- *"Expanding the Pie."* Our goal is to obtain significant market share using technological innovations and by expanding the total BGMS market size "pie" by offering a user-friendly diabetes management solution that utilizes an existing platform and installed potential user base (smart mobile devices and smart mobile device users, respectively). We will endeavor to emphasize the user-friendly nature of the Dario Smart Diabetes Management Solution to expand the total BGMS market size by encouraging existing diabetes patients to test their glucose levels more frequently and by encouraging the "non-testing" population to adopt glucose monitoring.

- *Competitive Cost of Goods Sold.* Based on our market research and discussions with our test strip manufacturer, we believe that our anticipated outsourced manufacturing cost of the test strips is similar to our estimate of our competitors' cost for existing single-use disposable strips. In addition, we believe the manufacturing costs of our Dario Blood Glucose Monitoring System are competitive with those of the leading glucose meters.

- *Opportunities for Commercialization Partnerships.* Healthcare and pharmaceutical company entrants into the BGMS market (such as Perrigo and Sanofi) are licensing and/or acquiring technologies, seeking differentiation, thereby providing us with opportunities for more rapid commercialization through partnerships. Therefore, we plan to explore the possibility of entering into commercialization agreements, including upfront payment, a supply agreement, and royalty payments, with strategic partners.

Currently, there are a few new market entrants in the BGMS space that are attempting to utilize computer or smart mobile device connectivity, including Sanofi iBGStar, Medisana GlucoDock, Philosys Gmate Smart, One Drop, and iHealth Align. We believe that none of these devices offer the integration of an all-in-one unit that includes a lancing device and strip cartridge as the Dario Blood Glucose Monitoring System does. We further believe that these competitors provide limited capabilities over their diabetes management apps as compared to the Dario Smart Diabetes Management application.

In summary, we believe we bring an entirely new dynamic to the BGMS device market. We believe that our primary business model for the Dario Smart Diabetes Management Solution is clean and simple - sales of proprietary glucose test strips (the disposable component) directly to consumers, leveraging an installed base of mobile phones. The entire mechanism consists of a small and simple adaptor combined with a strip which is connected to the smart mobile device's headphone jack, or Lightning connector, with the strip test results being read by the smart mobile device.

We also believe that this business model is the foundation for a broader push to improve the health care system. An application that is always in your pocket and used multiple times per day is an ideal platform to support people living with diabetes, their health care providers, and health systems. Our application is designed to improve health outcomes and reduce costs through increased insights, motivating tools and automation.

DarioEngage

DarioEngage represents our new customer engagement management software platform, which is intended to help healthcare providers in all aspects of user engagement, including enrollment, coaching and ongoing communications with the end-users based on user consent. DarioEngage was developed in order to allow for a one stop scalable management tool to improve efficacy and outcomes of caregivers. We believe that DarioEngage will assist healthcare providers and employers by offering them an open platform, thereby empowering them to implement their own clinical expertise in a more digital, user-centric and efficient way. We believe this approach can address two burgeoning issues: improving the quality of health for individuals, which in turn will lower healthcare costs across the spectrum.

The DarioEngage platform empowers health providers offering diabetes services with:

· Monitoring - *100% data capture, access to users' real-time clinical and behavioral data*

· Engagement - *Personalized coaching in response to users' habits and needs, response to user events, and enhanced communication and support*

· Management - *Clinical program integration, automated processes, scheduling tools and reporting*

The DarioEngage platform provides care givers with real-time access to data collected by a user such as, glucose level, carb counting, physical activity, weight tracking and other parameters. Such access allows care givers to prioritize user intervention based on real-time data and alerts and allows for multi-channel digital interaction with the user (chat, in-app messages, email and text). DarioEngage is a cloud-based SaaS solution that also includes open APIs for platform integration.

We believe that the DarioEngage platform is a user-centric, data-driven health solution which allows people with Diabetes to get the right care, at the right time, and allows for the effective monitoring, coaching and management of their chronic conditions, such as type 1 and 2 diabetes, gestational diabetes, and prediabetes.

Dario Intelligence

The last pillar in our planned suite of product offerings is Dario Intelligence. We are planning to offer Dario Intelligence, which utilizes the large amount of data that will be collected on our servers through the use of our Dario Smart Diabetes Management Solution and the DarioEngage platform, to develop predictive models and artificial intelligence algorithms to meet the potential demand of intelligence-driven analytics that healthcare providers will be looking to improve their services.

We believe the future development of Dario Intelligence will present an opportunity in the chronic disease management field and will help us leverage our data capturing platform, to be used for big data analytics, research, EMRs (Electronic Medical Record) / EHRs (Electronic Health Records), and the development of real-time and predictive-based health management solutions.

- Data Collection - *Real-time data collections and aggregation*
- Analytics - *Dario big data analytics solution*
- Discovery - *Data discovery and analysis*
- Insights - *Predictive models and AI driven insights*

Through Dario Intelligence, we believe we may be able to develop innovative artificial intelligence and machine learning approaches that will enable us to transform big data into individual and specific predictive models to meet the demands of both consumers and the health care providers. We believe that by coupling data and algorithmic development, Dario Intelligence may offer in the future the way to detect, predict and intervene most effectively for each individual using our platform.

Our Vision for Dario Intelligence

We intend to offer solutions built from a foundation of rich and robust data, ultimately transforming our revenue model from simple product volume to product value. We believe that the current ineffective care of diabetes and other chronic conditions reflects a need for more intelligent and nuanced approaches relating to predictive behaviors and real-time care. We believe that financial incentives tied to patient outcomes have the potential to generate sizeable revenue growth for us and position us as a leader in transforming the management of diabetes. Achieving the strategic vision of Dario Intelligence requires multiple steps and evolutions in order to harness the power from the data generated by a connected community, and subsequently impact individual behavior.

Phase 1 – Collect & Analyze

As the Dario Smart Diabetes Management Solution user-base has grown, we have collected a significant amount of user data and information. Initial efforts in Phase 1 are centered around an understanding of our user-base. Compiling basic demographic data such as age, gender, country geography, etc., and establishing links to test strip usage and blood glucose control are critically important. Further, examining variation amongst population cohorts in both utilization and blood glucose outcomes is fundamental to future targeting and retention campaigns. We intend to generate analytical insights on individuals who achieve improvement in blood glucose levels in order to develop an in-depth understanding of those who maintain such an improvement over time, which we believe will form the backbone of interventional program development that we intend to generate with our potential partners.

Phase 2 – Expand Collection of Data Types, Experiment with Outreach Campaigns

As continued growth of users accelerates globally, concerted efforts will be undertaken at expanding the collection of highly relevant data types. In addition, we intend to expand data collection on user data points such as carbohydrate intake, exercise, and physical activity, medication and medication adherence, GPS location, time stamps, insurance coverage type/status. When more data elements are gathered, the intention is for Dario Intelligence to apply its artificial intelligence and machine learning capabilities to enhance understanding of individuals and detailed profiles that will be generated with comprehensive user information such as the type of advertising that was used to recruit patients or how frequently an individual interacts with the Dario Smart Diabetes Management app. The result is intended to be a cohort-specific predictive model that can be used to develop interventional programs on a wide basis.

Phase 3 – Monetize De-Identified Data, Learn, Expand Intervention Programs

We believe that pharmaceutical companies, device manufacturers, insurers, governments, researchers, advertisers, and start-up companies would be willing to pay for the de-identified data that we will obtain through our Dario Intelligence platform. As such, we believe there is an opportunity to develop a consistent revenue stream from this data.

In addition to data that reports on the activity and performance of the population as a whole, we believe that will be able to provide access to a globally connected community of patients and consumers. We are planning to monetize access to specific patient cohorts, designing programs to improve utilization, engagement, and outcomes. These future programs will be adapted, modified, and enhanced based on continuous learning and additional data inputs from external third parties that we are planning to engage with in the future. Pay for performance models will be developed and experimented with, as we will implement next-generation artificial intelligence and machine learning programs designed to influence user's behavior.

Background on Diabetes

Diabetes is a chronic disease that arises when the pancreas does not produce enough (or ceases to produce) insulin, or when the body cannot effectively use the insulin it produces (insulin resistance). Insulin is a hormone made by the pancreas that enables cells to take in glucose from the blood and use it for energy. Failure to produce insulin, or of insulin to act properly, or both, leads to raised glucose (sugar) levels in the blood (hyperglycemia), which can be detected with a blood test. Excess glucose in the blood has been shown to cause damage to blood vessels and is thus associated with long-term damage to the body and failure of various organs and tissues, including the retina and the kidneys. There are three main types of diabetes:

Type 1 diabetes, sometimes called insulin-dependent, or juvenile, diabetes, is caused by an auto-immune reaction where the body's defense system attacks the insulin-producing cells located in a person's pancreas. The reason why this occurs is not fully understood. People with Type 1 diabetes produce very little or no insulin. The disease can affect people of any age but usually occurs in children or young adults. People with this form of diabetes need injections or infusions of insulin several times a day in order to control the levels of glucose in their blood. The use of insulin may lead to excessively low levels of glucose in the blood, also known as hypoglycemia, leading to other health problems. Type 1 diabetes patients constitute approximately 10% of the overall number of patients, but are much more extensive users of BGMS, as these diabetics need to measure their glucose levels 4-10 times a day to avoid both hyperglycemia and hypoglycemia (versus once or twice a day for most Type 2 non-insulin dependent diabetic patients). The vast majority of Type 1 diabetes patients are insulin dependent.

Type 2 diabetes is sometimes called adult-onset diabetes and accounts for at least 90% of all cases of diabetes. It is characterized by insulin resistance and relative insulin deficiency, either of which may be present at the time that diabetes becomes clinically manifest. The diagnosis of Type 2 diabetes usually occurs after the age of 40 but can occur earlier, especially in populations with high diabetes incidence. Type 2 diabetes can remain undetected for many years, and the diagnosis is often made from associated complications or incidentally through abnormal blood or urine glucose test. It is often, but not always, associated with obesity, which may contribute to insulin resistance and lead to elevated blood glucose levels. A portion of the Type 2 diabetes patients are insulin dependent or use insulin as part of their treatment.

Gestational diabetes (GDM) is a form of diabetes consisting of high blood glucose levels during pregnancy. It develops in one in 25 pregnancies worldwide and is associated with complications in the time period immediately before and after birth. GDM usually disappears after pregnancy but women with GDM and their offspring are at an increased risk of developing Type 2 diabetes later in life. Approximately half of women with a history of GDM go on to develop Type 2 diabetes within five to ten years after delivery.

We also believe we will be able to support patients with *pre-diabetes*, also called metabolic syndrome. Metabolic syndrome is a combination of medical disorders that increase the risk of developing cardiovascular disease and diabetes. According to the American Diabetes Association, in 2015, 84.1 million Americans age 18 and older had pre-diabetes. This population is typically prescribed with periodic lab-based glucose level testing (which requires a doctor visit, significantly reducing the compliance level) and typically does not involve the utilization of self-monitoring glucose devices.

The Diabetes and BGMS Markets and the Dario Smart Diabetes Management Solution

Diabetes is a growing epidemic for which no cure exists, but for which treatments (including a regimen of frequent blood glucose testing) are available. The medical journal Lancet has reported that the number of worldwide diabetics has doubled over the past thirty years. While about 70% of the increase has been attributed in the Lancet report to population growth and aging, the balance was linked to changing diets, rising obesity levels, and less physical activity.

According to the information published in 2017 by the International Diabetes Foundation (IDF), in its 8th edition of the "IDF Diabetes Atlas," approximately 425 million people worldwide were estimated to have diabetes in 2017, or one in eleven adults worldwide. The greatest numbers are between 40 and 59 years old. If these trends continue, by 2045, some 629 million people are forecasted by the IDF to have diabetes. According to the IDF Diabetes Atlas, in Europe, there were 58 million adults over the age of 20 with diabetes in 2017 and approximately 30.2 million adults over the age of 20 with diabetes in the U.S. in 2017. As of 2017, approximately 187 million adults with diabetes live in China and India, with approximately 12.4 million in Brazil and 8.5 million in Russia.

It is estimated that the costs of diabetes complications account for between 5% and 10% of total healthcare spending in the world. In the United States, the ADA estimated that the total cost of diagnosed diabetes has risen from $174 billion in 2007 to $245 billion in 2012. Early diagnosis of warning signs and ongoing monitoring of diabetes are the keys to the prevention and treatment of the disease, with blood glucose monitoring being the primary method of diagnosis and disease management, coupled with matching blood glucose readings with food (i.e., carbohydrate) and insulin or another medication intake.

Since blood glucose self-monitoring is a key part of managing diabetes, the market for BGMS products required to service these many patients is also large. As reported in a press release published by Allied Market Research, the blood glucose self-monitoring market was estimated to be $7.76 billion in 2017 and is expected to grow to an estimated $10.82 billion by 2025. The biggest drivers for growth in the diabetes device market will be the increased prevalence and awareness of diabetes. The U.S. is the largest market, contributing close to 40% of the global market for these devices.

Key factors driving market growth include an increasing number of people with diabetes, growing patient awareness, technological advancements and the increasing number of patients adopting blood glucose self-monitoring. In addition, the affordable cost of blood glucose test strips, and increase in daily monitoring, are also expected to contribute to market growth. As such, BGMS represents a large market that has grown significantly over the past 30 years and is expected to continue to grow.

It is important to note that the diabetic market is the first point of entry for the Dario Smart Diabetes Management Solution and we believe that our goal of providing mHealth health solutions for a variety of chronic and wellness related conditions based on mobile device testing will grant us access to a much larger market. The Dario Smart Diabetes Management Solution is targeted at the digital health market, which was estimated by Zion Market Research at around $122 billion globally in 2017, and is expected to reach $423 billion by 2024.

Industry Background and the Dario Smart Diabetes Management Solution Opportunity

From a competition perspective, four companies currently dominate the BGMS business, controlling a majority of the market: Roche Diagnostics (part of Hoffman-LaRoche), LifeScan (a Johnson & Johnson company), Ascensia (formerly Diabetes care), and Abbott Laboratories. These "big four" offer a wide variety of BGMS products and have led the market since the late 1990s. Numerous second-tier and third-tier competitors, including several in Asia, hold the remaining 10% of the market. We believe that the BGMS offerings by all vendors are comparable, with mild differentiation of the main feature sets of the devices. This is akin to the differentiation among personal computers (PCs) during the 1990s and 2000s, where most of them had the same key feature set of Microsoft Windows and Intel Processors.

We believe that the increasing global adoption of mobile phones has created an opportunity for disruption in the BGMS market. The Dario Smart Diabetes Management Solution, which features our compact all-in-one Dario Blood Glucose Monitoring System device coupled with iOS, Android and web-based apps, is intended to eliminate the need for separate glucose monitors, carb-calculators and cumbersome dependency on wired, computer-based logging tools. Our intention is for Dario to not only deliver the best blood glucose monitoring experience but also use the unique capabilities of mobile smart mobile devices to deliver better health outcomes.

With respect to the U.S. BGMS market, the principal barriers to entry (all of which we believe the features of the Dario Smart Diabetes Management Solution can overcome) can be summarized as follows:

- *Achieving significant product differentiation in the eyes of diabetes patients or insurance payers*. We believe that Dario offers a novel design that is compatible with the usability of the current devices yet offers a modern look and feel when compared to products in the marketplace. Marketing of the product directly to consumers will emphasize the product's distinguishing attributes, without incurring the significant product introduction expenses typically incurred for the marketing of a standard glucose meter via traditional retail channels.

- *Costs.* We anticipate that low manufacturing costs for the dongle (the part of the Dario Blood Glucose Monitoring System that attaches to the phone jack or Lightning connector) and the similarity to our competitors' estimated cost of manufacturing the strips, when coupled with our direct-to-consumer marketing, creates the potential for providing us with a meaningful cost advantage versus most vendors of traditional glucose meters.

- *Difficulty obtaining shelf space at the pharmacy*. With many products on the market, a new entrant has to battle for visibility on the shelf or in e-commerce stores. The Dario Smart Diabetes Management Solution will limit this obstacle by emphasizing internet based direct-to-consumer marketing and sales.

- *The challenge of influencing diabetes specialists to recommend another BGMS product to patients*. We make efforts to introduce and present the Dario Smart Diabetes Management Solution to the medical community through our participation in academic and professional conferences. The Dario Smart Diabetes Management Solution will continue to be marketed directly to our target users ("Business to Consumer," or B2C), who we believe are increasingly becoming the primary decision-makers in choosing their glucose monitoring equipment. We have also started marketing our products in a "Business-to-Business," or B2B, business model, selling to large organizations that include distributors, retailers, pharmacies and hospitals.

We believe that Dario's specific features and trends in the marketplace create a significant opportunity to penetrate the market and effectively compete with and gain market share against the established players.

Utilization of Mobile Health Applications

Smart mobile device applications combine easy-to-use interfaces with continuous internet access to create transformational mobile health solutions (often called mHealth, eHealth or digital health). Although the potential benefits of mHealth solutions have been widely discussed for over a decade, the market is now starting to emerge from the trial phase. The need to reduce long waiting periods in order to access health care facilities from specialists is the primary driver responsible for the adoption of mHealth. We believe that Dario is designed to play directly into this market trend.

In addition, the Grand View Research report states that the availability of applications for consumers is continuing to grow rapidly, especially healthcare apps. These applications assist users in self-management of wellness, disease and chronic abnormalities. This has led to the patient playing an important and active role in staying informed and updated on their own healthcare decisions, contributing to the rise in adoption of mHealth apps globally.

Healthcare is gradually transitioning towards a precision-based model, better known as a “personalized medicine” model. mHealth is becoming a widespread trend due to the introduction of technologies such as electronic medical records, remote monitoring, and other communication platforms. mHealth leverages the 4Ps of healthcare delivery: personalized, predictive, participatory, and preventive, to ensure delivery of optimal care to its users. In addition, the growing penetration of smartphones, especially in low- & middle-income countries and the growing focus on utilizing mobile technology to leverage healthcare delivery and ensure a population health plan is anticipated to benefit the market.

The Dario Smart Diabetes Management Solution includes the Dario Blood Glucose Monitoring System and software application for people with diabetes. Dario currently allows users to easily record, analyze, transmit and store key data points such as glucose level, insulin, and carbohydrate intake. Moreover, the Dario Smart Diabetes Management application provides knowledge and motivation with the aim of improving health outcomes. In addition, we are developing software for health care providers and payers to help better support patients and intelligently manage large patient populations.

Sales and Marketing

Our initial marketing efforts in the United States were focused on the early adopter users who have diabetes and who are paying out of pocket for their monitoring tools to manage their chronic condition, and we have concentrated our efforts in gaining market share and brand awareness through direct to consumer marketing efforts.

In 2018, we began to expand our marketing efforts to the insured population by offering our DarioEngage platform to a variety of healthcare providers who are supporting and coaching individuals with diabetes. We believe this will help us to diversify our revenues, from only selling our Dario Blood Glucose Monitoring System and its consumables, to revenues generated from providing online real-time monitoring, supervising and coaching capabilities to all relevant healthcare providers who support individuals with diabetes. As part of these efforts, we recently announced our planned cooperation with Attain Health, Giant Eagle, BestBuy, Canadian-based LMC Healthcare and Better Living Now (BLN).

In Australia, we revised our sales and marketing strategy during the third quarter of 2016 and moved to a hybrid direct to consumer model in combination with an on the ground out-sourced channel sales organization staff focused on the pharmacies. This model will allow us to accelerate our penetration into this market while building a diabetes community via direct engagement through our digital marketing campaigns and online store.

In the U.K., the Dario Blood Glucose Monitoring System is a fully reimbursed product distributed by a new distributor since the second quarter of 2016. The Dario Blood Glucose Monitoring System is now available via all main pharmacies in the U.K. Our sales and marketing efforts have been focused on wholesalers, pharmacies, HCP’s (Health Care Professionals), diabetes educators and hospitals via the distributor. This has created awareness and understanding of the value proposition we offer to people with diabetes. In addition, we will be focusing on increasing our presence in the U.K. market via our direct to consumer strategy, utilizing the countrywide availability of the strips in pharmacy and clinical awareness of the product via the healthcare providers.

In Canada, the Dario Blood Glucose Monitoring System is available through major pharmacy chains across Canada that includes brands like London Drugs. We also offer consumers the ability to buy direct via our online platform or to get their prescriptions serviced online via Bayshore. Similar to the U.K., in Canada, we work on both promoting and marketing Dario to the medical establishment via our distributor and expanding its awareness via our direct to consumer strategy which we have been ramping up.

On the marketing side, we primarily utilize online marketing in order to create awareness of Dario. Rather than solely rely on an online advertisement, we will also consider revenue sharing with affiliate networks and a variety of other pay-for-performance methods commonly used in online commerce.

As a precursor to the DarioEngage platform, in December 2014, we entered into an agreement with Israel's leading healthcare HMO, Maccabi Healthcare, to implement a comprehensive digital suite for patients and professionals. The agreement with MOMA (Maccabi TeleCare unit) represented the beginning of an additional revenue channel. We believe the DarioEngage channel for revenues presents a significant potential based on software licensing and added value services with HMOs and other strategic partners worldwide. The Dario application for MOMA is a proprietary customized diabetes management solution that enables remote treatment for diabetes which aims to improve overall outcomes for patients leveraging mHealth technology for effective engagement of health care professionals.

We also expect to collaborate with the medical community to showcase what we expect will be the Dario Smart Diabetes Management Solution's clinical equivalence and usability superiority through DarioEngage and Dario Intelligence.

Manufacturing

As we do not directly manufacture our products ourselves, we have supply agreements with manufacturers for the Dario Blood Glucose Monitoring System, glucose test strips, lancing devices, and lancets. We have arrangements in place with commercial-scale manufacturers for both the Dario Blood Glucose Monitoring System and for our test strips. As a result of investments we have made over the past several years, we own the specialized equipment used to manufacture Dario Blood Glucose Monitoring System.

During 2015, we commenced the manufacturing of our Dario Blood Glucose Monitoring System with a Chinese manufacturer as part of our efforts to further reduce manufacturing cost. At the beginning of 2016, we transitioned our manufacturing to a new Chinese manufacturer as part of our effort to increase our manufacturing capacity and improve cost savings.

Insurance Reimbursement

In the United States and in other jurisdictions such as Germany and England, we expect that Dario's test strips should generally be available for full or partial patient reimbursement by third-party payers. We expect to work with third-party payers in the countries into which we expect to market Dario in order to establish coverage for test strips, although we cannot be sure of coverage being obtained. In April 2014, we announced the receipt of reimbursement coverage for the use of the Dario Blood Glucose Monitoring System in Italy, making 600,000 Italians eligible for reimbursement coverage. In June 2014, we were granted (effective September 1, 2014) reimbursement status in England, Wales, Scotland and Northern Ireland for strips and lancets to be utilized together with the Dario Blood Glucose Monitoring System. In December 2014, we were granted reimbursement status for the Dario test strips Australia. In May 2015 we launched Dario in Canada and the majority of Canadian medical plans are now covering test strips for the Dario Blood Glucose Monitoring System with reimbursement. We expect the balance of Canadian insurance plans to provide reimbursement coverage in the near future. We are planning to pursue reimbursement coverage in other jurisdictions.

Clinical Trials

As part of our CE Mark clearance, in 2013 we conducted positive User Performance studies for the Dario Blood Glucose Monitoring System in Israel with 161 diabetic patients. This study aimed to collect measurement data from capillary blood with a defined distribution of glucose concentrations in order to perform system accuracy evaluation according to ISO 15197:2013, the current international standard requirements for BGMS systems. The results of this study showed that the test strips are well within limits for system accuracy defined by ISO 15197:2013 in that 100% of results fell within zones A and B of the Consensus Error Grid for all systems, which means that the system accuracy requirements of the ISO 15197:2013 have been met. The acceptance criteria for accuracy of BGMS per ISO 15197:2013 is "95 % of the individual glucose measured values shall fall within ± 0,83 mmol/l (±15 mg/dl) of the measured values of the manufacturer's measurement procedure at glucose concentrations < 5,55 mmol/l (<100 mg/dl) and within ± 15% at glucose concentrations ≥ 5,55 mmol/l (≥100 mg/dl)".

In January 2015, we completed, and in March 2015, we announced positive results from, a required User Performance evaluation study in the U.S. to evaluate the accuracy of blood glucose level results obtained from fingertip using the Dario Blood Glucose Monitoring System compared to reference equipment (YSI 2300 STATPLUS) and to evaluate the ease of use of the Dario Blood Glucose Monitoring System by the first time user. This study was in connection with our regulatory submissions for the product in the U.S. and Canada and accordance with ISO 15197:2013. The study was performed at Remington Davis Clinical Research in Columbus, Ohio with the Dario Blood Glucose Monitoring System and included 368 participants with varying demographics. As required by the FDA, the study was approved by the institutional review board (IRB) which supervises the clinical studies performed in their institutions.

The purpose of the study was to demonstrate the accuracy of the Dario Blood Glucose Monitoring System compared with the Yellow Springs Instruments ("YSI") reference standard and to evaluate how the first time users of the Dario Blood Glucose Monitoring System (1) use it under the Dario guidance materials (i.e., quick user guide and video clip) in an effort to demonstrate how the use of the Dario Blood Glucose Monitoring System and related software could potentially improve patient care and diabetic compliance, (2) to understand the potential weaknesses of the device and introduce methods of overcoming them to the users and (3) to establish the proposition that lay users can operate the device.

We evaluated the accuracy and user performance in this clinical trial with 368 diabetic patients, each of whom tested fresh capillary finger prick blood glucose levels while using the Dario Blood Glucose Monitoring System for the first time, as instructed by Dario's instruction material. System accuracy was determined with samples obtained from each subject measured both on the Dario Blood Glucose Monitoring System by individual subjects and by a reference YSI analyzer. We documented sample collection or measurement errors. When required, repeated sampling by each subject was limited to three per subject. The interval of glucose levels tested was within BGMS range 43.0-477.0 mg/dL, and YSI range 42.3-435.5 mg/dL. There were no outliers. Accuracy for the Dario Blood Glucose Monitoring System met ISO 15197:2013 criteria, as can be seen in the accuracy tables below. Below 100 mg/dL, 97.8% of values were within ±15mg/d of YSI reference glucose values. For samples with glucose above or equal to 100 mg/dL, 96.4% of values were within ± 15% of YSI glucose levels. Lay subject performance assessment of Dario's instruction clarity and usefulness showed that 100% successfully obtained a measurement result, and 97.1% of subjects found instructions easy to follow with 70.7% rating they were very satisfied (5/5) and 26.4% rating they were satisfied (4/5). Reading the result on the smart mobile device was rated easy to understand by 99.1% of lay subjects, with 86.1% rated it very easy (5/5) and 13% rated it easy (4/5). If an error message displayed on the report screen, 100% of lay subjects were clear about how to resolve the error, with 56.5% reporting it was very clear (5/5) and 43.5% reported it was clear (4/5).

System accuracy results: DBGMS platform

System accuracy results for glucose concentrations <100 mg/dL			System accuracy results for glucose concentrations ≥100 mg/dL		
Within ± 5 mg/dL	**Within ± 10 mg/dL**	**Within ± 15 mg/dL**	**Within ± 5 %**	**Within ± 10 %**	**Within ± 15 %**
42/93	**73/93**	**91/93**	**111/275**	**211/275**	**265/275**
45.2%	**78.5%**	**97.8%**	**40.4%**	**76.7 %**	**96.4%**

System accuracy results for glucose concentrations between 42.3 mg/dL and 435.5 mg/dL

Within ± 5 mg/dL or ± 5 %	Within ± 10 mg/dL or ± 10 %	Within ± 15 mg/dL or ± 15 %
153/368	**284/368**	**356/368**
41.5%	**77.2%**	**96.7%**

To conclude, the Dario Blood Glucose Monitoring System meets ISO 15197:2013 standards for clinical performance as determined by lay user accuracy and by satisfactory experience with the Dario instructions clarity and system utility.

In November 2015, we completed an additional User Performance evaluation study in the U.S. as requested by the FDA. We evaluated the accuracy of blood glucose level results obtained from fingertip using the Dario Blood Glucose Monitoring System compared to reference equipment (YSI 2300 STATPLUS). We also assessed the usability of the Dario Blood Glucose Monitoring System by first-time users on iOS smart mobile devices. The study was performed at the University of Colorado Barbara Davis Center for Diabetes in Aurora, Colorado with the Dario Blood Glucose Monitoring System and included 100 participants with varying demographics. As required by the FDA, the study was approved by the Western Institutional Review Board (WIRB) which supervises clinical studies performed in their institutions.

The purpose of the study was to demonstrate the accuracy of the Dario Blood Glucose Monitoring System compared with the YSI reference standard and to evaluate how first time users of the Dario (1) use it under the Dario guidance materials (i.e., quick user guide and user guide) in an effort to demonstrate how the use of the Dario Smart Diabetes Management Solution could potentially improve patient care and diabetic compliance, (2) to understand the potential weaknesses of the device and introduce methods of overcoming them to the users and (3) to establish the proposition that lay users can operate the device.

The acceptance criteria for accuracy of BGMS per ISO 15197:2003 is “Ninety-five percent (95%) of the individual glucose results shall fall within ± 15mg/dL of the results of Dario’s measurement at glucose concentrations < 75mg/dL and within ± 20% at glucose concentrations greater than or equal to 75mg/dL”. The study evaluated the accuracy and user performance in this clinical trial with 100 diabetic patients, each of whom tested fresh capillary finger prick blood glucose levels while using Dario for the first time, as instructed by Dario's instruction material. System accuracy was determined with samples obtained from each subject measured both on the Dario by individual subjects and by a reference YSI analyzer. We documented sample collection or measurement errors. When required, repeated sampling by each subject was limited to three per subject. The interval of glucose levels tested was within BGMS range 42-396 mg/dL, and YSI range 37-386 mg/dL. There were no outliers. Accuracy for Dario met ISO 15197:2003 criteria, as can be seen in the accuracy tables below. Below 75 mg/dL, 100% of values were within ±15mg/dL of YSI reference glucose values. For samples with glucose above or equal to 75 mg/dL, 98.88% of values were within ± 20% of YSI glucose levels. Lay subject performance assessment of Dario’s instruction clarity and usefulness showed that 100% successfully obtained a measurement result. The average rating of the users for successful operation of the Dario was 4.35 (out of 5 when 1 is “completely failed” and 5 is “very successful”) and an average rate of 3.66 (out of 5 when 1 is “very hard” and 5 is “very easy”) for operating the Dario for the first time.

System accuracy results: DBGMS platform

System accuracy results for glucose concentrations <75 mg/dL			System accuracy results for glucose concentrations ≥75 mg/dL			
Within ± 5 mg/dL	**Within ± 10 mg/dL**	**Within ± 15 mg/dL**	**Within ± 5 %**	**Within ± 10 %**	**Within ± 15 %**	**Within ± 20 %**
4/11	**9/11**	**11/11**	**39/89**	**68/89**	**85/89**	**88/89**
36.36%	**81.82%**	**100%**	**40.4%**	**76.7%**	**96.4%**	**98.88%**

To conclude, the Dario meets the requirements of ISO 15197:2003 for clinical performance as determined by lay user accuracy and by satisfactory experience with the Dario instructions clarity and system utility.

In April 2017, we completed a study in the U.S. as requested by FDA. We evaluated the accuracy of blood glucose level results obtained from fingertip using the Dario Blood Glucose Monitoring System compared to reference equipment (YSI 2300 STATPLUS). We also assessed the usability of the Dario Blood Glucose Monitoring System by first-time users on Android smart mobile devices. The study was performed at the University of Colorado Barbara Davis Center for Diabetes in Aurora, Colorado with the Dario Blood Glucose Monitoring System and included 350 participants with varying demographics. As required by the FDA, the study was approved by the Western Institutional Review Board (WIRB) which supervises clinical studies performed in their institutions.

The purpose of the study was to demonstrate the accuracy of the Dario Blood Glucose Monitoring System compared with the YSI reference standard and to evaluate how first time users of the Dario (1) use it under the Dario guidance materials (i.e., quick user guide and user guide) in an effort to demonstrate how the use of the Dario Smart Diabetes Management Solution could potentially improve patient care and diabetic compliance, (2) to understand the potential weaknesses of the device and introduce methods of overcoming them to the users and (3) to establish the proposition that lay users can operate the device.

The acceptance criteria for accuracy of BGMS according to FDA guidance “Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use - Guidance for Industry and Food and Drug Administration Staff" 95% of all Self-Monitoring of Blood Glucose (“SMBG”) results shall fall within ±15% of the YSI results across the entire claimed measuring range of the device and that 99% of all SMBG results shall fall within ±20% of the YSI results across the entire claimed measuring range of the device. The study evaluated the accuracy and user performance in this clinical trial with 350 diabetic patients, each of whom tested fresh capillary finger prick blood glucose levels while using Dario for the first time, as instructed by Dario's instruction material. System accuracy was determined with samples obtained from each subject measured both on the Dario by individual subjects and by a reference YSI analyzer. We documented sample collection or measurement errors. When required, repeated sampling by each subject was limited to three per subject. The interval of glucose levels tested was within the BGMS range:

Device		**Min (mg/dL)**	**Max (mg/dL)**
Samsung Note 3	Dario	43	410
	YSI	37.5	423
Samsung S3	Dario	41	443
	YSI	36.6	442
LGG2	Dario	40.0	432
	YSI	36.2	414

There were two outliers per representative device. Accuracy for Dario met the FDA criteria, as can be seen in the accuracy tables below:

Samsung Galaxy S3

	Results for glucose concentrations across the entire range			
	Within ±5 %	**Within ±10%**	**Within ±15 %**	**Within ±20%**
Subjects who used Samsung S3 first	59/117 (50.4)%	93/117 (79.5)%	114/117 (97.4)%	117/117 (100)%
All Samsung S3 measurements	176/350 (50.3)%	276/350 (78.9)%	338/350 (96.6)%	348/350 (99.4)%

Samsung Galaxy Note 3

	Results for glucose concentrations across the entire range			
	Within ±5 %	**Within ±10%**	**Within ±15 %**	**Within ±20%**
Subjects who used Samsung Note 3 first	58/117 (49.6)%	96/117 (82.1)%	113/117 (96.6)%	117/117 (100)%
All Samsung Note 3 measurements	162/350 (46.3)%	278/350 (79.4)%	336/350 (96)%	348/350 (99.4)%

LG G2

	Results for glucose concentrations across the entire range			
	Within ±5 %	**Within ±10%**	**Within ±15 %**	**Within ±20%**
Subjects who used LG G2 first	60/116 (51.7)%	96/116 (82.8)%	111/116 (95.7)%	116/116 (100)%
All Samsung LG G2 measurements	159/350 (45.4)%	284/350 (81.1)%	334/350 (95.4)%	348/350 (99.4)%

Lay subject performance assessment of Dario’s instruction clarity and usefulness showed the following results:

	Rating of successfully obtained measurement results using Dario	**Rating success in operating Dario**	**Rating how easy was it to operate Dario for the first time**
Acceptance criteria	**Over 90% answered "Yes"**	**Average score of 3.5 or above**	**Average score of 3 or above**
Samsung Galaxy S3	100%	4.6	4.4
Samsung Galaxy Note 3	100%	4.6	4.3
LG G2	100%	4.6	4.3

In 2017, as part of our 510(k) submission to the FDA relating to the Lightning meter, a user evaluation study was conducted at the University of Colorado, Barbara Davis Center for Diabetes. The acceptance criteria for accuracy of BGMS with a Lightning meter according to FDA guidance contained in “Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use - Guidance for Industry and Food and Drug Administration Staff" requires that 95% of all SMBG results shall fall within ±15% of the YSI results across the entire claimed measuring range of the device and that 99% of all SMBG results shall fall within ±20% of the YSI results across the entire claimed measuring range of the device. The study evaluated accuracy and user performance in this clinical trial with 350 diabetic patients, each of whom tested fresh capillary finger prick blood glucose levels while using the Dario meter for the first time, as instructed by Dario's instruction materials. System accuracy was determined with samples obtained from each subject measured both on the Dario meter by individual subjects, using iPhone 5 as the iOS representative device, and by a reference YSI analyzer. We documented sample collection or measurement errors. When required, repeated sampling by each subject was limited to three per subject. The interval of glucose levels tested was within BGMS range:

Device		Min (mg/dL)	Max (mg/dL)
iPhone 5	Dario	40	465
	YSI	35.6	466.5

Two outliers were found and evaluated during the study. Accuracy for Dario met the FDA criteria, as can be seen in the accuracy tables below:

	Results for glucose concentrations across the entire range			
	Within ±5 %	Within ±10%	Within ±15 %	Within ±20%
iPhone 5 measurements	191/350 (54.5)%	295/350 (84.3)%	338/350 (96.6)%	349/350 (99.7)%

Lay subject performance assessment of Dario's instruction clarity and usefulness showed the following results:

Acceptance criteria	Rating of successfully obtained measurement results using Dario Over 90% answered "Yes"	Rating success in operating Dario Average score of 3.5 or above	Rating how easy was it to operate Dario for the first time Average score of 3 or above
iPhone 5	100%	4.5	3.9

In conclusion, Dario with the Lightning meter meets the requirements of the FDA guidance "Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use - Guidance for Industry and Food and Drug Administration Staff" for clinical performance as determined by lay user accuracy and by satisfactory experience with the Dario instructions clarity and system utility.

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 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.

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.

In January 2014, we completed the registration with Medsafe, the New Zealand Medicines and Medical Devices Safety Authority, through their WAND (Web-Assisted Notification of Devices) system allowing us to sell the Dario in New Zealand. We also have completed the process of registering the Dario with the Australian TGA, in the ARTG (Australian Register of Therapeutic Goods), which is required in order to bring and sell the Dario in Australia and effective March 3, 2015, our product is approved for reimbursement in Australia. In February 2015, we also gained National Pharmaceutical Product Interface (known as NAPPI) approval and registered the Dario in South Africa. In May 2015, we also received Health Canada approval to market the Dario blood glucose monitoring system and commenced marketing the product. We have also received reimbursement status from the majority of insurance plans in Canada.

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 took 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) were very positive, including only two "Y" citations, meaning no significant prior art was found with regards to novelty and inventiveness of the application. Corresponding national applications of our PCT were filed in November 2012 in the U.S., Europe, and other major territories.

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 September 2015, we have issued a U.S. patent (No. 9,125,549) that broadens our registered patent No. 8,797,180 to include testing of other bodily fluids through an audio jack connection. We believe this represents 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. Additional corresponding patents were granted in Israel. Corresponding applications for this invention are still pending in the U.S., China, and Australia. On November 11, 2017, U.S. patent No. 9,832,301 titled "Systems and methods for adjusting power levels on a monitoring device" was granted. This latest patent enhances the way the Dario Blood Glucose Monitoring System communicates with users' smartphone devices.

Additionally, a U.S. non-provisional and corresponding PCT application were filed, and are still pending, which cover new connection related technologies.

Additional patent applications are in the process of being prepared for filing, and we believe that we have a rich pipeline of future technologies that we are actively developing.

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 and data usability.

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. These applications were granted and registered in the United States. We have also filed national applications for the cartridge in many other jurisdictions, the great majority of which have been granted.

Design patents and patent applications on the Dario Smart Diabetes Management App

In addition, three U.S. Design Applications have been filed and granted covering our smart mobile device display screens with the graphical user interface. These design applications were also filed in several major jurisdictions, all of which have been granted.

Trademark applications

We have also filed three trademark applications covering the “Dario” name and logo, and our company’s name “DarioHealth.” “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.

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, a large amount of data will be collected from diabetic patients, comprising their blood sugar levels, meal composition, and timing, physical exercise (intensity and duration) as well as many other factors, which are 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

We face competition in each segment of our offering (device, applications, coaching and analytics) and more importantly from competitors integrating these four components.

Blood Glucose Monitors (BGM). Our device competes directly and primarily with other BGM suppliers including, but not limited to, Abbott Laboratories, Ascensia (formerly Bayer Diabetes Care), Johnson & Johnson LifeScan, Roche Diabetes and a large number of low-price private label manufacturers. Some of these devices connect to smartphones and tablets, such as, but not limited to, the Sanofi iBGStar, Medisana GlucoDock, Philosys Gmate Smart, One Drop, and iHealth Align.

Continuous blood Glucose Monitors (CGM). Continuous blood glucose monitors have made significant market progression in the last few years. More insulin-using patients are using them on a continuing basis rather than an intermittent basis.

While the market is highly competitive, we believe that we have important comparative advantages.

- We offer an all-in-one glucose monitoring system, including a small form factor glucose reader, lancing device and a strip cartridge connected to existing smart mobile devices
- We cover largely non-insulin using patients and therefore do not compete with CGM. A large percentage of insulin-using patients prefer to test with a BGM rather than a CGM
- Most importantly, in our opinion, is our integrated solution separates us from BGM and CGM competitors.

Diabetes management applications. There are hundreds of diabetes management applications available for download (such as Glucose Buddy, mySugr (now part of Roche Diabetes), Carb Manager, Sugar Sense and Welldoc). We believe that the existing diabetes management application do not offer a good value and users quickly stop using them.

We believe that our application is differentiated as compared to our competitors by the high level of engagement by our users, coming from a unique know-how in terms of user experience, as well as the nature of our integrated solution.

Coaching services. Pure coaching services such as Cecilia Health (formerly Fit4D), or services delivered by medical distributors or healthcare providers are often relatively expensive and mostly offered on a limited time basis (e.g. one month after the discharge of a patient, or three months for onboarding of a new drug). We believe that our coaching services is differentiated as compared to our competitors in that our coaching services are an essential part of our solution and is maintained throughout a patient's use of our application.

Digital health integrated competitors. Several digital health competitors integrate several, or all of, the four components of our offering, including but not limited to: Livongo, Glooko, Omada, OneDrop. In practice, we believe that the closest competitor in terms of an integrated offering is Livongo.

Our differentiation versus such integrated competitors includes

- Proven and significant results, placing us in the category of "Digital Therapeutics" (DTx);
- Open platform (capable of integrating non-proprietary devices and coaching services);
- Operating in the U.S., Canada, Europe and Australia/New Zealand;
- Small form factor glucose reader whereas most devices from competitors have the size of another cell phone that the user needs to carry around;
- Instant connection of the reader with the phone, thus maximizing opportunities to engage with the user; and
- Flexibility of our product to integrate with the workflows of its business partners (e.g. with the health communication generated by a retailer, with the coaches operating from a diabetes clinic).

Employees

We currently have 69 full-time employees and 7 part-time employees. We have employment agreements with our three 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 only recently 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 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 material revenues, and it is still too early to predict if we will be able to generate significant 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 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 only into March 2020.

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 do not currently have any arrangements or credit facilities in place as a source of funds, and 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, particularly due to certain offering participation rights afforded to a lead investor that participated in our January 2017 private placement. 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 of common stock and have incurred losses in each year since inception including net losses of $17,803,000 and $15,743,000 in 2018 and 2017, respectively. Our accumulated deficit at December 31, 2018 was approximately $89,254,000. 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.

Our independent registered public accounting firm has expressed in its report to our 2018 audited consolidated financial statements a substantial doubt about our ability to continue as a going concern.

We only recently entered the commercialization stage, and the development and commercialization of Dario is uncertain and expected to require substantial expenditures. We have not yet generated sufficient revenues from our operations to fund our activities and are therefore dependent upon external sources for financing our operations. There is a risk that we will be unable to obtain the necessary financing to continue our operations on terms acceptable to us or at all. As a result, our independent registered public accounting firm has expressed in its auditors' report on the consolidated financial statements for December 31, 2018, a substantial doubt regarding our ability to continue as a going concern. Our consolidated financial statements do not include any adjustments that might result from the outcome of the uncertainty regarding our ability to continue as a going concern. This going concern opinion could materially limit our ability to raise additional funds through the issuance of equity or debt securities or otherwise. Future reports on our financial statements may include an explanatory paragraph with respect to our ability to continue as a going concern. If we cannot continue as a going concern, our stockholders may lose their entire investment in the common stock.

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 the sale of 1,333,333 shares of common stock, 1,533,333 warrants to purchase common stock, 1,533,333 shares of common stock underlying such warrants, and underwriters' warrants to purchase up to 143,333 shares of common stock. Sales of approximately 55,555 shares of common stock, approximately 255,555 shares of common stock underlying warrants and approximately 25,555 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

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;
- 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 diabetics 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.

There is no assurance that our recently launched DarioEngage software platform will success or be adopted by Dario users.

We have recently launched a new product offering 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. However, the success of our DarioEngage software platform will depend entirely on our Dario user's adoption of the platform and we cannot assure you that our Dario users will do so. If we cannot encourage Dario users 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 may not be successful in launching Dario Intelligence and even if we are successful in doing so, there is no assurance that we will be successful in marketing and/or selling our product in the marketplace.

We intend to launch our Dario Intelligence program, which will utilize a large amount of data collected on our servers to develop predictive models and artificial intelligence algorithms to meet the potential demand of intelligence-driven analytics that healthcare providers may be looking for to improve their services. However, the launch of Dario Intelligence will require significant financial and technical resources. There is no assurance that we will successfully develop or launch Dario Intelligence. Even if we are successful in doing so, there is no assurance that the marketplace will accept or adopt the usage of Dario Intelligence. If we cannot successfully develop Dario Intelligence, or encourage the use and adoption of Dario Intelligence by market participants, our business and operating results may be materially and adversely affected.

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

We may be faced with lengthy customer evaluation and approval processes associated with Dario. Consequently, we may incur substantial expenses and devote significant management effort and expense in developing customer adoption of Dario which may not result in revenue generation. We must also obtain regulatory approvals of Dario in certain jurisdictions as well as approval for insurance reimbursement in order to initiate sales of Dario, each of which is subject to risk and potential delays, and neither of which may actually occur. As such, we cannot accurately predict the volume or timing of any future sales.

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

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

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

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

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

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

- we are not a major customer of many of our suppliers, and these suppliers may therefore give other customers' needs higher priority than ours;
- third parties may threaten or enforce their intellectual property rights against our suppliers, which may cause disruptions or delays in shipment, or may force our suppliers to cease conducting business with us;
- we may not be able to obtain an adequate supply in a timely manner or on commercially reasonable terms;
- our suppliers, especially new suppliers, may make errors in manufacturing that could negatively affect the efficacy or safety of the Dario Blood Glucose Monitoring System or cause delays in shipment;
- we may have difficulty locating and qualifying alternative suppliers;
- switching components or suppliers may require product redesign and possibly submission to FDA, European Economic Area Notified Bodies, or other foreign regulatory bodies, which could significantly impede or delay our commercial activities;
- one or more of our sole- or single-source suppliers may be unwilling or unable to supply components of the Dario Blood Glucose Monitoring System;
- other customers may use fair or unfair negotiation tactics and/or pressures to impede our use of the supplier;
- the occurrence of a fire, natural disaster or other catastrophe impacting one or more of our suppliers may affect their ability to deliver products to us in a timely manner; and
- our suppliers may encounter financial or other business hardships unrelated to our demand, which could inhibit their ability to fulfill our orders and meet our requirements.

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

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

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

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

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

Our Dario Smart Diabetes Management application, which is a key to our business model, is available via Apple's iOS 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.

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 audio jack of a mobile device. In addition, we have recently completed the development of a version of the Dario Blood Glucose Monitoring System that connects to an iPhone 7 and later models through the Lightning jack instead of the missing audio jack. 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, 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, Zvi Ben David, our Chief Financial Officer, Treasurer and Secretary and Olivier Jarry, our President and Chief Commercial Officer. 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.

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 the 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;
- 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, U.S. President Donald Trump has recently publicly indicated an intent to lower healthcare costs through various potential initiatives. In addition, 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 self-monitoring of blood glucose market, and as a result we may be unable to effectively compete in our industry.

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.

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 BGMS markets 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 Dario, our revenue will be negatively impacted.

In the United States and other jurisdictions such as Germany and England, we expect that Dario's test strips should generally be available for full or partial patient reimbursement by third-party payers. Our success in marketing Dario depends 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.

In the United States, we expect to derive nearly all our sales from sales of Dario from direct to consumer cash sales 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 and other healthcare-related organizations, to cover all or a portion of the costs and fees associated with Dario 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 Dario (and our other products 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. For example, the government healthcare system in the Netherlands, New Zealand and Israel have not yet approved reimbursement of Dario. 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.

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 and Warrants

Our officers, directors and founding stockholders 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, directors and affiliated stockholders (including Dicilyon Consulting and Investment Ltd., or Dicilyon, an affiliate of David Edery) collectively have an approximately 25.5% beneficial ownership 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.

Our common stock has less liquidity than many other stocks listed on the Nasdaq Capital Market.

Historically, the trading volume of our common stock has been relatively low when compared to larger companies listed on the Nasdaq Capital Market or other stock exchanges. While we have experienced increased liquidity in our stock during the year ended December 31, 2018, we cannot say with certainty that a more active and liquid trading market for our common stock will continue to develop. Because of this, it may be more difficult for shareholders to sell a substantial number of shares for the same price at which shareholders could sell a smaller number of shares.

If we fail to continue to meet all applicable Nasdaq requirements, Nasdaq may delist our common stock, which could have an adverse impact on the liquidity and market price of our common stock.

Our common stock is currently listed on Nasdaq, which has qualitative and quantitative listing criteria. If we are unable to meet any of the Nasdaq listing requirements in the future, including, for example, if the closing bid price for our common stock falls below $1.00 per share for 30 consecutive trading days, Nasdaq could determine to delist our common stock, which could adversely affect the market liquidity of our common stock and the market price of our common stock could decrease. In that regard, on December 28, 2018, we received a written notice from Nasdaq indicating that we were not in compliance with Nasdaq Listing Rule 5550(a)(2), as the closing bid price for our common stocks was below $1.00 per share for the preceding 30 consecutive business days. If our closing bid price again falls below $1.00 per share for 30 consecutive trading days, we may be subject to delisting and such delisting could also adversely affect our ability to obtain financing for the continuation of our operations and could result in the loss of confidence by investors, customers and employees.

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 or warrants adversely, the price of our common stock or warrants and trading volume could decline.

The trading market for our common stock or warrants 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 or warrants adversely, or provide more favorable relative recommendations about our competitors, the price of our common stock or warrants 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 warrants or trading volume to decline.

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

The market price for our common stock and warrants 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 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 our headquarters at 8 HaTokhen St., Caesarea Industrial Park, 3088900, Israel. On September 8, 2016, we signed a lease agreement for these headquarters 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 $17,920. 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 $4,160.

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 4, 2019, we had 251 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, 2018:

The following table provides information as of December 31, 2018 with respect to options outstanding under the Company's Amended and Restated 2012 Equity Incentive Plan (the "2012 Equity Incentive Plan") and the Company's other equity compensation arrangements.

Plan category	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	1,729,479	$ 4.45	2,789,536
Equity compensation plans not approved by security holders *	12,029	$ 126.04	-
Equity compensation plans not approved by security holders **	4,225	$ 125.10	-
Equity compensation plans not approved by security holders ***	39,290	$ 5.76	-
Equity compensation plans not approved by security holders ****	2,778	$ 7.02	-
Total	1,787,801	$ 5.59	2.789,536

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

** 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 $125.10, vest in 4 quarterly installments in arrears, have a cashless exercise feature and a ten-year term.

*** In September 2015, our Board approved the grant of non-plan options to our Board members and members of our SAB. These options have an exercise price of $5.76 per share, one-third vesting immediately and the balance vest over 8 quarterly installments, have a cashless exercise feature and a six-year term.

**** In December 2015, our Board approved the grant of non-plan options to a member of the SAB. The options to the SAB member have an exercise price of $7.02 per share, and vest over a three-year period. One third vest after one year and the balance vest over 8 quarterly installments after the first anniversary; these options have a cashless exercise feature and a six-year term.

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. Following amendments, there are currently 2,638,461 shares of common stock reserved for issuance under the 2012 Equity Incentive Plan.

The purpose of our 2012 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 2012 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 2012 Equity Incentive Plan will 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 Tamir Fishman Equity Plan Services to act as a trustee for grants of options under the Israeli sub-plan to Israeli residents.

In connection with the administration of our 2012 Equity Incentive Plan, our Compensation Committee will:

- determine which employees and other persons will be granted awards under our 2012 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 2012 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 2012 Equity Incentive Plan.

The 2012 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 2012 Equity Incentive Plan at any time. However, without stockholder approval, our 2012 Equity Incentive Plan may not be amended in a manner that would:

- increase the number of shares that may be issued under our 2012 Equity Incentive Plan;
- materially modify the requirements for eligibility for participation in our 2012 Equity Incentive Plan;
- materially increase the benefits to participants provided by our 2012 Equity Incentive Plan; or
- otherwise disqualify our 2012 Equity Incentive Plan for coverage under Rule 16b-3 promulgated under the Exchange Act.

Awards previously granted under our 2012 Equity Incentive Plan may not be impaired or affected by any amendment of our 2012 Equity Incentive Plan, 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

On December 27, 2018, we entered into a form of securities purchase agreement with a non-U.S. investor relating to an offering and sale of 50,000 shares of our common stock, at a purchase price of $1.00 per share, and warrants to purchase up to 50,000 shares of our common stock (the "Warrant Shares") at an exercise price of $1.25 per share. The warrants will be exercisable after the six-month anniversary of the closing at which they were issued and will expire on the 36-month anniversary of their issuance. The warrants contain customary anti-dilution protections and are exercisable for cash or on a cashless basis if there is no effective registration statement registering the resale of the Warrant Shares. We claimed exemption from registration requirements of the Securities Act for the foregoing transaction pursuant to Section 4(a)(2) and Regulation S under the Securities Act.

During the fourth quarter of 2018, we issued an aggregate of 143,915 shares of our common stock to certain of our service providers as compensation in lieu of cash compensation owed to them for services rendered. We claimed exemption from registration under the Securities Act for the foregoing transactions under Section 4(a)(2) of the Securities Act.

Item 6. Selected Financial Data

Not applicable.

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 global digital health (mHealth) company serving our users with dynamic mobile health solutions. We employ what we believe to be a revolutionary approach to health management. We have developed unique ways for people to analyze and personalize their chronic disease management as it relates to diabetes. We have accomplished this through the combination of wearable technology and health monitoring. In addition, our solution is changing the way people with diabetes can manage their condition as a result of us providing them with continuous, as opposed to periodic, data.

Our flagship product, Dario, which we also refer to as our Dario Smart Diabetes Management Solution, is a mobile, real-time, cloud-based, diabetes management solution based on an innovative, multi-feature software application to track and monitor all factets of diabetes, combined with a stylish, 'all-in-one', pocket-sized, blood glucose monitoring device, which we call the Dario Blood Glucose Monitoring System, that essentially turns a smartphone into a glucometer.

Our principal operating subsidiary, LabStyle Innovation Ltd., is an Israeli company with its headquarters in Caesarea, Israel. We were formed on August 11, 2011 as a Delaware corporation.

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 and 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 Innovation Ltd., 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 diabetes 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 Smart Diabetes Management Solution, the DarioEngage platform and the Dario Intelligence tools and capabilities);
- 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.

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 March 2020 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 a material alternations 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

We derive revenues from the sale of our device-specific disposables test strip cartridges, lancets and our Dario Blood Glucose Monitoring System through distributors or directly to end users. The Dario Smart Diabetes Management application is offered for a free download and we do not have a recurring hosting commitment with our end users relating specifically to the application.

Revenues from product sales are recognized in accordance with Accounting Standards Codification ("ASC") 605-10, "Revenue Recognition", when delivery has occurred, persuasive evidence of an agreement exists, the vendor's fee is fixed or determinable, no further obligation exists and collectability is probable. We generally do not grant a right of return. We assess whether the fee is fixed or determinable based on the nature of the fee charged for the products delivered, the existing contractual arrangements and the distributor's consistency of payments. When evaluating collectability, we consider whether we have sufficient history to reliably estimate the distributor's payment patterns.

When a sales arrangement contains multiple elements, such as services and products, we allocate revenue to each element based on a selling price hierarchy as required according to ASC 605-25, "Multiple-Element Arrangements". The selling price for a deliverable is based on its Vendor Specific Objective Evidence ("VSOE"), if available, third party evidence ("TPE") if VSOE is not available or estimated selling price ("ESP") if neither VSOE nor TPE is available. The best estimate of selling price is established considering several internal factors including, but not limited to, historical sales, pricing practices and geographies in which the Company offers its products.

Revenues from services are recognized when persuasive evidence of an arrangement exists, delivery of the product has occurred, or the services have been rendered, the fee is fixed or determinable and collectability is probable.

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, 2018, total inventory write-off expenses amounted to $41.

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 five 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, 2018 to Year Ended December 31, 2017

Revenues

Revenues for the year ended December 31, 2018 amounted to $7,394,000, compared to $5,170,000 during the year ended December 31, 2017.

Revenues generated during the year ended December 31, 2018 were derived mainly from the sales of the Dario Blood Glucose Monitoring System, through direct sales to consumers located mainly in the United States through our on-line store and through distributors, and from the offering of our membership services to our customers located mainly in the United States. This increase in revenues is attributable to additional commercialization of sales in 2018.

Cost of Revenues

During the years ended December 31, 2018 and 2017, we recorded costs related to revenues in the amount of $5,629,000 and $3,859,000, respectively. The increase in cost of revenues was mainly due to the increase in the quantities of products sold during 2018.

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, shipping and handling costs and inventory write-downs.

Research and Development Expenses

Our research and development expenses increased by $379,000 to $3,676,000 for the year ended December 31, 2018 compared to $3,297,000 for the year ended December 31, 2017. This increase was mainly due to increase in salaries, stock-based compensation expenses, and software and product development costs.

Research and development expenses consist mainly of payroll expenses to employees involved in research and development activities, expenses related to our Dario Smart Diabetes Management Solution, expenses related to the development of our DarioEngage platform, labor contractors and engineering expenses, depreciation and maintenance fees related to equipment and software tools used in research and development, clinical trials performed in the United States to satisfy the FDA product approval requirements and facilities expenses associated with and allocated to research and development activities.

Sales and Marketing

Our sales and marketing expenses increased by $2,602,000 to $10,309,000 for the year ended December 31, 2018 compared to $7,707,000 for the year ended December 31, 2017. This increase was mainly due to the increase in salaries and, expenses on digital marketing campaigns primarily in the U.S. and Australia.

Sales and marketing expenses consist mainly of payroll expenses, trade show expenses, customer support expenses and on-line marketing campaigns.

General and Administrative Expenses

Our general and administrative expenses increased by $742,000 to $5,468,000 for the year ended December 31, 2018 compared to $4,726,000 for the year ended December 31, 2017. The increase was mainly due to an increase in salaries, share based compensation expenses and consulting expenses.

Our general and administrative expenses consist mainly of payroll and stock-based compensation expenses for management, employees, directors and consultants, legal 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, decreased by $1,209,000 to $115,000 for the year ended December 31, 2018 compared to $1,324,000 financing expenses for the year ended December 31, 2017. Finance expenses includes mainly the results of revaluation of warrants issued to investors, which were recorded as a liability and were presented at their fair value for each reporting period until liability expiration.

Net loss

Net loss for the year ended December 31, 2018 was $17,803,000. Net loss for the year ended December 31, 2017 was $15,743,000. The increase from 2017 was mainly due to the increase in our operating expenses.

Net operating loss carryforwards

We had U.S. federal net operating loss carryforwards of approximately $7,120,000 at December 31, 2018. This loss carryforwards expire principally beginning in 2031 through 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, we generated an additional $1,965 of net operating loss carryforwards which are not subject to the annual limitation described above.

Our Israeli subsidiary has accumulated net operating losses for Israeli income tax purposes as of December 31, 2018 in the amount of approximately $47,233,000. 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 $18,296,000 and $15,998,000 for the year ended December 31, 2018 and 2017, respectively.

Non-GAAP Financial Measures

To supplement our unaudited condensed 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 unaudited condensed 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 unaudited condensed consolidated financial statements to understand the effects of the non-cash impact on our (U.S. GAAP) unaudited condensed consolidated 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)		
	2018	2017	$ Change
Net Loss Reconciliation			
Net loss attributable to common stockholders	$ (18,296)	$ (15,998)	$ (2,298)
Deemed dividend – related to Warrant Exchange Agreement	493	255	238
Net loss - as reported	(17,803)	(15,743)	(2,060)
Adjustments			
Depreciation expense	207	195	12
Other financial expenses, net	115	1,324	(1,209)
EBITDA	(17,481)	(14,224)	(3,257)
Stock-based compensation expenses	3,758	3,824	(66)
Revaluation of warrants	(1)	1,168	(1,169)
Non-GAAP adjusted loss	$ (13,724)	$ (9,232)	$ (4,492)

Liquidity and Capital Resources

As of December 31, 2018, we had approximately $10,997,000 in cash and cash equivalents compared to $3,718,000 at December 31, 2017.

We have experienced cumulative losses of $89,254,000 from inception (August 11, 2011) through December 31, 2018, and have a stockholders' equity of $8,925,000 at December 31, 2018. 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. There are no assurances that we will be able to obtain an adequate level of financing needed for our near term requirements or the long-term development and commercialization of our product. These conditions raise substantial doubt about our ability to continue as a "going concern."

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 $71,179,000 as of December 31, 2018.

On March 3, 2016, we conducted a public offering, pursuant to which we issued 1,333,333 shares of common stock and warrants exercisable for an aggregate of 1,333,333 shares of common stock for an aggregate net consideration of $5,038,000.

Concurrently with our public offering, on March 3, 2016, we conducted a concurrent private placement pursuant to which we issued 555,555 units, with each unit consisting of one share of common stock and one warrant to purchase 1.2 shares of common stock, such that an aggregate of 555,555 shares of common stock and a warrant to exercisable for an aggregate of 666,666 shares of common stock was issued and sold for an aggregate net consideration of approximately $2,500,000.

On January 9, 2017, we commenced a private placement offering of up to $5,100,000 consisting of up to 1,821,437 shares of common stock and warrants to purchase up to 1,821,437 shares of common stock. The warrants are exercisable after the six month anniversary of each respective closing and will expire on the 5 year anniversary of their issuance. On January 9, 2017, we held the initial closing of the offering with a lead investor and an additional investor and issued and sold 1,113,922 shares of Common Stock and Warrants to purchase 1,113,922 shares of common stock for aggregate gross proceeds of approximately $3,119,000. On January 11, 2017, we entered into securities purchase agreements with 18 investors for the future issuance and sale of 707,515 shares of common stock and warrants to purchase 707,515 shares of common stock, provided that the issuance and sale of such securities shall only occur upon our obtaining stockholder approval, pursuant to Nasdaq rules. On March 9, 2017, following receipt of stockholder approval, we issued and sold 707,515 shares of common stock and warrants to purchase 707,515 shares of common stock to the 18 investors.

On March 31, 2017, we conducted a public offering, pursuant to which we issued 1,450,000 shares of common stock for aggregate gross consideration of $4,500,000.

Between August 16, 2017 and August 22, 2017, we executed securities purchase agreements with a total of 23 accredited and non-U.S. investors relating to two concurrent placement offerings of 483,333 shares of our common stock at a purchase price of $1.80 per share and 2,307,654 shares of our designated Series B Preferred Stock at a purchase price of $1.80 per share, for aggregate gross proceeds of approximately $5,000,000. The closing of the offering took place on August 22, 2017.

On February 28, 2018 and March 6, 2018, we closed two concurrent private placements offerings consisting of 2,262,269 shares of our common stock at $1.40 per share, 1,234,080 shares of our Series C Convertible Preferred Stock at $2.80 per share and warrants to purchase up to 3,784,351 shares of common stock for aggregate gross proceeds of approximately $6,623,000.

On September 13, 2018 and September 26, 2018, we closed two concurrent private placements offerings consisting of 4,266,800 shares our common stock at $0.90 per share, 1,890,257 shares of our Series D Convertible Preferred Stock at $3.60 per share, and warrants to purchase up to 9,462,272 shares of common stock, for aggregate gross proceeds of approximately $10,645,000.

On December 13, 2018 and December 27, 2018, we closed a private placement offering of 3,050,000 shares of our common stock at a purchase price of $1.00 per share and warrants to purchase up to 3,050,000 shares of our common stock at $1.25 per share for aggregate gross proceeds of approximately $3,050,000.

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 into March 2020 without raising additional capital. This includes an amount of anticipated inflows from sales of Dario through distribution partners and to direct customers.

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 generate any revenue at all), 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.

Additionally, 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, testing of our Dario Smart Diabetes Management Solution, (2) our efforts to obtain regulatory clearances or approvals necessary to be able to commercially launch Dario, DarioEngage and Dario Intelligence, (3) expenses which will be required in order to expand production of Dario, (4) sales and marketing efforts and (5) 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 launch Dario, DarioEngage and Dario Intelligence 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,	
	2018	**2017**
	$	**$**
Cash used in operating activities:	(11,470,000)	(10,619,000)
Cash used in investing activities:	6,000	(219,000)
Cash provided by financing activities:	18,743,000	13,463,000

Net cash used in operating activities

Net cash used in operating activities was $11,470,000 for the year ended December 31, 2018 compared to $10,619,000 used in operations for the same period in 2017. Cash used in operations increased mainly due to increase in our research and development expenses and in our sales and marketing activities in promoting our product sales.

Net cash used in investing activities

Net cash derived from investing activities was $6,000 for the year ended December 31, 2018 compared to cash used in investing activities of $219,000 for the year ended December 31, 2017. Cash used in investing activities increased mainly due to lower investment in manufacturing facilities to support the increase in sales.

Net cash provided by financing activities

Net cash provided by financing activities was $18,743,000 for the year ended December 31, 2018 compared to $13,463,000 for the year ended December 31, 2017. During the year ended December 31, 2018, we raised net proceeds in an amount of approximately $18,743,000 through our March, September and December 2018 offerings.

Contractual Obligations

Set forth below is a summary of our current obligations as of December 31, 2018 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 (U.S. dollars)		
Contractual Obligations	**Total**	**Less than 1 year**	**1-5 years**
Operating Lease Obligations	$ 985	$ 302	$ 683
Purchasing Obligations	1,160	1,160	
Total contractual cash obligations	$ 2,145	$ 1,462	$ 683

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements as defined under Securities and Exchange Commission rules.

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 May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standard Update (“ASU”) 2014-09, “Revenue from Contracts with Customers” Topic 606). This ASU provides a five-step approach to account for revenue arising from contracts with customers. The ASU requires an entity to recognize revenue in a way that depicts the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. This revenue standard will be effective for us starting the first quarter of 2019. The new revenue standard permits companies to either apply the requirements retrospectively to all prior periods presented or apply the requirements in the year of adoption through a modified retrospective approach with a cumulative adjustment. We will adopt the new standard effective January 1, 2019, using the modified retrospective transition method. We expect the adoption of this guidance will not have a material impact on our consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, “Leases” (Topic 842) (ASC 842), relating to the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e., lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use (“ROU”) asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less will be accounted for in a manner similar to the accounting under existing guidance for operating leases today. The new standard requires lessors to account for leases using an approach that is substantially equivalent to existing guidance for sales-type leases, direct financing leases and operating leases. ASC 842 supersedes the previous leases standard, ASC 840, "Leases". The guidance is effective for the interim and annual periods beginning on or after December 15, 2018, and we adopted the standard on January 1, 2019. A modified retrospective transition approach is required, applying the new standard to all leases existing at the date of initial application. The standard provides a number of optional practical expedients in transition. We elected the ‘package of practical expedients,’ which permits not to reassess, under the new standard, our prior conclusions about lease identification, lease classification and initial direct costs. We expect adoption of the standard to have a material impact on our consolidated balance sheets which will result in the recognition of ROU assets and lease liabilities of approximately $850,000 to $890,000 at January 1, 2019. The most significant impact from recognition of ROU assets and lease liabilities relates to our office space. However, we do not anticipate that the adoption of this standard will have a material impact on the operating expenses in our consolidated statements of operations since the expense recognition under this new standard will be similar to current practice. Our financial income (expenses), net will be impacted by the revaluation of the lease liabilities in non-USD denominated currencies.

In November 2016, the FASB issued Accounting Standards Update No. 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash (ASU 2016-18), which requires companies to include amounts generally described as restricted cash and restricted cash equivalents in cash and cash equivalents when reconciling beginning-of-period and end-of-period total amounts shown on the statement of cash flows. This guidance will be effective from the first quarter of 2019 and early adoption is permitted. We do not expect that the adoption of this guidance will have a material impact on our consolidated financial statements and related disclosures.

In June 2018, the FASB issued ASU 2018-07, “Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting.” This ASU supersedes ASC 505-50, “Equity—Equity Based Payments to Non-Employees,” and expands the scope of ASC 718, “Compensation – Stock Compensation,” to include all share-based payment arrangements related to the acquisition of goods and services from both nonemployees and employees. For public companies that file with the Securities and Exchange Commission, the standard is effective for financial statements issued for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. Early adoption is permitted, but no earlier than an entity’s adoption date of Topic 606, “Revenue from Contracts with Customers.” The adoption of this guidance is not expected to have a material impact on our 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-30 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, 2018, 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, 2018 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, 2018. 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, 2018.

Item 9B. Other Information

None.

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	46	Chief Executive Officer and Director
Zvi Ben David	58	Chief Financial Officer, Treasurer and Secretary
Dror Bacher	44	Chief Operating Officer
Olivier Jarry	58	President and Chief Commercial Officer
Yoav Shaked	47	Chairman of the Board of Directors
Yalon Farhi	57	Director
Allen Kamer	48	Director
Hila Karah	50	Director
Dennis M. McGrath	62	Director
Glen D. Moller	47	Director
Prof. Richard B. Stone	76	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 (NYSE: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. (Nasdaq:ELOS). 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.

Dror Bacher has served as our Chief Operating Officer since July 25, 2017. Mr. Bacher previously served as our Vice President of Research and Development as well as Vice President of Operations since 2013 where he worked on product development as well as building a scalable supply chain. Mr. Bacher has over 18 years of experience in various technological companies and his expertise includes product management, product development and business operations in multi disciplinary environments. Between 2008 and 2013, Mr. Bacher Served in several leadership roles at Amdocs Limited (NYSE:DOX), including working as a part of the Chief Technology Office, managing enterprise development. programs for a variety of software products associated with service delivery, as well as serving as head of process Prior to Amdocs, Mr. Bacher served in a senior role at Tower Semiconductor (Nasdaq:TSEM), the global specialty foundry leader for IC manufacturing, where he was responsible for business operations and commercialization expansion. Mr. Bacher holds a B.Sc. in computer science and an MBA degree from Haifa University.

Olivier Jarry has served as our President and Chief Commercial Officer since August 30, 2018. Mr. Jarry has served on our Advisory Board and as a Strategic Advisory consultant since 2017. Between 2015 and 2016, Mr. Jarry served as Senior Vice-President of the Consumer Sector and Officer at Intrexon Corp. (NYSE:XON), a biotechnology company focused on engineering biological systems to enable DNA-based control over the function and output of living cells. Prior to Intrexon, from 2011 to 2012, Mr. Jarry served as the Head of Strategy, Operations and Market Access, focusing on Emerging Markets, for Bristol-Myers Squibb (NYSE:BMY), where he oversaw the product launch and growth of innovative medicines relating to oncology, virology, rheumatology, cardiovascular, and diabetes. Prior to that, between 2009 and 2010, Mr. Jarry served as the Global Business Unit Head of Bayer Diabetes Care, a division of Bayer HealthCare Pharmaceuticals LLC. Prior to his time at Bayer HealthCare, from 2001 to 2009, Mr. Jarry served in several leadership roles at Novartis International AG (NYSE:NVS), including working as Global Division Head of Strategy, Business Development & Licensing at Novartis Headquarters in Switzerland, Senior Vice President and Region Head for Latin America and for Asia-Pacific for Novartis' Consumer Health Division, Head of India Rural Business and Head of Western/Eastern Europe, Russia, CIS - Vaccines division. Mr. Jarry holds a M.Sc. degree from Ecole Centrale de Paris, a MEng. degree from Délégation Générale pour l'Armement, and a Trium Executive MBA degree jointly awarded by NYU Stern School of Business, London School of Economics and Political Science and Hautes Études Commerciales Paris.

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. The Company believes 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.

Yalon Farhi has been a director of our company since May 31, 2016. Since 1998, Mr. Farhi, a Colonel in the Israeli Defense Forces (reserves), has served as a motivational lecturer and educator at Bnei-David Institutions, a pre-army and post-army educational program in Israel. From 1998 to January 2016, Mr. Farhi worked as an administrative manager for El-Ami, a non-governmental organization in Israel. Previously, from 1988 to 1992, Mr. Farhi served as a private security consultant to several security companies in Israel. In addition, for the past thirty years, Mr. Farhi has been the owner of a private gardening and land development services company based in Israel. Mr. Farhi received a degree in Education Studies and holds a Teaching Certificate from the Moreshet Yaacov College in Jerusalem. We believe Mr. Farhi is qualified to serve on our Board of Directors because of his business expertise and experience.

Allen Kamer has been a director of our company since February 28, 2017. Since September 2016, Mr. Kamer serves as a managing partner at OurCrowd, a digital health fund. From January 2014 until June 2016, Mr. Kamer served as Chief Commercial Officer, or CCO, of Optum Analytics, a division within Optum, Inc., United Healthcare's health services unit. Optum Analytics was focused on converting health information to health intelligence and delivering solutions that improve care delivery, quality and cost-effectiveness. As the CCO, Mr. Kamer led the group's commercialization efforts of analytics software products and solutions, including the award-winning Optum OneTM, to U.S. provider and payer organizations. In July 2008, Mr. Kamer was co-founder of the Humedica Inc., which was acquired by United Healthcare in January 2013. As co-founder, Mr. Kamer helped lead efforts to raise capital, hire the management team, and launch the business. Mr. Kamer led Corporate Development & Marketing at Humedica, Inc., and was responsible for formulating and managing the company's strategic partnerships, all marketing & branding activities, and new business opportunities. Mr. Kamer has a B.A. from Brandeis University. We believe Mr. Kamer is qualified to serve on our Board of Directors because of his business expertise and experience with life sciences companies.

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. 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. 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.

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 the 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.

Glen D. Moller has been a director of our company since October 16, 2018. Mr. Moller has 25-year career leading healthcare and technology businesses, including a background in managed care and in technology enabled health services. Since April 2018, Mr. Moller has been an Operating Partner at Frazier Healthcare Partners. Previously, from 2011 to 2017, he served as the Chief Executive Officer and Director of ArroHealth, Inc. ArroHealth's services included population health analytics, mass medical data aggregation, and human- and computer-assisted medical chart analysis. Prior to ArroHealth, from 2010 to 2011, Mr. Moller served as the interim Chief Executive Officer of Centene Corporation. From 2008 to 2010, he served as the President of Fidelis SecureCare, a growth equity-backed Medicare Institutional Special Needs Plan providing a holistic care experience and insurance plan for nursing home-eligible enrollees with multiple chronic conditions. Prior to Fidelis, he served as Chief Operations Officer of the Express Scripts Insurance Company, where he launched and grew the company's Medicare program, including its national prescription drug plan, now a multi-billion-dollar business and the largest in the U.S. Earlier in his career, Mr. Moller held the position of Chief Marketing Officer at consumer-directed pioneer, HealthMarkets Inc., and at regional operating units of Oxford Health Plans, where he started his career. Mr. Moller is a board member of 340(b) Technologies. Mr. Moller has a B.A. in Economics and English from Boston College and M.B.A. from Harvard Business School. We believe Mr. Moller 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.

Prof. Richard B. Stone has been a director of our company since July 7, 2014. For more than twenty-five years, Prof. Stone has been active participant in early stage business enterprises as a director or investor, including technology and biotechnology companies. He currently serves on the board of directors of multiple technology companies, including Powermat, Espro-Accoustiguide Group, Wellsense Technologies, NanoX Imaging Plc, Illumigyn Ltd, Cardiologic Innovations, Quality Inflow Ltd., and Check-Cap. Since 1974, Prof. Stone has been a member of the faculty of Columbia Law School, where he held the Wilbur Friedman Chair in Tax Law for twenty years. In addition to basic and advanced tax courses, Prof. Stone has taught in the areas of contracts, business planning and real estate planning. Among other not-for-profit organizations he has been associated with, from 2011 to 2013, Prof. Stone served as Chairman of the Conference of Presidents of Major American Jewish Organizations. Prof. Stone began his career in 1967 in private practice in Washington, D.C, and thereafter joined the staff of the Solicitor General of the United States, where from 1969 to 1973 he was Assistant to the Solicitor General. He is a graduate of Harvard College and Harvard Law School. We believe Prof. Stone is qualified to serve on our Board of Directors because of his legal expertise and 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 are the biographies of our SAB members.

Prof. Itamar Raz is a world renowned expert in diabetes care and research. He currently services as the head of the Diabetes Unit of Hadassah Hebrew University Medical Center in Jerusalem, the head of the Israel National Council of Diabetes of the Israel Ministry of Health (which is responsible for formulating Israeli national policies), the President of D-Cure, a diabetes not-for-profit organization and the head of the Israel Diabetes Research Group. He also serves as a member of Advisory Boards at Novo Nordisk (NYSE: ADR), Astra Zeneca/Bristol-Myers Squibb (NYSE: BMY), Sanofi (NYSE: SNY), Merck Sharp & Dohme (NYSE: MRK), and Eli Lilly (NYSE: LLY) and as a consultant for InsuLine Medical Ltd, Andromeda Biotech Ltd and Astra Zeneca/Bristol-Myers Squibb. Prof. Raz has published over 260 research papers including biennial publications of a Supplement to Diabetes Care summarizing proceedings of the European Controversies to Consensus in Obesity, Diabetes and Hypertension (CODHy) meeting. He also holds editorial positions on a number of medical journals. Prof. Raz's medical career began in 1985 at Hadassah University Hospital as Senior Physician, specializing in Internal Medicine. From 1986 to 1992, Prof. Raz was head of Hebrew University Student Services, and in 1988 he was appointed Senior Lecturer at Hadassah University Hospital's Department of Internal Medicine. In 1989, Prof. Raz was appointed Chief Physician of Internal Medicine, and as head of the Diabetes Clinic at Hadassah University Hospital in 1992. In 1995, Prof. Raz became an Associate Professor at the Department of Internal Medicine, Hadassah University Hospital. In 2001, he was appointed Director of the hospital's Center for Prevention of Diabetes and its Complications. Since 2003, Prof. Raz has served as Professor of Internal Medicine at the Department of Internal Medicine, Hadassah University Hospital. Prof. Raz graduated from Hebrew University & Hadassah School of Pharmacy with a Bachelor of Science in 1973. In 1981, he graduated from Hebrew University & Hadassah School of Medicine with an M.D. and completed his residency at Hadassah University Hospital from 1981 to 1985, specializing in internal medicine.

Mr. Robert G. Faissal is a Managing Partner of Lebita Consulting Services LLC, a Toronto based business development and investment group with emphasis on commercial relationships in North America, Europe, Africa and the Middle East. Lebita Consulting focuses on healthcare, technology, finance, oil and gas and real estate. Mr. Faissal was the Managing Partner of Richmond Development, an Abu Dhabi based multi-disciplinary investment group. From 1997 until 2000, Mr. Faissal served as the Managing Director/Middle East & Africa for the Philadelphia based Wharton Econometrics Forecasting Associates (WEFA Group, currently IHS Global Insight) advising various governments and private sector clients on economics and financial matters in the Middle East and Africa. He holds a Master of Arts degree in Economics & International Finance from McMaster University in Canada and an undergraduate Honors Degree in Economics from the University of Western Ontario.

Board Composition

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

Under the terms of the Securities Purchase Agreement of the September 2014 Private Placement, for so long as David Edery or his controlled affiliates held 25%, 15% and 10% of the outstanding shares of our common stock, Mr. Edery had the right to nominate, respectively, three, two or one member of our seven-member Board of Directors. Mr. Edery has waived his director nomination rights effective February 28, 2016. Mr. Yehudiha and Ms. Karah were appointed to our Board of Directors as nominees of Mr. Edery. Mr. Yehudiha resigned from our Board of Directors effective as of October 15, 2018.

Under the terms of the Securities Purchase Agreement relating to our January 2017 Private Placement, our lead investor in the offering, OurCrowd Digital Health L.P., was given the right to appoint two members to our Board of Directors with such Board designees to serve on the Company's Nominating and Corporate Governance Committee. Messrs. Kamer and Bahagon were appointed to our Board of Directors as nominees of OurCrowd. Mr. Bahagon resigned from our Board of Directors effective as of March 15, 2018. As of November 29, 2018, OurCrowd Digital Health L.P.'s right to appoint members to our Board of Directors expired.

Except for the appointment of Yalon Farhi, whose nomination was suggested by Shmuel Farhi, a significant stockholder of the company and a cousin of Yalon Farhi, there are no family relationships between any of our directors or executive officers.

Except for the foregoing, 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 Stone, 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.

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 Prof. Stone and Messrs. Kamer and Shaked. Prof. Stone 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 Prof. Stone, Messrs. Kamer, Shaked, Moller, Farhi and McGrath 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. Our Code of Business Conduct and Ethics is available on our website at www.mydario.com under the Investors/Governance section.

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.

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.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our executive officers and directors, and persons who own more than 10% of our common stock, to file reports regarding ownership of, and transactions in, our securities with the SEC and to provide us with copies of those filings. Based solely on our review of the copies of such forms received by us, or written representations from certain reporting persons, except for the Form 3 filed by Shehnee Lawrence Farhi on February 14, 2018, we believe that during fiscal year ended December 31, 2018, all filing requirements applicable to our officers, directors and ten percent beneficial owners were complied with.

Item 11. Executive Compensation

The following table summarizes compensation of our named executive officers, as of December 31, 2018 and 2017.

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 (Chief Executive Officer)	2018	$ 204,762(1)	$ 120,336(2)	$ 1,320,931(3)	$			$ 94,098(5)	$ 1,740,127
	2017	$ 146,679(1)		$ 1,063,401(3)	$ 389,406(4)			$ 75,341(5)	$ 1,674,827
Zvi Ben David (Chief Financial Officer)	2018	$ 131,610(6)		$ 387,649(7)	$			$ 41,328(9)	$ 560,587
	2017	$ 131,136(6)		$ 398,500(7)	$ 86,559(8)			$ 43,786(9)	$ 659,981
Dror Bacher (Chief Operating Officer)	2018	$ 139,060(10)	$ 26,203(11)	$ 382,231(12)	$			$ 60,955(14)	$ 608,449
	2017	$ 130,011(10)		$ 304,970(12)	$ 95,878(13)			$ 59,254(14)	$ 590,113
Olivier Jarry (President and Chief Commercial Officer)	2018	$ 43,577(15)		$ 63,885(16)	$ 62,400(17)			$ 8,060(18)	$ 177,922
	2017	$		$ 22,500(16)	$			$	$ 22,500

* 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, 2018 and December 31, 2017, 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 $22,038 per month). On June 1, 2018, his monthly salary was increased to NIS 134,167 (approximately $36,960). During 2017 and 2018, Mr. Raphael agreed to a waiver of 45% of his cash salary according to our salary program (see further details in “Employment and Related Agreements” below).

(2) On June 2018, Mr. Raphael was paid a bonus of $120,336 for his performance during 2017.

(3) On January 10, 2017, Mr. Raphael was granted 11,205 shares of our common stock under our 2012 Equity Incentive Plan against waiver of cash salary for the period from October to December 2016. On January 30, 2017, Mr. Raphael was granted 11,381 shares of our common stock under our 2012 Equity Incentive Plan against waiver of cash salary for the period from January to March 2017. On April 13, 2017, Mr. Raphael was granted 10,369 shares of our common stock under our 2012 Equity Incentive Plan against waiver of cash salary for the period from April to June 2017. On July 10, 2017, Mr. Raphael was granted 17,036 shares of our common stock under our 2012 Equity Incentive Plan against waiver of cash salary for the period from July to September 2017. On October 23, 2017, Mr. Raphael was granted 21,128 shares of our common stock under our 2012 Equity Incentive Plan against waiver of cash salary for the period from October to December 2017. On January 30, 2017, Mr. Raphael was granted 227,616 shares of our common stock under our 2012 Equity Incentive Plan, and on April 20, 2017, Mr. Raphael was granted 50,000 shares of our common stock under our 2012 Equity Incentive Plan, as a bonus for the 2016 achievements of the Company.

On January 4, 2018, Mr. Raphael was granted 25,439 shares of our common stock under our 2012 Equity Incentive plan against waiver of cash salary for the period from January to March 2018. On April 23, 2018, Mr. Raphael was granted 25,536 shares of our common stock under our 2012 Equity Incentive plan against waiver of cash salary for the period from April to June 2018. On July 9, 2018, Mr. Raphael was granted 49,942 shares of our common stock under our 2012 Equity Incentive plan against waiver of cash salary for the period from July to September 2018. On October 3, 2018, Mr. Raphael was granted 64,392 shares of our common stock under our 2012 Equity Incentive plan against waiver of cash salary for the period from October to December 2018. On June 6, 2018, Mr. Raphael was granted 649,414 shares of our common stock under our 2012 Equity Incentive Plan, and 56,880 shares of our common stock under our 2012 Equity Incentive Plan, as a bonus, in lieu of cash, for the 2017 achievements of the Company.

(4) During 2017, Mr. Raphael was granted 143,164 options to purchase shares of our common stock. The balance shall vest in twelve equal quarterly installments from the grant date during a three-year period. We may grant Mr. Raphael additional options to purchase shares of common stock from time to time at the discretion of our Board of Directors or the Compensation Committee thereof (see further details in “Employment and Related Agreements” below).

(5) 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.”

(6) In accordance with his employment agreement with our company effective January 8, 2015, Mr. Ben David was initially entitled to a monthly salary and additional compensation (excluding social benefits under applicable Israeli law) of NIS 31,200 (approximately $8,595) for providing eighty percent of his working time to our company. Beginning on March 1, 2015, Mr. Ben David began working for us on a full-time basis pursuant to the terms of his employment agreement at which point Mr. Ben David’s salary was increased to NIS 39,000 (approximately $10,744 per month, commencing April 1, 2016, his monthly salary was updated to NIS 60,000 (approximately $16,529), and commencing June 1, 2018, his monthly salary was updated to NIS 67,200 (approximately $18,512). During 2017 and 2018, Mr. Ben David agreed to a waiver of 35% and 39% respectively of his cash salary according to our salary program (see further details in “Employment and Related Agreements” below).

(7) On January 10, 2017, Mr. Ben David was granted 6,536 shares of our common stock under our 2012 Equity Incentive Plan against waiver of cash salary for the period from October to December 2016. On January 30, 2017, Mr. Ben David was granted 6,639 shares of our common stock under our 2012 Equity Incentive Plan against waiver of cash salary for the period from January to March 2017. On April 13, 2017, Mr. Ben David was granted 6,049 shares of our common stock under our 2012 Equity Incentive Plan against waiver of cash salary for the period from April to June 2017. On July 10, 2017, Mr. Ben David was granted 9,938 shares of our common stock under our 2012 Equity Incentive Plan against waiver of cash salary for the period from July to September 2017. On October 23, 2017, Mr. Ben David was granted 12,325 shares of our common stock under our 2012 Equity Incentive Plan against waiver of cash salary for the period from October to December 2017. On January 30, 2017, Mr. Ben David was granted 74,896 shares of our common stock under our 2012 Equity Incentive Plan, and on April 20, 2017, Mr. Ben David was granted 20,000 shares of our common stock under our 2012 Equity Incentive Plan, as a bonus for the 2016 achievements of the Company.

On January 4, 2018, Mr. Ben David was granted 14,839 shares of our common stock under our 2012 Equity Incentive plan against waiver of cash salary for the period from January to March 2018. On April 23, 2018, Mr. Ben David was granted 14,896 shares of our common stock under our 2012 Equity Incentive plan against waiver of cash salary for the period from April to June 2018. On July 9, 2018, Mr. Ben David was granted 22,279 shares of our common stock under our 2012 Equity Incentive plan against waiver of cash salary for the period from July to September 2018. On October 3, 2018 Mr. Ben David was granted 30,075 shares of our common stock under our 2012 Equity Incentive plan against waiver of cash salary for the period from October to December 2018. On June 6, 2018, Mr. Ben David was granted 155,861 shares of our common stock under our 2012 Equity Incentive Plan, and 21,682 shares of our common stock under our 2012 Equity Incentive Plan, as a bonus, in lieu of cash, for the 2017 achievements of the Company.

(8) During 2017, Mr. Ben David was granted 31,823 options to purchase shares of our common stock. The balance shall vest in twelve equal quarterly installments from the grant date during a three-year period. We may grant Mr. Ben David additional options to purchase shares of common stock from time to time at the discretion of our Board of Directors or the Compensation Committee thereof (see further details in “Employment and Related Agreements” below).

(9) 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.”

(10) 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 $13,223 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 $15,151 per month) and commencing June 1, 2018 his monthly salary was increased to NIS 61,490 (approximately $16,939 per month). During 2017 and 2018, Mr. Bacher agreed to a waiver of 24% and 29% of his cash salary respectively, according to our salary program (see further details in “Employment and Related Agreements” below).

(11) On June 2018, Mr. Bacher was paid a bonus of $26,203 for his performance during 2017.

(12) On January 30, 2017, Mr. Bacher was granted 2,845 shares of our common stock under our 2012 Equity Incentive Plan against waiver of cash salary for the period from January to March 2017. On April 13, 2017, Mr. Bacher was granted 2,592 shares of our common stock under our 2012 Equity Incentive Plan against waiver of cash salary for the period from April to June 2017. On July 10, 2017, Mr. Bacher was granted 7,572 shares of our common stock under our 2012 Equity Incentive Plan against waiver of cash salary for the period from July to September 2017. On October 23, 2017, Mr. Bacher was granted 9,390 shares of our common stock under our 2012 Equity Incentive Plan against waiver of cash salary for the period from October to December 2017. On January 30, 2017, Mr. Bacher was granted 49,745 shares of our common stock under our 2012 Equity Incentive Plan, on April 20, 2017 Mr. Bacher was granted 20,000 shares of our common stock under our 2012 Equity Incentive Plan, as a bonus for the 2016 achievements of the Company, on July 25, 2017 Mr. Bacher was granted 10,000 shares of our common stock under our 2012 Equity Incentive Plan, upon his promotion to COO of the Company, and on October 23, 2017, Mr. Bacher was granted 8,080 shares of our common stock under our 2012 Equity Incentive Plan as a bonus for getting FDA clearance for certain Android smartphone devices in the U.S.

On January 4, 2018, Mr. Bacher was granted 11,306 shares of our common stock under our 2012 Equity Incentive plan against waiver of cash salary for the period from January to March 2018. On April 23, 2018, Mr. Bacher was granted 11,349 shares of our common stock under our 2012 Equity Incentive plan against waiver of cash salary for the period from April to June 2018. On July 9, 2018, Mr. Bacher was granted 13,464 shares of our common stock under our 2012 Equity Incentive plan against waiver of cash salary for the period from July to September 2018. On October 3, 2018, Mr. Bacher was granted 19,080 shares of our common stock under our 2012 Equity Incentive plan against waiver of cash salary for the period from October to December 2018. On June 6, 2018, Mr. Bacher was granted 159,832 shares of our common stock under our 2012 Equity Incentive Plan, and 6,183 shares of our common stock under our 2012 Equity Incentive Plan, as a bonus, in lieu of cash, for the 2017 achievements of the Company, and on April 23, 2018, Mr. Bacher was granted 32,452 shares of our common stock under our 2012 Equity Incentive Plan as a bonus in obtaining an FDA clearance for iPhone 7, 8 and X smartphone devices in the U.S.

(13) During January 2017, Mr. Bacher was granted 27,492 options to purchase shares of our common stock which will vest in twelve equal quarterly installments over a three-year period from the grant date. During July 2017, Mr. Bacher was granted 10,000 options to purchase shares of our common stock which will vest in twelve equal quarterly installments over a three-year period from the grant date. We may grant Mr. Bacher additional options to purchase shares of common stock from time to time at the discretion of our Board of Directors or the Compensation Committee thereof (see further details in “Employment and Related Agreements” below).

(14) 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.”

(15) In accordance with his employment agreement, effective in September 2018, Mr. Jarry was entitled to a monthly salary of $11,000. Mr. Jarry agreed to a waiver of 47% of his cash salary, according to our salary program (see further details in “Employment and Related Agreements” below).

(16) As part of his consulting agreement, commencing in March 2017 and expiring in August 2018, Mr. Jarry received a monthly consulting fee of $2,500 that was paid to him in shares of common stock. On July 11, 2017, Mr. Jarry was granted 2,437 shares of our common stock under our 2012 Equity Incentive Plan against waiver of cash consulting fee for the period from March to May 2017. On December 14, 2017, Mr. Jarry was granted 7,404 shares of our common stock under our 2012 Equity Incentive Plan against waiver of cash consulting fee for the period from June to November 2017. On April 23, 2018, Mr. Jarry was granted 6,552 shares of our common stock under our 2012 Equity Incentive Plan against waiver of cash consulting fee for the period from December 2017 to March 2017. On July 23, 2018, Mr. Jarry was granted 4,621 shares of our common stock in restricted shares against waiver of cash consulting fee for the period from April to June 2018. On November 22, 2018, Mr. Jarry was granted 4,103 shares of our common stock in restricted shares against waiver of cash consulting fee for the period July to August 2018, together with additional 3,000 shares granted to him a signature fee for signing his consulting agreement in 2017. On October 3, 2018, Mr. Jarry was granted 30,000 shares of our common stock under our 2012 Equity Incentive Plan, against waiver of cash salary for the period from September to December 2018.

(17) On November 22, 2018, Mr. Jarry was granted 120,000 options to purchase shares of our common stock which will vest over a three-year period from the grant date. One-third of the options will become fully vested and exercisable on the first anniversary elapsed from the grant date, and the balance will vest in eight equal quarterly installments following the first anniversary of the grant date, subject to Mr. Jarry’s continued employment by the Company. We may grant Mr. Jarry additional options to purchase shares of common stock from time to time at the discretion of our Board of Directors or the Compensation Committee thereof (see further details in “Employment and Related Agreements” below).

(18) In addition to his salary, Mr. Jarry is entitled to participate in any and other benefit plans and programs that the Company may offer to its employees from time to time according to the terms of such plans and the Company’s practices and policies as well as reimbursements for expenses accrued. These benefits are included as part of his “All Other Compensation.”

All compensation awarded to our executive officers was independently reviewed by our Compensation Committee.

Employment and Related Agreements

Except as set forth below, we currently have no other written employment agreements with any of our officers and directors. The following is a description of our current executive employment agreements:

Erez Raphael, Chief Executive Officer and a Member of the Board of Directors – On August 30, 2013, LabStyle Innovation Ltd., our Israeli subsidiary, entered into an amendment to a Personal Employment Agreement with Mr. Raphael in connection with his August 2013 appointment as our President and Chief Executive Officer. Pursuant to the terms of his employment agreement as amended, Mr. Raphael is entitled to a monthly salary of NIS 134,167 (approximately $36,960 per month). During 2017 and 2018, Mr. Raphael agreed to a waiver of 45% 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 January 10, 2017, the Compensation Committee of our Board of Directors approved the issuance to Mr. Raphael of 11,205 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $35,961 salary otherwise payable to Mr. Raphael from October to December 2016.

On January 30, 2017, the Compensation Committee of our Board of Directors approved the issuance to Mr. Raphael of 11,381 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $36,444 salary otherwise payable to Mr. Raphael from January to March 2017.

On April 13, 2017, the Compensation Committee of our Board of Directors approved the issuance to Mr. Raphael of 10,369 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $37,953 salary otherwise payable to Mr. Raphael from April to June 2017.

On July 10, 2017, the Compensation Committee of our Board of Directors approved the issuance to Mr. Raphael of 17,036 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $39,389 salary otherwise payable to Mr. Raphael from July to September 2017.

On October 23, 2017, the Compensation Committee of our Board of Directors approved the issuance to Mr. Raphael of 21,128 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $39,222 salary otherwise payable to Mr. Raphael from October to December 2017.

On January 4, 2018, the Compensation Committee of our Board of Directors approved the issuance to Mr. Raphael of 25,439 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $39,923 salary otherwise payable to Mr. Raphael from January to March 2018.

On April 23, 2018, the Compensation Committee of our Board of Directors approved the issuance to Mr. Raphael of 25,536 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $39,344 salary otherwise payable to Mr. Raphael from April to June 2018.

On July 8, 2018, the Compensation Committee of our Board of Directors approved the issuance to Mr. Raphael of 49,942 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $72,725 salary otherwise payable to Mr. Raphael from July to September 2018.

On October 3, 2018, the Compensation Committee of our Board of Directors approved the issuance to Mr. Raphael of 64,392 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $64,003 salary otherwise payable to Mr. Raphael from October to December 2018.

Zvi Ben David, Chief Financial Officer, Treasurer and Secretary – On January 8, 2015, LabStyle Innovation Ltd., our Israeli subsidiary, entered into a Personal Employment Agreement with Mr. Ben David. Pursuant to his employment agreement, Mr. Ben David was initially entitled to a monthly salary and additional compensation (excluding social benefits under applicable Israeli law) of NIS 31,200 (approximately $8,595) for providing eighty percent of his working time to our company. Beginning on March 1, 2015, Mr. Ben David began working for us on a full-time basis pursuant to the terms of his employment agreement at which point Mr. Ben David's salary was increased to NIS 39,000 (approximately $10,744). Commencing April 1, 2016, Mr. Ben David's Salary was updated to NIS 60,000 (approximately $16,529) per month and commencing June 1, 2018, his monthly salary was updated to NIS 67,200 (approximately $18,512). During 2017 and 2018, Mr. Ben David agreed to a waiver of 35% and 39% 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 6 months base salary and severance payment pursuant to applicable Israeli severance law. 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 10, 2017, the Compensation Committee of our Board of Directors approved the issuance to Mr. Ben David of 6,536 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $20,977 salary otherwise payable to Mr. Ben David from October to December 2016.

On January 30, 2017, the Compensation Committee of our Board of Directors approved the issuance to Mr. Ben David of 6,639 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $21,259 salary otherwise payable to Mr. Ben David from January to March 2017.

On April 13, 2017, the Compensation Committee of our Board of Directors approved the issuance to Mr. Ben David of 6,049 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $ $22,139 salary otherwise payable to Mr. Ben David from April to June 2017.

On July 10, 2017, the Compensation Committee of our Board of Directors approved the issuance to Mr. Ben David of 9,938 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $22,977 salary otherwise payable to Mr. Ben David from July to September 2017.

On October 23, 2017, the Compensation Committee of our Board of Directors approved the issuance to Mr. Ben David of 12,325 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $22,879 salary otherwise payable to Mr. Ben David from October to December 2017.

On January 4, 2018, the Compensation Committee of our Board of Directors approved the issuance to Mr. Ben David of 14,839 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $23,288 salary otherwise payable to Mr. Ben David from January to March 2018.

On April 23, 2018, the Compensation Committee of our Board of Directors approved the issuance to Mr. Ben David of 14,896 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $ $22,951 salary otherwise payable to Mr. Ben David from April to June 2018.

On July 8, 2018, the Compensation Committee of our Board of Directors approved the issuance to Mr. Ben David of 22,279 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $32,442 salary otherwise payable to Mr. Ben David from July to September 2018.

On October 3, 2018, the Compensation Committee of our Board of Directors approved the issuance to Mr. Ben David of 30,075 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $29,893 salary otherwise payable to Mr. Ben David from October to December 2018.

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 $15,151), effective as of July 2017, and commencing June 1, 2018 his monthly salary was increased to NIS 61,490 (approximately $16,939 per month).. Pursuant to Mr. Bacher's existing personal employment agreement as amended, either Mr. Bacher or we may terminate his employment agreement upon thirty days 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 10,000 shares of common stock, and 10,000 options that will vest in 12 equal quarterly installments over a three-year period with an exercise price of $2.46 per share, all issued pursuant to the Registrant's Amended and Restated 2012 Equity Incentive Plan.

During the years 2017 and 2018, Mr. Bacher agreed to waive approximately 24% and 29% of his cash salary, respectively, pursuant to our shares for salary program and its 2012 Equity Incentive Plan, and as a result Mr. Bacher received shares of common stock in lieu of a portion of his annual cash salary.

On January 10, 2017, the Compensation Committee of our Board of Directors approved the issuance to Mr. Bacher of 2,801 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $8,990 salary otherwise payable to Mr. Bacher from October to December 2016.

On January 30, 2017, the Compensation Committee of our Board of Directors approved the issuance to Mr. Bacher of 2,845 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $9,111 salary otherwise payable to Mr. Bacher from January to March 2017.

On April 13, 2017, the Compensation Committee of our Board of Directors approved the issuance to Mr. Bacher of 2,592 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $9,488 salary otherwise payable to Mr. Bacher from April to June 2017.

On July 10, 2017, the Compensation Committee of our Board of Directors approved the issuance to Mr. Bacher of 7,572 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $17,506 salary otherwise payable to Mr. Bacher from July to September 2017.

On October 23, 2017, the Compensation Committee of our Board of Directors approved the issuance to Mr. Bacher of 9,390 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $17,432 salary otherwise payable to Mr. Bacher from October to December 2017.

On October 23, 2017, the Compensation Committee of our Board of Directors approved the issuance to Mr. Bacher of 8,080 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $15,000 of a cash bonus otherwise payable to Mr. Bacher for his efforts in obtaining FDA clearance for certain Android smartphone devices in the U.S.

On January 4, 2018, the Compensation Committee of our Board of Directors approved the issuance to Mr. Bacher of 11,306 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $17,744 salary otherwise payable to Mr. Bacher from January to March 2018.

On April 23, 2018, the Compensation Committee of our Board of Directors approved the issuance to Mr. Bacher of 11,349 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $ $17,486 salary otherwise payable to Mr. Bacher from April to June 2018.

On April 23, 2018, the Compensation Committee of our Board of Directors approved the issuance to Mr. Bacher of 32,452 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $50,000 of a cash bonus otherwise payable to Mr. Bacher for his efforts in obtaining FDA clearance for iPhone 7, 8 and X smartphone devices in the U.S.

On July 8, 2018, the Compensation Committee of our Board of Directors approved the issuance to Mr. Bacher of 13,464 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $19,606 salary otherwise payable to Mr. Bacher from July to September 2018.

On October 3, 2018, the Compensation Committee of our Board of Directors approved the issuance to Mr. Bacher of 19,080 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $18,964 salary otherwise payable to Mr. Bacher from October to December 2018.

Olivier Jarry, President and Chief Commercial Officer – On August 30, 2018, we appointed Mr. Jarry as our President and Chief Commercial Officer. In connection with Mr. Jarry's appointment, we agreed to pay Mr. Jarry an annual base salary of $252,000 out of which $132,000 is paid in cash and the balance is paid in our shares of common stock. Mr. Jarry's employment is subject to a one (1) year non-competition and non-solicitation provision, certain confidentiality covenants and assignment of any of his company-related inventions. Mr. Jarry is also entitled to certain expense reimbursements and other standard benefits, including vacation and sick leave. In addition, Mr. Jarry is entitled to receive an annual incentive bonus of up to 35,000 shares of common stock and an annual over performance bonus of up to 20,000 shares of common stock, with each such bonus subject to certain milestones and performance targets to be determined by our Board of Directors. In addition, and in conjunction with Mr. Jarry's appointment as President and Chief Commercial Officer, we agreed to issue Mr. Jarry a stock option to purchase up to 120,000 shares of common stock at a future date and at the discretion of our Board of Directors.

During the fiscal year ended December 31, 2018, Mr. Jarry agreed to waive approximately 47% of his cash salary pursuant to our shares for salary program and its 2012 Equity Incentive Plan, and as a result, Mr. Jarry received shares of common stock in lieu of a portion of his annual cash salary.

On October 3, 2018, the Compensation Committee of our Board of Directors approved the issuance to Mr. Jarry of 39,237 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $39,000 salary otherwise payable to Mr. Jarry from September to December 2018.

Outstanding Equity Awards at December 31, 2018

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	2,001	-	-	$ 121,50	March 14, 2023
(Chief Executive Officer)	223	-	-	$ 270.00	June 5, 2023
	3,334	-	-	$ 240.30	August 28, 2023
	889	-	-	$ 166.50	January 6, 2024
	4,667	-	-	$ 88.20	July 6, 2024
	168,904	-	-	$ 5.76	September 3, 2021
	83,512	59,652(1)	-	$ 3.202	January 30, 2023
Zvi Ben David	43,073	-	-	$ 5.76	September 3, 2021
(Chief Financial Officer, Secretary and Treasurer)	18,563	13,260(1)	-	$ 3.202	January 30, 2023
Dror Bacher	1,334	-	-	$ 166.50	January 6, 2024
(Chief Operating Officer)	1,334	-	-	$ 88.20	July 6, 2024
	25,338	-	-	$ 5.76	September 3, 2021
	9,584	-	-	$ 7.02	December 17, 2021
	16,037	11,455(1)	-	$ 3.202	January 30, 2023
	4,170	5,830(1)	-	$ 2.46	July 25, 2023
Olivier Jarry	120,000	120,000		$ 0.795	November 22, 2024
(President and Chief Commercial Officer)					
Total Option Shares	**502,963**	**210,197**	-	$ -	-

(1) Vests in 12 equal quarterly 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, Farhi, Kamer, McGrath and Moller, Prof. Stone and Ms. Karah) will receive the following cash payments for each fiscal year: (i) $25,000 per year, to be paid quarterly in arrears and (ii) $16,000 for Board committee service, to be paid quarterly in arrears; *provided*, *however*, that such quarterly payments and committee meeting fees shall accrue and shall be payable upon the approval of Mr. Raphael at such time when our company is adequately capitalized in his reasonable discretion.

Stock and Option Awards

On January 10, 2017, the Compensation Committee of our Board of Directors approved the issuance to each of Prof. Stone, Mr. Hoenlein, Mr. McGrath, Ms. Karah and Mr. Yehudiha of 6,388 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of $20,500 in fees otherwise payable to each of Prof. Stone, Mr. Hoenlein, Mr. McGrath, Ms. Karah and Mr. Yehudiha for the period from July 1, 2016, to December 31, 2016. In addition, the Compensation Committee of our Board of Directors approved the issuance to Mr. Farhi of 4,544 shares of our common stock under the 2012 Equity Incentive Plan. Such shares were issued in lieu of $14,583.33 in fees otherwise payable to Mr. Farhi for the period June 1, 2016, to December 31, 2016.

On January 30, 2017, the Compensation Committee of our Board of Directors approved a grant of an aggregate of 111,242 options to our non-employee directors. These options have an exercise price of $3.202 per share. The options shall vest in 12 quarterly installments over a three-year period from the grant date.

On April 13, 2017, the Compensation Committee of our Board of Directors approved the issuance to each of Prof. Stone, Mr. Hoenlein, Mr. McGrath, Ms. Karah and Mr. Yehudiha of 2,800 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of $10,250 in fees otherwise payable to each of Prof. Stone, Mr. Hoenlein, Mr. McGrath, Ms. Karah and Mr. Yehudiha for the period from January 1, 2017, to March 31, 2017. In addition, the Compensation Committee of our Board of Directors approved the issuance to Mr. Farhi of 1,708 shares of our common stock under the 2012 Equity Incentive Plan. Such shares were issued in lieu of $6,250 in fees otherwise payable to Mr. Farhi for the period January 1, 2017, to March 31, 2017. In addition, the Compensation Committee of our Board of Directors approved the issuance to each of Mr. Kamer and Mr. Bahagon of 569 shares of our common stock under the 2012 Equity Incentive Plan. Such shares were issued in lieu of $2,083.33 in fees otherwise payable to each of Mr. Kamer and Mr. Bahagon for the period March 1, 2017, to March 31, 2017.

On July 9, 2017, the Compensation Committee of our Board of Directors approved the issuance to each of Prof. Stone, Mr. Hoenlein, Mr. McGrath, Ms. Karah and Mr. Yehudiha of 4,433 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of $10,250 in fees otherwise payable to each of Prof. Stone, Mr. Hoenlein, Mr. McGrath, Ms. Karah and Mr. Yehudiha for the period from April 1, 2017, to June 30, 2017. In addition, the Compensation Committee of our Board of Directors approved the issuance to each of Mr. Farhi, Mr. Kamer and Mr. Bahagon of 2,703 shares of our common stock under the 2012 Equity Incentive Plan. Such shares were issued in lieu of $6,250 in fees otherwise payable to Mr. Farhi, Mr. Kamer and Mr. Bahagon for the period April 1, 2017, to June 30, 2017.

On October 23, 2017, the Compensation Committee of our Board of Directors approved the issuance to each of Prof. Stone, Mr. Hoenlein, Mr. McGrath, Ms. Karah and Mr. Yehudiha of 5,521 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of $10,250 in fees otherwise payable to each of Prof. Stone, Mr. Hoenlein, Mr. McGrath, Ms. Karah and Mr. Yehudiha for the period from July 1, 2017, to September 30, 2017. In addition, the Compensation Committee of our Board of Directors approved the issuance to each of Mr. Farhi, Mr. Kamer and Mr. Bahagon of 3,367 shares of our common stock under the 2012 Equity Incentive Plan. Such shares were issued in lieu of $6,250 in fees otherwise payable to Mr. Farhi, Mr. Kamer and Mr. Bahagon for the period July 1, 2017, to September 30, 2017.

On January 4, 2018, the Compensation Committee of our Board of Directors approved the issuance to each of Prof. Stone, Mr. Hoenlein, Mr. McGrath, Ms. Karah and Mr. Yehudiha of 6,531 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of $10,250 in fees otherwise payable to each of Prof. Stone, Mr. Hoenlein, Mr. McGrath, Ms. Karah and Mr. Yehudiha for the period from October 1, 2017, to December 31, 2017. In addition, the Compensation Committee of our Board of Directors approved the issuance to each of Mr. Farhi, Mr. Kamer and Mr. Bahagon of 3,983 shares of our common stock under the 2012 Equity Incentive Plan. Such shares were issued in lieu of $6,250 in fees otherwise payable to Mr. Farhi, Mr. Kamer and Mr. Bahagon for the period October 1, 2017, to December 31, 2017.

On April 23, 2018, the Compensation Committee of our Board of Directors approved the issuance to each of Prof. Stone, Mr. Hoenlein, Mr. McGrath, Ms. Karah and Mr. Yehudiha of 6,653 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of $10,250 in fees otherwise payable to each of Prof. Stone, Mr. Hoenlein, Mr. McGrath, Ms. Karah and Mr. Yehudiha for the period from January 1, 2018, to March 31, 2018. In addition, the Compensation Committee of our Board of Directors approved the issuance to each of Mr. Farhi and Mr. Kamer of 4,057 shares of our common stock under the 2012 Equity Incentive Plan. Such shares were issued in lieu of $6,250 in fees otherwise payable to Mr. Farhi and Mr. Kamer for the period January 1, 2018, to March 31, 2018. In addition, the Compensation Committee of our Board of Directors approved the issuance to Mr. Bahagon 3,335 shares of our common stock under the 2012 Equity Incentive Plan. Such shares were issued in lieu of $5,139 in fees otherwise payable to Mr. Bahagon for the period January 1, 2018, to March 15, 2018.

On July 9, 2018, the Compensation Committee of our Board of Directors approved the issuance to each of Prof. Stone, Mr. Hoenlein, Mr. McGrath and Ms. Karah of 7,039 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of $10,250 in fees otherwise payable to each of Prof. Stone, Mr. Hoenlein, Mr. McGrath and Ms. Karah for the period from April 1, 2018, to June 30, 2018. In addition, the Compensation Committee of our Board of Directors approved the issuance to each of Mr. Farhi, Mr. Kamer, Mr. Yehudiha and Mr. Zanco of 4,292 shares of our common stock under the 2012 Equity Incentive Plan. Such shares were issued in lieu of $6,250 in fees otherwise payable to Mr. Farhi, Mr. Kamer, Mr. Yehudiha and Mr. Zanco for the period April 1, 2018, to June 30, 2018.

On October 3, 2018, the Compensation Committee of our Board of Directors approved the issuance to each of Prof. Stone, Mr. Shaked, Mr. McGrath, and Ms. Karah of 10,312 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of $10,250 in fees otherwise payable to each of Prof. Stone, Mr. Shaked, Mr. McGrath, and Ms. Karah for the period from July 1, 2018, to September 30, 2018. In addition, the Compensation Committee of our Board of Directors approved the issuance to each of Mr. Farhi, Mr. Kamer, Mr. Yehudiha and Mr. Zanco of 6,288 shares of our common stock under the 2012 Equity Incentive Plan. Such shares were issued in lieu of $6,250 in fees otherwise payable to Mr. Farhi, Mr. Kamer, Mr. Yehudiha and Mr. Zanco for the period July 1, 2018, to September 30, 2018.

On January 27, 2019, the Compensation Committee of our Board of Directors approved the issuance to each of Prof. Stone, Mr. Shaked, Mr. McGrath, and Ms. Karah of 10,250 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of $10,250 in fees otherwise payable to each of Prof. Stone, Mr. Shaked, Mr. McGrath, and Ms. Karah for the period from October 1, 2018, to December 31, 2018. The Compensation Committee of our Board of Directors also approved the issuance to each of Mr. Farhi and Mr. Kamer of 6,250 shares of our common stock under the 2012 Equity Incentive Plan. Such shares were issued in lieu of $6,250 in fees otherwise payable to Mr. Farhi and Mr. Kamer for the period October 1, 2018, to December 31, 2018. In addition, the Compensation Committee of our Board of Directors approved the issuance to Mr. Moller 5,231 shares of our common stock under the 2012 Equity Incentive Plan. Such shares were issued in lieu of $5,231 in fees otherwise payable to Mr. Moller for the period October 16, 2018, to December 31, 2018.

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, 2018:

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 ($)	Total ($)
Yossi Bahagon (1)	2018	$ -	$ 11,389(2)	$ (3)	$ -	$ -	$ -	$
Malcolm Hoenlein (4)	2018	$ -	$ 74,997(5)	$ (6)	$ -	$ -	$ -	$
Dennis McGrath	2018	$ -	$ 78,747(7)	$ (8)	$ -	$ -	$ -	$
Prof. Richard B. Stone	2018	$ -	$ 78,747(9)	$ (10)	$ -	$ -	$ -	$
Rami Yehudiha (11)	2018	$ -	$ 44,039(12)	$ (13)	$ -	$ -	$ -	$
Yalon Farhi	2018	$ -	$ 36,039(14)	$ (15)	$ -	$ -	$ -	$
Hila Karah	2018	$ -	$ 78,747(16)	$ -(17)	$ -	$ -	$ -	$
Allen Kamer	2018	$ -	$ 65,061(18)	$ (19)	$ -	$ -	$ -	$
Ori Zanco (20)	2018	$ -	$ 39,208(21)	$ -(22)	$ -	$ -	$ -	$
Yoav Shaked	2018	$ -	$ 10,250(23)	$ (24)	$ -	$ -	$ -	$
Glen D. Moller	2018	$ -	$ -(25)	$ (26)	$ -	$ -	$ -	$

* 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, 2018, computed in accordance with the provisions of ASC 718. Assumptions used in accordance with ASC 718 are included in Note 9 to our consolidated financial statements included in this Annual Report.

(1) Mr. Bahagon resigned from our Board of Directors effective as of March 15, 2018.

(2) 13,957 stock awards are outstanding as of December 31, 2018.

(3) No option awards are outstanding as of December 31, 2018.

(4) Mr. Hoenlein resigned from our Board of Directors effective as of July 5, 2018.

(5) 90,072 stock awards are outstanding as of December 31, 2018.

(6) 2,223 option awards are outstanding as of December 31, 2018.

(7) 88,036 stock awards are outstanding as of December 31, 2018.

(8) 33,152 option awards are outstanding as of December 31, 2018.

(9) 87,992 stock awards are outstanding as of December 31, 2018.

(10) 32,874 option awards are outstanding as of December 31, 2018.

(11) Mr. Yehudiha resigned from our Board of Directors effective as of October 15, 2018.

(12) 62,743 stock awards are outstanding as of December 31, 2018.

(13) 23,203 option awards are outstanding as of December 31, 2018.

(14) 38,064 stock awards are outstanding as of December 31, 2018.

(15) 31,207 option awards are outstanding as of December 31, 2018.

(16) 84,855 stock awards are outstanding as of December 31, 2018.

(17) 31,207 option awards are outstanding as of December 31, 2018.

(18) 51,105 stock awards are outstanding as of December 31, 2018.

(19) No option awards are outstanding as of December 31, 2018.

(20) Mr. Zanco resigned from our Board of Directors effective as of October 15, 2018.

(21) 27,811 stock awards are outstanding as of December 31, 2018.

(22) No option awards are outstanding as of December 31, 2018.

(23) 10,312 stock awards are outstanding as of December 31, 2018.

(24) No option stock awards are outstanding as of December 31, 2018.

(25) No stock awards are outstanding as of December 31, 2018.

(26) No option stock awards are outstanding as of December 31, 2018.

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

The following table sets forth information regarding the beneficial ownership of our common stock as of March 22, 2019 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., 8 HaTokhen Street, Caesarea North Industrial Park, 3088900, Israel.

Name of Beneficial Owner	Shares of Common Beneficially Stock Owned	Percent of Common Stock Beneficially Owned [1]
Officers and Directors		
Erez Raphael [2]	2,442,335	6.6%
Zvi Ben David [3]	951,843	2.6%
Dror Bacher [4]	466,018	1.3%
Olivier Jarry [5]	97,354	*
Dennis M. McGrath [6]	127,436	*
Prof. Richard B. Stone [7]	286,448	*
Hila Karah [8]	133,088	*
Yalon Farhi[9]	67,719	*
Allen Kamer[10] [12]	1,452,244	3.9%
Yoav Shaked [13]	83,637	*
Glen Moller	5,231	*
All Executive Officers and Directors as a group (10 persons)	**6,113,353**	**16.5%**
5% Stockholders		
David Edery[11]	3,456,859	9.0%
Agate JT Healthcare Fund L.P.[12]	2,571,428	6.2%
Nantahala Capital Partners SI, LP[14]	3,500,494	9.1%
Nantahala Capital Management, LLC[15]	3,695,199	9.9%
Shmuel Farhi [16]	1,059,684	2.9%
Shehnee Lawrence Farhi[17]	1,917,445	5.1%

* Less than 1%.

(1) Percentage ownership is based on 36,821,173 shares of our common stock outstanding as of March 22, 2019 and, for each person or entity listed above, warrants or options to purchase shares of our common stock which exercisable within 60 days of the such date.

(2) Includes 287,390 vested options. Excludes 35,792 options which are not vested. Also includes 757,509 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 7 B'Chshvan St No. 8, Ramat HaSharon, Israel.

(3) Includes 66,940 vested options to purchase common stock and 111,112 warrants to purchase common stock. Excludes 7,956 options which are not vested. Includes 35,716 shares and 28,573 warrants owned by his spouse, for which Mr. Ben David disclaims beneficial ownership except to the extent of his pecuniary interest therein.

(4) Includes 64,047 vested options to purchase common stock. Excludes 11,035 options which are not vested.

(5) Includes 0 vested options to purchase common stock. Excludes 120,000 options which are not vested.

(6) Includes 29,150 vested options to purchase common stock. Excludes 4,002 options which are not vested.

(7) Includes 25,000 warrants to purchase common stock, and 28,872 vested options to purchase common stock. Excludes 4,002 options which are not vested.

(8) Includes 27,005 vested options to purchase common stock. Excludes 4,002 options which are not vested.

(9) Includes 23,405 vested options to purchase common stock. Excludes 7,802 options which are not vested.

(10) Mr. Kamer is a Managing Partner of OurCrowd Digital Health L.P. and therefore the securities held by OurCrowd Digital Health L.P. may be deemed to be beneficially owned by Mr. Kamer. Mr. Kamer disclaims beneficial ownership of the securities owned by OurCrowd Digital Health L.P. except to the extent of his pecuniary interest therein.

(11) Based solely on information contained in the filed Schedule 13G filed with the SEC on October 10, 2018, reporting beneficial ownership of David Edery. The address of david Edery is 10 Nataf St., Ramat Hasharon 4704063, Israel.

(12) Based on the Securities Purchase Agreement executed by and between Agate JT Healthcare Fund L.P. and the Company dated February 28, 2018.

(13) Includes 33,336 shares and 26,669 warrants owned by his spouse, for which Mr. Shaked disclaims beneficial ownership except to the extent of his pecuniary interest therein.

(14) Based solely on information contained in Form S-3 filed with the SEC on January 15, 2019. Includes 1,653,521 warrants to purchase common stock.

(15) Based solely on information contained in Form 13G filed with the SEC on February 14, 2019.

(16) Based on information contained in the filed Schedule 13D filed with the SEC on May 18, 2018, reporting beneficial ownership of Mr. Shmuel Farhi, as well as information provided by Mr. Shmuel Farhi to the Company. Mr. Shmuel Farhi's address is 484 Richmond St., London, England, N6A 3E6.

(17) Based on information contained in the filed Schedule 13G filed with the SEC on February 14, 2018, reporting beneficial ownership of Ms. Farhi, as well as information provided by Ms. Farhi to the Company. Includes 616,445 warrants to purchase Common Stock issued to Ms. Farhi. Ms. Farhi's address is 413 Grangeover Crt., London, Ontario, Canada.

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.

September 2014 Private Placement

On September 23, 2014, we entered into and closed the transactions contemplated by a definitive Securities Purchase Agreement. The lead investor in the financing memorialized in such agreement was Dicilyon Consulting and Investment Ltd. ("Dicilyon"), an affiliate of Israeli investor David Edery who invested $3 million in the private placement purchasing 1,667 shares of our Series A Convertible Preferred Stock (which converted into 525,564 shares of our Common Stock on March 8, 2016 in conjunction with a closing of our public offering) and 231,248 warrants to purchase Common Stock following the entry into a warrant replacement agreement with Dicilyon whereby Dicilyon replaced 210,226 warrants issued in 2014 which contained a net settlement cash feature and liquidated damages penalties with 231,248 warrants which contain a standard anti-dilution clause, both groups of warrants with an exercise price of $8.559 per share and exercisable until September 23, 2018. Pursuant to the Securities Purchase Agreement, Mr. Edery and his controlled affiliates were granted certain special rights, including, among other things, (i) a two year pre-emptive right to participate in our future financings, subject to certain exceptions, in an amount which would allow Mr. Edery to maintain his fully-diluted percentage ownership of the Company, and (ii) a right that, for so long as Mr. Edery holds 25%, 15% and 10% of the outstanding shares of Common Stock, Mr. Edery shall have the right to appoint, respectively, three, two or one member of our seven-person Board of Directors. The preemptive rights were waived in connection with the March 2016 public offering, and Mr. Edery has waived his director nomination rights effective February 28, 2016. In connection with the closing of the transactions contemplated by the Securities Purchase Agreement, Mr. Edery's company appointed Rami Yehudiha to serve as a member of the Board of Directors and on November 18, 2014, Mr. Edery's company exercised its right to appoint two members to the Board of Directors by requesting that Dr. Oren Fuerst and Dr. Steven A. Kaplan resign from the Board of Directors. Accordingly, Dr. Kaplan resigned from the Board of Directors effective as of November 21, 2014, and Dr. Fuerst resigned from the Board of Directors effective as of November 23, 2014. On November 23, 2014, the remaining members of the Board of Directors acted by unanimous written consent to name two appointees of Mr. Edery's company, Dr. Peter M. Kash and Ms. Hila Karah, as members of the Board of Directors. On February 25, 2015, Dr. Peter M. Kash resigned from his position as a member of the Board of Directors for personal reasons. On June 15, 2015, both Mr. Yehudiha and Ms. Karah were elected to our Board of Directors by our shareholders. On March 1, 2016, Dicilyon irrevocably granted voting and dispositive power over our shares held by it to Erez Raphael, our Chairman, and Chief Executive Officer.

January 2017 Private Placement

On January 9, 2017, we held the initial closing of our private placement offering with OurCrowd Digital Health L.P., the lead investor, and an additional investor, and issued and sold an aggregate of 1,113,922 shares of common stock and warrants to purchase 1,113,922 shares of our common stock. Pursuant to the terms of the securities purchase agreement with OurCrowd Digital Health L.P., we granted OurCrowd Digital Health L.P. the right to nominate two individuals to our Board of Directors for so long as the investor holds 13% and 5% of our outstanding shares of our common stock. We further agreed to permit such designees to serve on our Nominating and Corporate Governance Committee. In addition, we granted OurCrowd Digital Health L.P. the right, for a two year period, to participate in future securities offerings of the Company. On February 28, 2017, OurCrowd Digital Health L.P. appointed Allen Kamer and Yossi Bahagon to serve on our Board of Directors as well as appointed each of Messrs. Kamer and Bahagon to serve on our Nominating and Corporate Governance Committee. Such investor no longer holds in excess of 5% of our outstanding shares of common stock and currently has no right to appoint a director to our Board of Directors. Mr. Bahagon resigned from our Board of Directors effective as of March 15, 2018.

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.

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, 2018 and December 31, 2017 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, 2018	December 31, 2017
Audit Fees	$ 86,000	$ 86,000
Audited Related Fees	$ -	$ -
Tax Fees (1)	$ 9,000	$ 12,000
All Other Fees (2)	$ 15,000	$ 56,000
Total	$ 110,000	$ 154,000

(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 (1)
3.2	Bylaws (2)
3.3	Amendment No. 1 to the Company's Bylaws (3)
3.4	Certificate of Designation of Preferences, Rights and Limitations of Series D Convertible Preferred Stock of the Company (4)
3.5	Certificate of Elimination of Preferences, Rights and Limitations of Series A, B and C Convertible Preferred Stock of the Company (4)
4.1	Warrant Agent Agreement, dated as of March 8, 2016, between LabStyle Innovations Corp. and VStock Transfer, LLC (5)
4.2	Form of Representatives' Warrant (5)
4.3	Form of Warrant (6)
10.1	Employment Agreement, dated October 11, 2012, between LabStyle Israel and Erez Raphael+ (8)
10.2	Amendment to Employment Agreement, dated April 1, 2013, between LabStyle Israel and Erez Raphael+ (7)
10.3	Amendment to Employment Agreement, dated August 30, 2013, between LabStyle Israel and Erez Raphael+ (7)
10.4	Personal Employment Agreement, dated January 8, 2015, between the Company and Zvi Ben David+ (8)
10.5	Amended and Restated 2012 Equity Incentive Plan of the Company+(9)
10.6	Amendment to the Amended and Restated 2012 Equity Incentive Plan of the Company+(3)
10. 7	Securities Purchase Agreement between the Company and OurCrowd Digital Health L.P., dated January 9, 2017 (10)
10. 8	Form of Registration Rights Agreement by and between the Company and OurCrowd in connection with the Company's January 2017 Private Placement (10)
10. 9	Securities Purchase Agreement between the Company and Shmuel Farhi, dated January 9, 2017 (10)
10.10	Form of Securities Purchase Agreement by and between the Company and the Purchasers named therein in connection with the Company's January 2017 Private Placement (11)
10.11	Form of Registration Rights Agreement by and between the Company and the Purchasers named therein in connection with the Company's January 2017 Private Placement (11)
10.12	Amended and Restated Employment Agreement, dated as of July 25, 2017, between Erez Raphael and LabStyle Innovation Ltd. + (12)
10.13	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. + (12)
10.14	Form of Securities Purchase Agreement for the purchase of shares of Common Stock (13)
10.15	Form of Securities Purchase Agreement for the purchase of shares of Preferred Stock (13)
10.16	Form of Securities Purchase Agreement for the purchase of shares of Common Stock (14)
10.17	Form of Securities Purchase Agreement for the purchase of shares of Series C Convertible Preferred and/or Common Stock (14)
10.18	Form of Securities Purchase Agreement for the purchase of shares of Common Stock and Series D Convertible Preferred Stock (4)
10. 9	Form of Securities Purchase Agreement (6)
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	Interactive Data File (XBRL)*

\+ Management contract or compensatory plan or arrangement

* Filed herewith

** Furnished herewith

(1) Incorporated by reference to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 10, 2016.
(2) Incorporated by reference to the Company's Registration Statement on Form S-1, filed with the Securities and Exchange Commission on January 16, 2013.
(3) Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 29, 2018.
(4) Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 6, 2018.
(5) Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 9, 2016.
(6) Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on December 18, 2018.
(7) Incorporated by reference to the Company's Current Report on Form 8-K, filed with the Securities and Exchange Commission on September 6, 2013.
(8) Incorporated by reference to the Company's Current Report on Form 8-K, filed with the Securities and Exchange Commission on January 9, 2015.
(9) Incorporated by reference to the Company's Definitive Proxy Statement filed with the Securities and Exchange Commission on October 19, 2016.
(10) Incorporated by reference to the Company's Registration Statement on Form S-3, filed with the Securities and Exchange Commission on March 10, 2017.
(11) Incorporated by reference to the Company's Definitive Proxy Statement on Form 14-A filed with the Securities and Exchange Commission on February 13, 2017.
(12) Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 26, 2017.
(13) Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 6, 2018.
(14) Incorporated by reference to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 19, 2018.
(15) Incorporated by reference to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 8, 2016.

Item 16. Form 10-K Summary.

None.

SIGNATURES

In accordance with Section 13 or 15(d) of the Exchange Act, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 25, 2019

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

In accordance with the Exchange Act, 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 25, 2019
/s/ Zvi Ben David Zvi Ben David	Chief Financial Officer, Secretary and Treasurer (Principal Financial and Accounting Officer)	March 25, 2019
/s/ Yoav Shaked Yoav Shaked	Chairman of the Board	March 25, 2019
/s/ Yalon Farhi Yalon Farhi	Director	March 25, 2019
/s/ Allen Kamer Allen Kamer	Director	March 25, 2019
/s/ Hila Karah Hila Karah	Director	March 25, 2019
/s/ Dennis M. McGrath Dennis M. McGrath	Director	March 25, 2019
/s/ Glen Moller Glen Moller	Director	March 25, 2019
/s/ Richard B. Stone Richard B. Stone	Director	March 25, 2019

DARIOHEALTH CORP. AND ITS SUBSIDIARY

CONSOLIDATED FINANCIAL STATEMENTS

AS OF DECEMBER 31, 2018

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of DarioHealth Corp.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of DarioHealth Corp. (the "Company") and its subsidiary as of December 31, 2018 and 2017, the related consolidated statements of comprehensive loss, changes in stockholders' equity (deficiency) and cash flows for each of the two years in the period ended December 31, 2018, 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 and its subsidiary at December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1c to the financial statements, the Company has suffered recurring losses from operations and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1c. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

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 and its subsidiary 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.

/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 25, 2019

DARIOHEALTH CORP. AND ITS SUBSIDIARY

CONSOLIDATED BALANCE SHEETS
U.S. dollars in thousands

	December 31,	
	2018	**2017**
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 10,997	$ 3,718
Short-term restricted bank deposits	180	258
Trade receivables	168	282
Inventories	1,377	1,184
Other accounts receivable and prepaid expenses	591	604
Total current assets	13,313	6,046
LEASE DEPOSITS	43	42
PROPERTY AND EQUIPMENT, NET	733	869
Total assets	$ 14,089	$ 6,957

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

DARIOHEALTH CORP. AND ITS SUBSIDIARY

CONSOLIDATED BALANCE SHEETS
U.S. dollars in thousands (except stock and stock data)

	December 31,	
	2018	**2017**
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Trade payables	$ 2,574	$ 1,852
Deferred Revenues	736	-
Other accounts payable and accrued expenses	1,854	1,163
Total current liabilities	5,164	3,015
LIABILITY RELATED TO WARRANTS	-	1
STOCKHOLDERS' EQUITY		
Common Stock of $0.0001 par value - Authorized: 160,000,000 shares at December 31, 2018 and 2017; Issued and Outstanding: 36,607,755 and 14,074,238 shares at December 31, 2018 and 2017, respectively	8	7
Preferred Stock of $0.0001 par value - Authorized: 5,000,000 shares at December 31, 2018 and 2017; Issued and Outstanding: None at December 31, 2018 and 2017	-	-
Additional paid-in capital	98,171	74,892
Accumulated deficit	(89,254)	(70,958)
Total stockholders' equity	8,925	3,941
Total liabilities and stockholders' equity	$ 14,089	$ 6,957

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

DARIOHEALTH CORP. AND ITS SUBSIDIARY

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
U.S. dollars in thousands (except stock and stock data)

	Year ended December 31,	
	2018	**2017**
Revenues	$ 7,394	$ 5,170
Cost of revenues	5,629	3,859
Gross profit	1,765	1,311
Operating expenses:		
Research and development	$ 3,676	$ 3,297
Sales and marketing	10,309	7,707
General and administrative	5,468	4,726
Total operating expenses	19,453	15,730
Operating loss	17,688	14,419
Financial expenses, net:		
Expenses (income) from revaluation of warrants	(1)	1,168
Other financial expense, net	116	156
Total financial expenses, net	115	1,324
Net loss	$ 17,803	$ 15,743
Deemed dividend	493	255
Net loss attributable to holders of Common Stock	$ 18,296	$ 15,998
Net loss per share:		
Basic and diluted loss per share	$ 0.78	$ 1.64
Weighted average number of Common Stock used in computing basic and diluted net loss per share	23,412,891	9,628,256

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

DARIOHEALTH CORP. AND ITS SUBSIDIARY

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIENCY)
U.S. dollars in thousands (except stock and stock data)

	Common Stock		Preferred Stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity (deficiency)
	Number	Amount	Number	Amount			
Balance as of December 31, 2016	5,713,383	$ 6	-	$ -	$ 48,413	$ (54,960)	$ (6,541)
Issuance of Common Stock in January 2017 Private Placement, net of issuance cost	1,113,922	*) -	-	-	2,936	-	2,936
Payment for executives and directors under Stock for Salary Program	271,880	*) -	-	-	707	-	707
Issuance of Common Stock to Employees	474,880	*) -	-	-	1,514	-	1,514
Issuance of Common Stock to consultants and service provider	281,681	*) -	-	-	874	-	874
Issuance of Common Stock in March 2017 Private Placement, net of issuance cost	707,515	*) -	-	-	1,878	-	1,878
Reclassification of warrants from liability to equity on March 8, 2017	-	-	-	-	8,655	-	8,655
Issuance of Common Stock in April 2017 Public offering, net of issuance cost	1,450,000	1	-	-	3,854	-	3,855
Exercise of options	91,855	*) -	-	-	*)-	-	*) -
Issuance of Common Stock in August 2017 Private Placement, net of issuance cost	483,333	*) -	-	-	801	-	801
Issuance of Preferred Stock in August 2017 Private placement, net of issuance cost	-	-	2,307,654	*) -	3,711	-	3,711
Issuance of Common stock in November 2017 warrant exchange agreement	1,039,676	*) -	-	-	-	-	*) -
Conversion of Preferred Stock to Common Stock	2,307,654	*) -	(2,307,654)	*) -	-	-	-
Deemed dividend related to Stock dividend	138,459	*) -	-	-	255	(255)	-
Stock-based compensation	-	-	-	-	1,294	-	1,294
Net loss	-	-	-	-	-	(15,743)	(15,743)
Balance as of December 31, 2017	14,074,238	$ 7	-	$ -	$ 74,892	$ (70,958)	$ 3,941
Payment for executives and directors under Stock for Salary Program	765,695	*) -	-	-	1,055	-	1,055
Issuance of Common Stock to Directors and Employees	1,152,840	*) -	-	-	1,786	-	1,786
Issuance of Common Stock to consultants and service provider	369,993	*) -	-	-	504	-	504
Issuance of Common stock in May 2018 warrant exchange agreement	636,752	*) -	-	-	493	(493)	-
Issuance of Common Stock in 2018 Private Placements, net of issuance cost	9,579,069	1	-	-	9,353	-	9,354
Issuance of Preferred Stock in 2018 Private placement, net of issuance cost	-	-	3,124,337	*) -	9,269	-	9,269
Conversion of Preferred Stock to Common Stock	10,029,188	*) -	(3,124,337)	*) -	-	-	-
Stock-based compensation	-	-	-	-	819	-	819
Net loss	-	-	-	-	-	(17,803)	(17,803)
Balance as of December 31, 2018	36,607,775	$ 8	-	$ -	$ 98,171	$ (89,254)	$ 8,925

*) Represents an amount lower than $1.
The accompanying notes are an integral part of the consolidated financial statements.

DARIOHEALTH CORP. AND ITS SUBSIDIARY

CONSOLIDATED STATEMENT OF CASH FLOWS
U.S. dollars in thousands

	Year ended December 31,	
	2018	**2017**
Cash flows from operating activities:		
Net loss	$ (17,803)	$ (15,743)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Stock-based compensation and Common Stock to service providers	3,758	3,824
Depreciation	207	195
Decrease (increase) in trade receivables	114	(56)
Decrease (increase) in other accounts receivable and prepaid expenses	13	(99)
Increase in inventories	(193)	(295)
Increase in trade payables	722	39
Increase in deferred revenues	736	-
Increase in other accounts payable and accrued expenses	977	334
Change in the fair value of warrants to purchase shares of Common Stock	(1)	1,168
Revaluation of short-term restricted bank deposits	-	(17)
Loss from disposal of fixed assets	-	31
Net cash used in operating activities	(11,470)	(10,619)
Cash flows from investing activities:		
Maturity (investment) in short-term restricted bank deposits	78	(17)
Investment in lease deposit	(1)	(7)
Purchase of property and equipment	(71)	(195)
Net cash provided by (used in) investing activities	6	(219)
Cash flows from financing activities:		
Proceeds from exercise of warrants	-	*)-
Proceeds from issuance of shares and warrants, net of issuance cost	18,743	13,463
Net cash provided by financing activities	18,743	13,463
Increase in cash and cash equivalents	7,279	2,625
Cash and cash equivalents at beginning of year	3,718	1,093
Cash and cash equivalents at end of year	$ 10,997	$ 3,718
Non-cash investing and financing activities:		
Reclassification of warrants from liability to equity	$ -	$ 8,655
Payment for executives and directors under Salary Program	$ 201	$ 183

*) Represents an amount lower than $1.

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

NOTE 1:- GENERAL

a. DarioHealth Corp. (the "Company") was incorporated in Delaware and commenced operations on August 11, 2011. In July 2016, the Company's Board of Directors approved the change of the Company's name to DarioHealth Corp., which became effective on July 28, 2016. The Company is a digital health (mHealth) company that is developing and commercializing a patented and proprietary technology providing consumers with laboratory-testing capabilities using smart phones and other mobile devices. The Company's flagship product, Dario™, also referred to as the Dario™ Smart Diabetes Management Solution, is a mobile, real-time, cloud-based, diabetes management solution based on an innovative, multi-feature software application combined with a stylish, 'all-in-one', pocket-sized, blood glucose monitoring device, which is called the Dario™ Smart Meter.

b. The Company's wholly owned subsidiary, LabStyle Innovation Ltd. ("Ltd." or "Subsidiary"), 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. Ltd. has a wholly-owned subsidiary, LabStyle Innovations US LLC, a Delaware limited liability company ("LabStyle US"), which was established in 2014, however it has not started its operations to date and was dissolved by the end of 2017.

c. During the year ended December 31, 2018, the Company incurred recurring operating losses and negative cash flows from operating activities amounting to $17,803 and $11,470, respectively. The Company will be required to obtain additional liquidity resources in the near term in order to support the commercialization of its products and maintain its research and development activities. The Company is addressing its liquidity needs by seeking additional funding from public and/or private sources and by ramping up its commercial sales. There are no assurances, however, that the Company will be able to obtain an adequate level of financial resources that are required for the short and long-term development and commercialization of its product.

   These conditions raise substantial doubt about the Company's ability to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments to reflect the possible future effects on recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

d. In December 2015, the United States Food and Drug Administration ("FDA") granted the Subsidiary 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.

e. On March 4, 2016, the Company's Common Stock and warrants were approved for listing on the Nasdaq Capital Market under the symbols "DRIO" and "DRIOW," respectively.

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 and 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, and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

b. Financial statements in U.S. dollars ("$", "dollar" or "dollars"):

The accompanying consolidated financial statements have been prepared in dollars.
The Company's financing activities are incurred in U.S. dollars. Although a portion of the Subsidiary's 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 subsidiary 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 Accounting Standard Codification ("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.

d. 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.

e. Short-term restricted bank deposits:

Short-term 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 Company's rent and credit payments. The short-term bank deposits are denominated in NIS and bear interest at an average rate of 0.02% and 0.01% as of December 31, 2018 and 2017, respectively. The short-term bank deposits are presented at their cost, including accrued interest.

U.S. dollars in thousands (expect stock and stock data)

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

f. Inventories:

Inventories are stated at the lower of cost plus allocable indirect costs or net realized value. Cost is determined on a "moving average" basis. Inventory write-down is provided to cover technological obsolescence, excess inventories and discontinued products. Inventory write-down represents the difference between the cost of the inventory and net realizable value. Inventory write-down is 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-offs during the years ended December 31, 2018 and 2017 amounted to $41 and $190, respectively.

g. Long-term lease deposits:

Long-term lease deposits include mainly long-term deposits for the Company's leased vehicles.

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:

Property and equipment (Cont.):

	%
Computers, and peripheral equipment	15-33
Office furniture and equipment	6
Production lines	33
Leasehold improvements	Over the shorter of the lease term or useful economic life

i. Impairment of long-lived assets:

Property and equipment 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.

Through December 31, 2018, no impairment was noted.

j. Revenue recognition:

Revenues from product sales are recognized in accordance with ASC 605-10 "Revenue Recognition", when delivery has occurred, persuasive evidence of an agreement exists, the vendor's fee is fixed or determinable, no further obligation exists and collectability is probable.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

Revenue recognition (Cont.):

The Company derives revenues from the sale of its devices and its related device-specific disposables test strip cartridges and lancets through independent distributors or directly to end users. The Dario software application is offered for a free download and the Company does not obtain a recurring hosting commitment towards the end users relating specifically to the application.

The Company generally has a standard contract with its distributors. According to the agreements, all sales to distributors are final, no rights of return or price protection right is granted to such distributors and the Company is not a party of the agreements between distributors and their customers.

When a sales arrangement contains multiple elements, such as services and products, the Company allocates revenue to each element based on a selling price hierarchy as required according to ASC 605-25, "Multiple-Element Arrangements". The selling price for a deliverable is based on its Vendor Specific Objective Evidence ("VSOE"), if available, third party evidence ("TPE") if VSOE is not available, or estimated selling price ("ESP") if neither VSOE nor TPE is available. The best estimate of selling price is established considering several internal factors including, but not limited to, historical sales, pricing practices and geographies in which the Company offers its products.

Revenues from services are recognized when persuasive evidence of an arrangement exists, delivery of the product has occurred or the services have been rendered, the fee is fixed or determinable and collectability is probable.

k. Cost of revenues:

Cost of revenues is comprised of the cost of production, shipping and handling inventory, personnel and related overhead costs, depreciation of production line and related equipment costs and inventory write-downs.

l. Concentrations of credit risk:

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents, short-term bank deposits and trade receivables.

All of the cash and cash equivalents and short-term bank deposits of the Company and its Subsidiary are invested in deposits and current accounts with major U.S. and Israeli banks. Such cash and cash equivalents and short-term bank deposits may be in excess of insured limits and are not insured in other jurisdictions. Generally, cash and cash equivalents and short-term bank deposits may be redeemed and therefore a minimal credit risk exists with respect to these deposits and investments.

The Company's trade receivables are derived mainly from sales to distributers and to end-users world-wide. 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 had no off-balance-sheet concentration of credit risk such as foreign exchange contracts, option contracts or other foreign hedging arrangements.

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, 2018 and 2017 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, 2018 and 2017, no liability for unrecognized tax benefits was recorded as a result of the implementation of ASC 740.

n. Research and development costs:

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

o. Liability Warrants:

The Company accounts for certain warrants held by investors and the Company's previous placement agent and its permitted designees which include certain net settlement cash features as a liability according to the provisions of ASC 815-40, "Derivatives and Hedging - Contracts in Entity's Own Equity" ("ASC 815"), which provides a new two-step model to be applied in determining whether a financial instrument or an embedded feature is indexed to an issuer's own stock and thus able to qualify to be a derivative financial instrument. The Company measures the warrants at fair value by using Black-Scholes-Merton option-pricing model in each reporting period until they are exercised or expired, with changes in the fair values being recognized in the Company's statement of comprehensive loss as financial income or expense.

p. Accounting for stock-based compensation:

The Company accounts for stock-based compensation in accordance with ASC 718, "Compensation - Stock Compensation" ("ASC 718"), which requires companies to estimate the fair value of equity-based payment awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as an expense over the requisite service periods in the Company's consolidated statement of comprehensive loss.

The Company recognizes compensation expenses for the value of its awards granted based on the straight-line method over the requisite service period of each of the awards, net of estimated forfeitures. ASC 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

The Company estimates the fair value of stock options granted using the Black-Scholes-Merton option-pricing model. The option-pricing model requires a number of assumptions, of which the most significant are the expected stock price volatility and the expected option term. Expected volatility was calculated based upon historical volatility of the Company. The expected option term represents the period that the Company's stock options are expected to be outstanding and is determined based on the simplified method until sufficient historical exercise data will support using expected life assumptions. The risk-free interest rate is based on the yield from U.S. treasury bonds with an equivalent term. The Company has historically not paid dividends and has no foreseeable plans to pay dividends.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

The Company applies ASC 505-50, "Equity-Based Payments to Non-Employees" with respect to options and warrants issued to non-employees.

q. Fair value of financial instruments:

The Company applies ASC 820, "Fair Value Measurements and Disclosures" ("ASC 820"). Under this standard, fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (i.e., the "exit price") in an orderly transaction between market participants at the measurement date.

In determining fair value, the Company uses various valuation approaches. ASC 820 establishes a hierarchy for inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability developed based on market data obtained from sources independent from the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the assumptions market participants would use in pricing the asset or liability developed based on the best information available in the circumstances.

The hierarchy is broken down into three levels based on the inputs as follows:

Level 1 - Valuations based on quoted prices in active markets for identical assets that the Company has the ability to access. Valuation adjustments and block discounts are not applied to Level 1 instruments. Since valuations are based on quoted prices that are readily and regularly available in an active market, valuation of these products does not entail a significant degree of judgment.

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

Level 3 - Valuations based on inputs that are unobservable and significant to the overall fair value measurement.

The availability of observable inputs can vary from investment to investment 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 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. Warrants were classified within Level 3 because they are valued using valuation techniques. Some of the inputs to these models are unobservable in the market and are significant. The Company has no financial assets or liabilities measured using Level 1, Level 2, or Level 3 inputs.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

r. Basic and diluted net loss per share:

Basic net loss per share is computed based on the weighted average number of shares of Common Stock outstanding during each year. Diluted net loss per share is computed based on the weighted average number of shares of Common Stock outstanding during each year, plus dilutive potential Common Stock considered outstanding during the year, in accordance with ASC 260, "Earnings Per Share".

The total number of shares related to the outstanding warrants and options excluded from the calculations of diluted net loss per share due to their anti-dilutive effect was 1,787,801 and 1,434,924 for the year ended December 31, 2018 and 2017, respectively.

s. Severance pay:

Since inception date, all of Ltd.'s employees who are entitled to receive severance pay in accordance with the applicable law in Israel are 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 on their behalf with insurance companies. Payments in accordance with Section 14 release Ltd. from any future severance payments in respect of those employees. Deposits under Section 14 are not recorded as an asset in the Company's balance sheet

t. Legal and other contingencies:

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.

u. Impact of recently issued accounting pronouncements:

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") 2014-09, "Revenue from Contracts with Customers" Topic 606). This ASU provides a five-step approach to account for revenue arising from contracts with customers. The ASU requires an entity to recognize revenue in a way that depicts the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. This revenue standard will be effective for the Company starting the first quarter of 2019. The new revenue standard permits companies to either apply the requirements retrospectively to all prior periods presented or apply the requirements in the year of adoption through a modified retrospective approach with a cumulative adjustment. The Company will adopt the new standard effective January 1, 2019, using the modified retrospective transition method. The Company expects the adoption of this guidance will not have a material impact on its consolidated financial statements.

U.S. dollars in thousands (expect stock and stock data)

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

In February 2016, the FASB issued ASU 2016-02, “Leases” (Topic 842) ("ASC 842"), relating to the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e., lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use (“ROU”) asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less will be accounted for in a manner similar to the accounting under existing guidance for operating leases today. The new standard requires lessors to account for leases using an approach that is substantially equivalent to existing guidance for sales-type leases, direct financing leases and operating leases. ASC 842 supersedes the previous leases standard, ASC 840, "Leases". The guidance is effective for the interim and annual periods beginning on or after December 15, 2018, and the Company has adopted the standard on January 1, 2019. A modified retrospective transition approach is required, applying the new standard to all leases existing at the date of initial application. The standard provides a number of optional practical expedients in transition. The Company is electing the ‘package of practical expedients,’ which permits it not to reassess under the new standard its prior conclusions about lease identification, lease classification and initial direct costs. The Company expects adoption of the standard to have a material impact on its consolidated balance sheets which will result in the recognition of ROU assets and lease liabilities of approximately $850 to $890 at January 1, 2019. The most significant impact from the recognition of ROU assets and lease liabilities relates to its office space. However, the Company does not anticipate that the adoption of this standard will have a material impact on the operating expenses in its consolidated statements of operations since the expense recognition under this new standard will be similar to current practices. The Company's financial income (expenses), net will be impacted by the revaluation of the lease liabilities in non-U.S. dollar denominated currencies.

In June 2018, the FASB issued ASU 2018-07, “Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting.” The updated guidance simplifies the accounting for nonemployee share-based payment transactions. The amendments in the new guidance specify that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor’s own operations by issuing share-based payment awards. For public companies that file with the Securities and Exchange Commission, the standard is effective for financial statements issued for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years. Early adoption is permitted, but no earlier than an entity’s adoption date of Topic 606, “Revenue from Contracts with Customers.” The adoption of this guidance is not expected to have a material impact on the Company’s financial statements.

In November 2016, the FASB issued Accounting Standards Update No. 2016-18, Statement of Cash Flows (Topic 230): Restricted Cash (ASU 2016-18), which requires companies to include amounts generally described as restricted cash and restricted cash equivalents in cash and cash equivalents when reconciling beginning-of-period and end-of-period total amounts shown on the statement of cash flows. This guidance will be effective from the first quarter of 2019 and early adoption is permitted. The Company does not expect that the adoption of this guidance will have a material impact on its consolidated financial statements and related disclosures.

NOTE 3:- OTHER ACCOUNTS RECEIVABLE AND PREPAID EXPENSES

	December 31,	
	2018	**2017**
Prepaid expenses	$ 454	$ 451
Deferred costs	71	-
Government authorities	66	153
	$ 591	$ 604

NOTE 4:- INVENTORIES

	December 31,	
	2018	**2017**
Raw materials	$ 424	$ 323
Finished products	953	861
	$ 1,377	$ 1,184

U.S. dollars in thousands (expect stock and stock data)

NOTE 5:- PROPERTY AND EQUIPMENT, NET

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

	December 31,	
	2018	2017
Cost:		
Computers and peripheral equipment	$ 180	$ 285
Office furniture and equipment	114	106
Production lines	736	814
Leasehold improvement	143	141
	1,173	1,346
Accumulated depreciation:		
Computers and peripheral equipment	97	208
Office furniture and equipment	25	20
Production lines	301	246
Leasehold improvement	17	3
	440	477
Property and equipment, net	$ 733	$ 869

Depreciation expenses for the year ended December 31, 2018 and 2017 amounted to $207 and $195, respectively.

NOTE 6:- OTHER ACCOUNTS PAYABLE AND ACCRUED EXPENSES

	December 31,	
	2018	2017
Employees and payroll accruals	$ 974	$ 735
Accrued expenses	880	428
	$ 1,854	$ 1,163

U.S. dollars in thousands (expect stock and stock data)

NOTE 7:- COMMITMENTS AND CONTINGENT LIABILITIES

a. The facilities and motor vehicles of the Company and its Subsidiary are leased under several operating lease agreements.

Ltd. is party to a lease agreement in Israel for a period of 5 years starting from November 2017, with a renewal option for additional 60 months. In addition, Ltd. is a party to a lease agreement expiring on November 2019.

Commencing November 13, 2011 and through the year ended 2021, Ltd. also entered into several motor vehicle lease agreements for a period of 36 months. As of December 31, 2018, the Company maintains 11 leased cars.

b. As of December 31, 2018, the future minimum aggregate lease commitments under non-cancelable operating lease agreements are as follows:

As of ended December 31,	Facilities	Motor vehicles	Total
2019	215	87	302
2020	215	43	258
2021	215	13	228
2022	197	-	197
	$ 842	$ 143	$ 985

Facility and motor vehicle lease expenses for the year ended December 31, 2018 and 2017 were $351 and $301, respectively.

c. As of December 31, 2018, Ltd. established guarantees to cover rent agreements and credit cards commitments that amounted to $118.

NOTE 8:- TAXES ON INCOME

The Company and Ltd. are separately taxed under the domestic tax laws of the state of incorporation of each entity

a. 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 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 8:- TAXES ON INCOME (Cont.)

Accounting for the TCJA
In March 2018, the FASB issued ASU 2018-05, "Income Taxes Topic (740): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 118" ("ASU 2018-05"), to address the application of GAAP in situations when a registrant does not have the necessary information available, prepared or analyzed (including computations), in reasonable detail, to complete the accounting for certain income tax effects of the TCJA.

The Company completed the accounting treatment related to the tax effects of the TCJA. As a result:

- The Company recognizes its accounting for changes in the U.S. federal rate and deferred tax impact for the rate change to be complete.

- The Company's analysis for the Deemed Repatriation Transition Tax has been filed with its December 31, 2017 tax return and the Company considered its accounting relating to the TCJA to be complete as of such date and did not make any measurement-period adjustments related to it.

- The Company accounted for the tax impact related to other areas of the TCJA and believes its analysis to be completed and consistent with the guidance in ASU 2018-05. In particular, the Company concluded that for 2018, it should not be subject to any tax on account of GILTI or base erosion and anti-abuse payments made by U.S. corporations to foreign related parties.

The Company recognizes that the Internal Revenue Service, the FASB and the Securities and Exchange Commission are continuing to publish and finalize ongoing guidance with respect to the TCJA which may modify accounting interpretation for the TCJA, the Company will account for these impacts in the period in which any changes are enacted.

b. Tax rates applicable to Ltd.:

Corporate tax rate in Israel in 2017 was 24% and 2018 was 23%.

In December 2016, the Israeli Parliament approved the Economic Efficiency Law (Legislative Amendments for Applying the Economic Policy for the 2017 and 2018 Budget Years), 2016 which reduces the corporate income tax rate to 24% (instead of 25%) effective from January 1, 2017 and to 23% effective from January 1, 2018.

U.S. dollars in thousands (expect stock and stock data)

NOTE 8:- TAXES ON INCOME (Cont.)

c. Net operating loss carryforward:

Ltd. has accumulated net operating losses for Israeli income tax purposes as of December 31, 2018 in the amount of approximately $47,233. The net operating losses may be carried forward and offset against taxable income in the future for an indefinite period.

As of December 31, 2018, the Company had a U.S. federal net operating loss carryforward of approximately $7,120 that can be carried forward and offset against taxable income and that expires during the years 2031 to 2037. Utilization of 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.

The TCJA also modified the rules regarding utilization of net operating losses ("NOL") and NOLs 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, the Company generated an additional $1,965 of NOLs which are not subject to the annual limitation described above. 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 we have a change of ownership, utilization of the carryforwards could be restricted.

d. 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,	
	2018	**2017**
Deferred tax assets:		
Net operating loss carry forward	$ 10,294	$ 10,794
Temporary differences	791	620
Deferred tax assets before valuation allowance	11,085	11,414
Valuation allowance	(11,085)	(11,414)
Net deferred tax asset	$ -	$ -

The deferred tax balances included in the consolidated financial statements as of December 31, 2018 are calculated according to the tax rates that were in effect as of the reporting date and do take into account the potential effects of the reduction in the tax rate.

U.S. dollars in thousands (expect stock and stock data)

NOTE 8:- TAXES ON INCOME (Cont.)

The net change in the total valuation allowance for the year ended December 31, 2018 was a decrease of $329 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 fully offset all the deferred tax assets.

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

	Year ended December 31,	
	2018	**2017**
Domestic	$ 3,801	$ 5,144
Foreign	14,002	10,599
	$ 17,803	$ 15,743

f. 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.

NOTE 9:- 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 in 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.

   During the year ended December 31, 2018 and 2017, the Company issued 765,695 and 271,880, respectively, Compensation Shares to certain members of the Board of Directors, officers and employees as consideration for a waiver of cash owed to such individuals amounting to $1,055 and $707, respectively.

c. On March 8, 2016, the Company closed a public offering (the "Public Offering") of 1,333,333 shares of the Common Stock, at a purchase price of $4.50 per share, and 1,333,333 immediately exercisable five-year warrants (the "March 2016 Warrants") each to purchase one share of Common Stock with an exercise price of $4.50 per share, at a purchase price of $0.01 per Warrant for a consideration of $5,038, net of issuance costs. Out of the above issuance, 111,112 shares of Common Stock were issued to the Chief Financial Officer of the Company for gross proceeds of $500.

   The March 2016 Warrants are exercisable for cash or on a cashless basis if no registration statement covering the resale of the shares issuable upon exercise of the Warrants is available. The March 2016 Warrant included an exercise price adjustment feature for a twelve months period from the issuance date that will adjust the warrant exercise price in case the Company will issue securities in a price lower than $4.50 per share and therefore accounted as a liability according to the provision of ASC 815-40 "Contracts in entity's own equity". Following the January 2017 private placement, the exercise price of the warrant was adjusted to $4.34 per share.

   On March 3, 2016, concurrent with the Public Offering, the Company entered into securities purchase agreements (the "Securities Purchase Agreements") with certain existing shareholders (the "Investors") with respect to the sale in a private placement (the "Private Offering") of 555,555 of the Company's units (the "Units"). The purchase price per Unit was $4.50 and the total consideration amounted to $2,500, net of issuance costs. Each Unit sold in the Private Offering is comprised of (i) one share of Common Stock, and (ii) one warrant to purchase 1.2 shares of Common Stock (the "2016 Series A Warrant") which is immediately exercisable at an exercise price of $4.50 per share of Common Stock and expires 5 years from the date of issuance. In total, in the Private Offering, the Company issued 555,555 shares of Common Stock and 2016 Series A Warrants exercisable for an aggregate of 666,666 shares of Common Stock. The 2016 Series A Warrants are exercisable for cash or on a cashless basis if no registration statement covering the resale of the shares issuable upon exercise of the 2016 Series A Warrants is available. The 2016 Series A Warrant included an exercise price adjustment feature for a twelve months period from the issuance date that will adjust the warrant exercise price in case the Company will issue securities in a price lower than $4.50 per share and therefore accounted as a liability according to the provision of ASC 815-40 "Contracts in entity's own equity". Following the January 2017 private placement, the exercise price of the warrant was adjusted to $4.34 per share.

   On March 8, 2017, the March 2016 Warrant and 2016 Series A Warrant exercise price adjustment feature expired. The Company re-measured the warrant liability on March 8, 2017 and recorded financial expense from revaluation of the warrant in an amount of $1,066 and an amount of $7,644 was classified from liability to equity.

NOTE 9:- STOCKHOLDERS' EQUITY (Cont.)

d. On August 10, 2016, the Company entered into an agreement (the "Agreement") with Dicilyon Consulting and Investment Ltd., an existing stockholder (the "Stockholder"), and David Edery, who previously purchased certain securities from the Company, which were granted certain registration right which required, among other things, the continued effectiveness of certain registration statements. In consideration of the Stockholder waiving its registration right with respect to the previously purchased securities, the Company agreed to issue to the Stockholder a warrant, or the Warrant, to purchase 300,000 shares of Common Stock at an exercise price of $4.50 per share exercisable for a period of 4.5 years from the date of the Agreement. In addition, the Company also agreed to register the shares of Common Stock underlying the Warrant. The Warrant is exercisable for cash or on a cashless basis if a registration statement covering the shares issuable upon exercise of the Warrants is unavailable. The Warrant included an exercise price adjustment feature for a seven months period from the issuance date that will adjust the warrant exercise price in case the Company will issue securities in a price lower than $4.50 per share and therefore accounted as a liability according to the provision of ASC 815-40 "Contracts in entity's own equity". As a result of the Agreement the Company recorded registration right waiver in the amount of $702 as financial expense, net in 2016. Following the January 2017 private placement, the exercise price of the warrant was adjusted to $4.34 per share.

On March 8, 2017, the Warrant exercise price adjustment feature expired. The Company re-measured the warrant liability on March 8, 2017 and recorded financial expense from revaluation of the warrant in an amount of $141 and an amount of $1,011 was classified from liability to equity.

e. On January 9, 2017, the Company commenced a private placement offering of up to $5,100 consisting of up to 1,821,437 shares of the Company's Common Stock and warrants to purchase up to 1,821,437 shares of Common Stock. The warrants are exercisable after the six-month anniversary of each respective closing and will expire on the 5-year anniversary of their issuance. On January 9, 2017, the Company held the initial closing of the offering with a lead investor and an additional investor and issued 1,113,922 shares of Common Stock and warrants to purchase 1,113,922 shares of Common Stock for aggregate gross proceeds of approximately $3,119 ($2,936 net of issuance expenses). On January 11, 2017, the Company entered into securities purchase agreements with certain investors for the future issuance and sale of 707,515 shares of Common Stock and warrants to purchase 707,515 shares of Common Stock, provided that the issuance and sale of such securities shall only occur upon obtaining stockholder approval, pursuant to Nasdaq rules. The Company's stockholders approved the issuance and sale of the securities on March 9, 2017 and the closing of the private placement offering, with aggregate gross proceeds of $1,981 ($1,878 net of issuance expenses), occurred on March 9, 2017.

f. During 2017, the Company's Compensation Committee of the Board of Directors approved the grants of 756,561 shares of Common Stock to officers, employees, service providers and consultants of the Company. 110,987 of these shares were issued to service provider in lieu of $298 owed in cash to them. The shares were issued under the 2012 Plan.

g. On April 5, 2017, the Company closed a public offering (the "2017 Public Offering") of 1,450,000 shares of Common Stock, at a purchase price of $3.10 per share, for an aggregate consideration of $3,855, net of issuance costs. The shares were offered, issued and sold pursuant to a shelf registration statement filed with the Securities and Exchange Commission. In connection with the 2017 Public Offering, the Company agreed to issue to the representative of the underwriters' five-year warrants to purchase up to 36,250 shares of Common Stock at an exercise price equal to $3.875 per share of Common Stock for cash or on a cashless basis if no registration statement covering the resale of the shares issuable upon exercise of the warrants is available.

h. On August 22, 2017, the Company closed two concurrent private placements offerings consisting of 483,333 shares of the Company's Common Stock, and 2,307,654 shares of the Company's Series B Convertible Preferred Stock (the "Series B Preferred Stock"), for aggregate gross proceeds of approximately $5,024 ($4,793 net of issuance expenses). The shares of Series B Preferred Stock were convertible into an aggregate of 2,307,654 shares of Common Stock based on a conversion price of $1.80 per share. Such conversion price was not subject to any future price-based anti-dilution adjustments except for standard anti-dilution protection. The shares of Series B Preferred Stock were not redeemable nor contingently redeemable. The holders of the Series B Preferred Stock were not entitled to convert such preferred stock into shares of the Company's Common Stock until the Company obtained stockholder approval for such issuance and upon obtaining such stockholder approval automatically converted into shares of Common Stock. In addition, the holders of the Series B Preferred Stock were entitled to a 6% fixed dividend, payable in shares of Common Stock, to be payable upon the automatic conversion of the Series B Preferred Stock. The holders of the Series B Preferred Stock did not possess any voting rights but the Series B Preferred Stock did carry a liquidation preference for each holder equal to the investment made by such holder in the Offering. In addition, the holders of Series B Preferred Stock were eligible to participate in dividends and other distributions by the Company on an as converted basis.

NOTE 9:- STOCKHOLDERS' EQUITY (Cont.)

Following the receipt of stockholders approval in December 2017, all the Series B Preferred Stock were converted into 2,307,654 shares of Common Stock and the holders of the Series B Preferred Stock were granted a 6% fixed dividend of 138,459 shares of Common Stock. The Company accounted for the 6% fixed dividend as a deemed dividend in a total amount of $255.

i. In November 2017, the Company entered into an exchange agreement (the "Exchange Agreement") with certain Company warrant holders who were granted warrants to purchase shares of Common Stock on August 10, 2016 and January 2017 private placement. Pursuant to the terms of the Exchange Agreement, the warrant holders agreed to surrender and cancellation of their warrants to purchase an aggregate of 1,871,436 shares of Common Stock and received, as consideration for such cancellation, an aggregate of 1,039,676 shares of Common Stock, creating no benefit to the warrant holders.

j. During 2018, the Company's Compensation Committee of the Board of Directors approved the grants of an aggregate of 369,993 shares of Common Stock in lieu of $504 owed to service providers and the grant of an option to purchase 201,818 shares of Common Stock in lieu of $298 owed to a service provider of the Company. 84,499 shares and the options were issued under the 2012 Plan.

k. On February 28, 2018 and March 6, 2018, the Company closed two concurrent private placements offerings consisting of 2,262,269 shares of the Company's Common Stock at $1.40 per share, 1,234,080 shares of the Company's Series C Convertible Preferred Stock (the "Series C Preferred Stock"), for aggregate gross proceeds of approximately $6,623 ($6,034 net of issuance expenses) at $2.80 per share, and warrants to purchase up to 3,784,351 shares of Common Stock. The shares of Series C Preferred Stock were convertible into an aggregate of 2,468,160 shares of Common Stock based on a conversion price of $1.40 per share. Such conversion price was not subject to any future price-based anti-dilution adjustments except for standard anti-dilution protection. The shares of Series C Preferred Stock were not redeemable nor contingently redeemable. The holders of the Series C Preferred Stock were not be entitled to convert such preferred stock into shares of the Company's Common Stock until the Company obtained stockholder approval for such issuance and upon obtaining such stockholder approval, automatically converted into shares of Common Stock. The holders of the Series C Preferred Stock did not possess any voting rights, but the Series C Preferred Stock did carry a liquidation preference for each holder equal to the investment made by such holder in the Offering. In addition, the holders of Series C Preferred Stock were eligible to participate in dividends and other distributions by the Company on an as converted basis. The warrants issued in the concurrent private placements are exercisable after the six-month anniversary of each respective closing and will expire on the 18-month anniversary of their issuance. Following the receipt of stockholder approval in May 2018, the shares of Series C Preferred Stock were converted into shares of Common Stock.

In conjunction with these offerings the Company issued 32,250 shares of Common Stock to certain finders. The shares were issued under the 2012 Plan.

l. In May 2018, the Company entered into exchange agreements (each an "Exchange Agreement") with certain Company warrant holders who were granted warrants to purchase shares of Common Stock in March 2016 and January 2017. Pursuant to the terms of the Exchange Agreements, the warrant holders agreed to surrender their warrants to purchase an aggregate of 1,020,357 shares of Common Stock for cancellation and received, as consideration for such cancellation, an aggregate of 636,752 restricted shares of Common Stock creating a benefit to the warrant holders. As such the Company recorded a deemed dividend in the amount of $493.

NOTE 9:- STOCKHOLDERS' EQUITY (Cont.)

m. In June and July 2018, the Company's Compensation Committee of the Board of Directors approved the grant of an aggregate of 1,152,840 shares to directors, officers, employees and consultants of the Company, and the grant of 244,000 and 21,000 options to employees and consultants of the Company, respectively, at an exercise price of $1.729 per share. The stock options vest over a period of three years commencing on the respective grant dates. All of the aforementioned options have a six-year terms. All shares and options were issued under the 2012 Plan.

n. On September 13, 2018 and September 26, 2018, the Company closed concurrent private placements offerings consisting of 4,266,800 shares of the Company's Common Stock at $0.90 per share, 1,890,257 shares of the Company's Series D Convertible Preferred Stock (the "Series D Preferred Stock") at $3.60 per share, and warrants to purchase up to 9,462,272 shares of Common Stock, for aggregate gross proceeds of approximately $10,645 ($9,686 net of issuance expenses). The shares of Series D Preferred Stock were convertible into an aggregate of 7,561,028 shares of Common Stock based on a conversion price of $0.90 per share. Such conversion price was not subject to any future price-based anti-dilution adjustments except for standard anti-dilution protection. The shares of Series D Preferred Stock were not redeemable nor contingently redeemable. The holders of the Series D Preferred Stock were not be entitled to convert such preferred stock into shares of the Company's Common Stock until the Company obtained stockholder approval for such issuance and upon obtaining such stockholder approval, automatically converted into shares of Common Stock. The holders of the Series D Preferred Stock did not possess any voting rights, but the Series D Preferred Stock did carry a liquidation preference for each holder equal to the investment made by such holder in the Offering. In addition, the holders of Series D Preferred Stock were eligible to participate in dividends and other distributions by the Company on an as converted basis. The warrants issued in the concurrent private placements are exercisable after the six-month anniversary of each respective closing and will expire on the 36-month anniversary of their issuance. Following receipt of stockholder approval in November 2018, the shares of Series D Preferred Stock were converted into shares of Common Stock.

In conjunction with these offerings the Company issued 83,333 shares of Common Stock to certain finders.

o. On December 13, 2018, and December 27, 2018, the Company closed a private placement offering consisting of 3,050,000 shares of the Company's Common Stock at $1.00 per share and warrants to purchase up to 3,050,000 shares of Common Stock, for aggregate gross proceeds of approximately $3,050 ($3,023 net of issuance expenses). The warrants issued in the private placement are exercisable after the six-month anniversary of each respective closing and will expire on the 36-month anniversary of their issuance.

U.S. dollars in thousands (expect stock and stock data)

NOTE 9:- STOCKHOLDERS' EQUITY (Cont.)

p. The table below summarizes the outstanding warrants as of December 31, 2018:

	Warrants outstanding as of December 31, 2018	Exercise price $	Expiration date
February 2015 PPM A (*)	4,630	4.32	November 25,2015
March 2016 PPM -Warrants	1,528,333	4.34	March 8, 2021
March 2016 Public Offering - Representative's Warrants	143,333	5.625	March 8, 2021
March 2017 Public Offering - Representative's Warrants	36,250	3.875	March 31, 2022
February 2018 PPM	2,811,450	1.80	August 28, 2019
March 2018 PPM	972,901	1.80	September 6, 2019
March 2018 PPM (Finder Warrants)	18,920	1.80	September 6, 2019
September 2018 PPM	9,195,604	1.25	September 13, 2021
September 2018 PPM (Finder Warrants)	140,556	1.25	September 13, 2021
September 2018 PPM 2nd closing	266,668	1.25	September 26, 2021
December 2018 PPM	3,000,000	1.25	December 14, 2021
December 2018 PPM – 2nd closing	50,000	1.25	December 27, 2021
Total outstanding	18,168,645		

(*) Warrants for which cash has been received by the Company but no securities issued.

No warrants were exercised in 2018 and 2017.

q. Stock-based compensation:

On January 23, 2012, an equity incentive plan (the "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.

During 2017, the Company stockholders approved an amendment to the 2012 Plan to increase the number of shares authorized for issuance under the 2012 Plan by 2,000,000 shares, from 1,873,000 to 3,873,000.

During 2018, 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 5,000,000 shares, from 3,873,000 to 7,873,000.

NOTE 9:- STOCKHOLDERS' EQUITY (Cont.)

The following options were issued under the 2012 Plan during 2018 and 2017:

On January 30, 2017, the Company's Compensation Committee of the Board of Directors approved the grant of 313,721 options to directors, officers and employees of the Company, at an exercise price of $3.202 per share. The options shall vest over a period of three years commencing on the grant date. All the options have a six-year term.

On February 6, 2017, the Company's Compensation Committee of the Board of Directors approved the grants of 174,000, and 55,050 options to employees and consultants of the Company, respectively, at exercise prices of between $0.0001 and $4.121 per share. The options shall vest over a period of three years commencing on the grant date. All the options have a six-year term. 34,050 of the option to consultants were granted instead of cash owed for services provided during the period from July through December 2016.

On June 26, 2017, the Company's Compensation Committee of the Board of Directors approved the grants of 69,000 and 194,142 options to employees and consultants of the Company, respectively, at exercise prices of between $0.0001 and $2.46 per share. The options shall vest over a period of up to three years commencing on the grant date. 8,142 of the options issued to a consultant were in lieu of a cash waiver of $30 by the consultant.

On September 14, 2017, the Company's Compensation Committee of the Board of Directors approved the grants of 40,000 options a consultant of the Company, at an exercise price of $2.50 per share. The option is fully vested on the grant date, and the option has a five-year term.

On December 14, 2017, the Company's Compensation Committee of the Board of Directors approved the grants of 40,424 options to a consultant of the Company, at an exercise price of $0.0001 per share. The option is fully vested on the grant date and has a six-year term This option was issued in lieu of a cash waiver of $95 by the consultant.

On April 23, 2018, the Company's Compensation Committee of the Board of Directors approved the grants of 93,755 options to a consultant of the Company, at an exercise price of $0.0001 per share. The option is fully vested on the grant date and has a six-year term. This option was issued in lieu of a cash waiver of $150 by the consultant.

On July 23, 2018, the Company's Compensation Committee of the Board of Directors approved the grants of 70,812 options to consultants of the Company, at an exercise price of $0.0001 per share. 62,812 options are fully vested on the grant date, and 8,000 will vest in 12 equal monthly installments. The options have a six-year term. These options were issued in lieu of a cash waiver of $102 by the consultants.

In June and July 2018, the Company's Compensation Committee of the Board of Directors approved the grant of an aggregate of 1,152,840 shares to directors, officers, employees and consultants of the Company, and the grant of 244,000 and 21,000 options to employees and consultants of the Company, respectively, at an exercise price of $1.729 per share. The stock options shall vest over a period of three years commencing on the respective grant dates. All of the aforementioned options have a six-year terms.

U.S. dollars in thousands (expect stock and stock data)

NOTE 9:- STOCKHOLDERS' EQUITY (Cont.)

On November 22, 2018, the Company's Compensation Committee of the Board of Directors approved the grants of 120,000 options to its President and Chief Commercial Officer, at exercise prices of $0.795 per share. The options will vest over a three years period from the grant date and have a six-year term.

On November 22, 2018, the Company's Compensation Committee of the Board of Directors approved the grants of 37,251 options to consultants of the Company, at an exercise price of $0.0001 per share. The options are fully vested on the grant date and have a six-year term. These options were issued in lieu of a cash waiver of $45 by the consultants. In addition, the Company's Compensation Committee of the Board of Directors approved the grants of 26,250 options to a consultant of the Company at an exercise price of $0.998 per share. The options will vest over a three years period from the grant date and have a six-year term.

On December 10, 2018, the Company's Compensation Committee of the Board of Directors approved the grants of an aggregate of 47,000 options to employees of the Company, at an exercise price of $0.927 per share. The stock options will vest over a three years period commencing on the grant date and have a six-year term.

Transactions related to the grant of options to employees, directors and non-employees under the above plans during the year ended December 31, 2018 were as follows:

	Number of options	Weighted average exercise price	Weighted average remaining contractual life	Aggregate Intrinsic value
		$	Years	$
Options outstanding at beginning of year	1,378,160	7.39	4.75	437
Options granted	660,068	0.94		
Options exercised	-	-		
Options forfeited	60,981	6.08		
Options expired	189,446	2.38		
Options outstanding at end of year	1,787,801	5.59	4.32	368
Options vested and expected to vest at end of year	1,640,510	5.61	4.32	367
Exercisable at end of year	1,261,914	7.11	3.98	364

Weighted average fair value of options granted during the year ended December 31, 2018 and 2017 is $0.56 and $2.07, respectively.

The aggregate intrinsic value in the table above represents the total intrinsic value (the difference between the Company's closing stock price on the last day of fiscal 2018 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, 2018. This amount is impacted by the changes in the fair market value of the Common Stock.

U.S. dollars in thousands (expect stock and stock data)

NOTE 9:- STOCKHOLDERS' EQUITY (Cont.)

The following table presents the assumptions used to estimate the fair values of the options granted to employees and directors in the period presented:

	Year ended December 31,	
	2018	**2017**
Volatility	83.41%-105.38%	103.52%-154.75%
Risk-free interest rate	2.69%-2.88%	1.54%-1.83%
Dividend yield	0%	0%
Expected life (years)	3.5-4.5	3.5-4.5

The following table presents the assumptions used to estimate the fair values of the options granted to non-employees in the period presented:

	Year ended December 31,	
	2018	**2017**
Volatility	82.61%-107.42%	100.65%-150.84%
Risk-free interest rate	2.41%-2.96%	1.78%-2.05%
Dividend yield	0%	0%
Expected life (years)	2.96-5.94	3.67-6

As of December 31, 2018, the total unrecognized estimated compensation cost related to non-vested stock options granted prior to that date was $572, which is expected to be recognized over a weighted average period of approximately 1.14 year.

The total compensation cost related to all of the Company's equity-based awards, recognized during year ended December 31, 2018 and 2017 were comprised as follows:

	Year ended December 31,	
	2018	**2017**
Cost of revenues	$ 116	$ 138
Research and development	404	316
Sales and marketing	607	581
General and administrative	2,631	2,789
Total stock-based compensation expenses	$ 3,758	$ 3,824

U.S. dollars in thousands (expect stock and stock data)

NOTE 10:- LIABILITY RELATED TO WARRANTS

a. On September 23, 2014, the Company consummated a private placement (the "September 2014 Private Placement").

b. The warrants issued in the September 2014 Private Placement contain a net settlement cash feature and liquidated damages penalties and therefore the Company accounts for such warrants as a liability according to the provisions of ASC 815-40 "Contracts in entity's own equity," and re-measures such liability using the Binomial option-pricing model as described below.

c. In estimating the investors' warrants in September 2014 Private Placement fair value, the Company used the following assumptions as of December 31, 2017: risk-free interest rates of 1.65%, volatility of 81.44%, dividend yields of 0% and a contractual life of 0.73 years. Fair value per warrant $0.01.

(1) Risk-free interest rate - based on yield rates of non-index linked U.S. Federal Reserve treasury bonds.

(2) Expected volatility - was calculated based on actual historical stock price movements of the Company over a term that is equivalent to the expected term of the option.

(3) Expected life - the expected life was based on the expiration date of the warrants.

(4) Expected dividend yield - was based on the fact that the Company has not paid dividends to its shareholders in the past and does not expect to pay dividends to its shareholders in the future.

The changes in Level 3 liabilities associated with the September 2014 Private Placement warrants is measured at fair value on a recurring basis. The following tabular presentation reflects the components of the liability associated with such warrants as of December 31, 2018:

	Fair value of liability related to warrants
Balance at December 31, 2017	$ 1
Change in fair value of warrants during the period	(1)
Balance at December 31, 2018	$ -

In September 2018, September 2014 Private Placement warrants expired with no exercise.

NOTE 11:- SELECTED STATEMENTS OF OPERATIONS DATA

Financial expenses (income), net:

	Year ended December 31,	
	2018	2017
Bank charges	$ 18	$ 171
Foreign currency adjustments losses (gain)	98	(15)
Change in the fair value of warrants	(1)	1,168
Total Financial income, net	$ 115	$ 1,324

NOTE 12:- SUBSEQUENT EVENTS

In January 2019, 213,402 Compensation Shares were issued to certain members of the Board of Directors, Officers and employees of the Company as consideration for a reduction in or waiver of cash salary or fees amounting to $213 owed to such individuals. The shares were issued under the 2012 Plan.

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Exhibit 21.1

Subsidiaries of the Registrant

Labstyle Innovation Ltd., an Israeli company (“Labstyle Israel”)

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statements on Form S-8 (File No. 333-225176 and 333-228654) and the Registration Statements on Form S-3 (File No. 333-224458, 333-228201, 333-221025, 333-216607, 333-212644, 333-211396, 333-214849 and 333-229259) of DarioHealth Corp. ("the Company"), of our report dated March 25, 2019 with respect to the consolidated financial statements of the Company and its subsidiaries included in this Annual Report on Form 10-K for the year ended December 31, 2018.

Tel-Aviv, Israel
March 25, 2019

/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 25, 2019

/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 25, 2019

/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, 2018 (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 25, 2019

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

Date: March 25, 2019

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