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, 2016

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

For the transition period from _____to_____

Commission File No. 333-186054

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)

9 Halamish Street
Caesarea Industrial Park
3088900, Israel
(Address of principal executive offices)

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

Securities Registered Pursuant to Section 12(b) of the Act:
Common Stock, par value $0.0001 per share
Warrants to purchase Common Stock

Securities Registered Pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No 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 and posted on it corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter time that the registrant was required to submit and post such files). Yes þ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K 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, or a smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company| in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☐ (Do not check if a smaller reporting company)	Smaller reporting company	þ

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 $22,396,346.

As of March 21, 2017, the registrant had outstanding 7,976,521 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 include 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™ diabetes management solution;
- 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 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.

PART I

Item 1. Business

Overview

We are 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. 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. 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 combined with a stylish, 'all-in-one', pocket-sized, blood glucose monitoring device, which we call the Dario™ Smart Meter.

The Dario™ Smart Diabetes Management Solution is targeted at the mHealth app market currently estimated at $10 billion globally with expected annual growth of 15% to $31 billion by 2020 according to Research2Guidance. In addition, we are also focusing on the global diabetes care devices market for diabetic blood glucose self-monitoring, known as BGMS, that is expected to reach approximately $24.6 billion by 2020 according to researchandmarkets.com. Diabetes is a disease where insufficient levels, or a total absence, of the hormone insulin 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 by allowing patients to properly monitor the disease, provide actionable insights in real-time and create an online link to healthcare providers, this will ultimately improve patient outcomes and reduce healthcare costs - both critical advantages for the diabetes industry.

Dario™ is a comprehensive, digital diabetes management solution utilizing our patented and proprietary technology delivered through a cutting edge software application (commonly known as an "app") available for iPhone or Android and cloud-based data services with a novel BGMS device (the Dario™ Smart Meter) that connect via a device's audio jack consisting of a lancet (to obtain a blood sample), a device-specific disposable test strip cartridge and a smart mobile device-driven glucose reader adaptor. Roughly the size of a pack of gum, we believe that the Dario™ Smart Meter has the potential to replace standalone glucose meters and their kits (lancing, lancets and strips vials) which are the current market standard, most of which have the necessary testing components separated from one another in what we believe is a cumbersome design. Moreover, all but a few glucose meters lack an interface with a smart mobile device, and none presently have the software features associated with Dario™, each of which we believe will distinguish Dario™ as an alternative in the marketplace.

Beyond the benefits of individual diabetes management, we envision the Dario™ application becoming the centerpiece in a new era of interconnected devices and services, providing healthier and better lives for diabetic patients worldwide. With every single measurement captured and stored on a secure cloud data base, DarioHealth's software driven, comprehensive data-management technology has the potential to deliver actionable insight and analytical tools to manage individual patients or large populations, as well as provide a complete and comprehensive "big data" solution for healthcare providers and payers.

Beyond blood glucose testing, DarioHealth's 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 Dario™); 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 headphone jack, 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 monitor draws power from and transmits data to a smart phone via the audio jack port and 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. We believe these represent critical intellectual property recognition and a significant initial validation of our intellectual property efforts.

On September 23, 2013, we announced our receipt of CE Mark certification to market Dario™. The receipt of the CE Mark (which incorporated positive data from clinical user performance studies undertaken in Israel) allows Dario™ to be marketed and sold in 32 countries across Europe as well as in certain other countries worldwide. On March 5, 2014, the Medical Device Safety Service, or MDSS, our European Authorized Representative, completed the registration of the Dario™ Smart Meter with the German Authority as required by Article 10 of Directive 98/79/EC on in vitro diagnostic medical devices.

On December 22, 2015, we announced that the United States Food and Drug Administration (FDA) has granted 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. The receipt of FDA clearance allows Dario™ to be marketed and sold in the United States and was a significant milestone towards marketing and commercialization of Dario in the United States in the first quarter of 2016.

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™ Smart Meter. We are actively pursuing reimbursement coverage in other jurisdictions.

In July 2014, we received approval from Israel's Ministry of Health to sell the Dario™ Smart Meter for diabetes in Israel and also released the Dario™ Diabetes Management App for Android smartphone users. The Android mobile application has the same user interface and features as the iOS Dario™.

In December 2014, we received Therapeutic Goods Administration, or TGA, certification to market the Dario™ in Australia. We were also granted reimbursement status for the Dario™ test strips in Australia by the NDSS.

In December 2014, we entered into an agreement with Israel's leading Health Maintenance Organization (healthcare HMO), Maccabi Healthcare, or MOMA, to implement a comprehensive Dario™ digital suite for patients and professionals. The agreement with MOMA (Maccabi TeleCare unit) represents an additional revenue stream channel for Dario™. We believe this revenue channel demonstrates the significant potential available in software-based services and value added 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 and aims to improve overall outcomes for patients leveraging mHealth technology for effective engagement of health care professionals.

In February 2015, we obtained National Pharmaceutical Product Interface (known as NAPPI) approval and have registered Dario™ for sale in South Africa.

In March 2015, we started marketing the Dario™ Smart Diabetes Management Solution in the Netherlands and New Zealand as a private, out of pocket offering (no reimbursement).

In May 2015, we received Health Canada approval to market and sell Dario™ in Canada and we commenced sales in Canada in June 2015. The majority of Canadian medical plans are currently providing reimbursement coverage for Dario™.

The Dario™ Smart Diabetes Management Solution has fully launched and begun penetrating the above mentioned markets with additional launch and market penetration plans for Germany and India. In 2017, we plan to consistently add additional features and functionality in order to make Dario™ Smart Diabetes Management Solution the new standard of care in diabetes data management. For example, we have recently completed the development of a version of the Dario™ Smart Meter that connects to an iPhone 7 through the lightning jack instead of the missing audio jack. We plan to start marketing our new meter product in the coming months after completing the clearance process with the relevant regulatory authorities like the FDA and obtaining a CE mark.

We commenced a commercial launch of the free Dario™ application in the United Kingdom in late 2013 and commenced an initial soft launch of the full Dario™ solution (including the app and the Smart Meter) 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. We are consistently adding additional features and functionality in making Dario™ Smart Diabetes Management Solution the new standard of care in diabetes data management.

In the United States we commenced commercialization in March 2016 and intend to continue to generate demand through a digital direct to consumer marketing campaign. Customers are currently able to purchase the product 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 Dario™ and to complement the Company's 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. Additional third party distribution channels are expected to be established through 2017, although there is no guarantee we will be successful. We also intend to continue to broaden our reach via distribution agreements with national and regional durable medical equipment and pharmacy chains.

In Europe, we plan to start our direct to consumer marketing efforts in 2017.

Although we are initially targeting only the large and growing 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 Initial Product - Dario™

We believe that the diabetic disease management market presents the most attractive initial application for our proprietary technology as there are millions of potential diabetic users of a smart mobile device-enabled glucose monitoring technology. As such, our first product, which we also refer to as the Dario™ Smart Diabetes Management Solution, will seek to revolutionize the way diabetic patients around the world manage their disease and connect with healthcare providers and others, making the Dario™ solution user-centric, engaging and accessible to all.

The full Dario™ diabetes management solution consists of a robust, real-time, cloud-based software application combined with the Dario™ Smart Meter. Roughly the size of a pack of gum, the Dario™ Smart Meter is an all-in-one device that includes the glucose reader which is connected to a smart mobile device via the device audio jack, along with a lancing device (a reusable blood-sampling device, when loaded with a disposable lancet) and an integrated, disposable cartridge for test strips. Beyond the benefits of individual diabetes management, we envision the Dario™ application becoming the centerpiece in a new era of interconnected devices and services, providing healthier and better lives for diabetic patients worldwide. With every single measurement captured and stored on a secure cloud data base, DarioHealth's software driven, comprehensive data-management technology has the potential to deliver actionable insight and analytical tools to manage individual patients or large populations, as well as provide a complete and comprehensive "big data" solution for healthcare providers and payers.

Our revenues are derived from sales of Dario™'s components, including the Smart Meter itself, and principally from the recurring sale of our disposable cartridges with 25 test strips and other consumables. Our customers receive access to our smart mobile device application, which incorporate tools to help diabetic patients manage their disease. Importantly, our revenue model is driven by the fact that only our test strips, purchased through us and our partners, are able to be utilized with the Dario™ Smart Meter and software, so it is our expectation that we will be the sole source for Dario™ compatible test strips. In addition to Smart Meter and test strip related revenue, we anticipate to generate revenues in the future from our ability to offer Dario™'s subscribers additional products and services based on personalized recommendations, such as location-based, low-sugar food recommendations and the ability to send alerts to caregivers and family and friends. It is our intention to generate and sustain revenue not only from the consumables but also from software licensing and added value services so that the data monetization revenue channel becomes a significant contributor to the company's gross margin. We plan to monetize the comprehensive data that is collected in the Dario™ cloud as a result of various offerings such as a platform for diabetes related clinical trials.

We believe the following features of our Dario™ 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 electro-chemical, blood-based measurement techniques as standard glucose monitors offers familiar usability, the Dario™ blood glucose monitor 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™ Smart Meter has an integrated lancing device and disposable strip cartridge. This eliminates the need for a separate glucose monitor, lancing device and strip vial and, we believe, will make Dario™ the Smart Meter 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. The most recent publicly available reports from Nielsen indicate that in the U.S., smartphone usage continues to climb. More than three out of five (61%) mobile subscribers in the U.S. owned a smartphone during the most recent three-month period for which data is available (March-May 2013), up more than 10% since smartphones became the mobile majority in early 2012. In March 2012, 50% of mobile subscribers used smartphones, making up the majority for the first time. Moreover, according to a Research2Guidance report from 2014, the percentage of people with diabetes who own a smartphone and will utilize apps to manage their condition is 1.2% or approximately 3.7 million people in 2014, growing to an anticipated 7.8%, or approximately 24 million people, by 2018, which would represent an increase of 650%. In many countries (including the U.S.), smart mobile devices are also typically subsidized by the cellular providers through discounted pricing associated with related plan subscriptions, enabling Dario™ to benefit from the extensive marketing by cellular companies of these devices. 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. 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 nonexclusive distributors and partners. In Europe, New Zealand and Canada, we use distribution partners to market and sell Dario™. In Israel, we have developed a direct sales and marketing channel through e-commerce. Our direct to consumer marketing channel supports our distributors' efforts in Canada, and we are planning to expand such efforts to the U.K. during 2017. 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. In some additional jurisdictions, we may adopt a direct sales model in addition to utilizing local distributors.

- *"Expanding the Pie"*. Our goal is to obtain significant market share using technological innovations and by expanding the total BGMS market size "pie" through 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 Dario™ 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 will be similar to our estimate of our competitors' cost for existing single-use disposable strips. In addition, we believe the manufacturing costs of our Dario™ Smart Meter will be competitive with those of the leading glucose meters.

- *Opportunities for Commercialization Partnerships.* Healthcare and pharmaceutical company entrants into the BGMS market (such as Perigo 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 an upfront payment, 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 Medisana GlucoDock, 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 Dario™ does. We further believe that these competitors provide limited capabilities over their diabetes management apps as compared to the Dario™ application.

As a result, we believe Dario™ will bring an entirely new dynamic to the BGMS device market. We believe that our primary business model for Dario™ 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, 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.

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 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 every day in order to control the levels of glucose in their blood. 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 day (versus once or twice a day for most Type 2 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 an 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 growing 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 National Institutes of Health, during the years 2009-2012, 37% of U.S. adults ages 20 years or older had pre-diabetes, with 51% of those ages 65 years or older, leading the NIH to estimate that approximately 86 million persons in the U.S. had pre-diabetes in 2012. 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 Diabetic and BGMS Markets and the Dario™ 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 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 International Diabetes Foundation (IDF), approximately 415 million people worldwide were estimated to have diabetes in 2015, or one in eleven adults. The greatest number are between 40 and 59 years old. If these trends continue, by 2040, some 642 million people. According to the IDF, in Europe, there were 59.8 million adults over the age of 20 with diabetes in 2015and approximately 29.2 million adults over the age of 20 with diabetes in the U.S. in 2015. In the U.S., one in four adults have diabetes. An additional 86 million U.S. adults had pre-diabetes in 2012, which puts them at high risk for developing Type 2 diabetes according to the ADA. Approximately 179 million adults with diabetes live in China and India, with approximately 14.2 million in Brazil and 12 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 estimates 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 other 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 Transparency Market Research, the blood glucose self-monitoring market is currently estimated to be $12 billion and is expected to grow to an estimated $27 billion by 2022. The same source also notes that the total diabetes management market was $50.8 billion in 2011 and is estimated to reach $98.4 billion by 2018. 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. In fact, the BGMS testing market, which barely existed in 1980, now accounts for approximately a quarter of the entire in vitro diagnostics industry.

Key factors driving market growth include increasing number of people with diabetes, growing patient awareness, technological advancements and 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 a first point of entry for Dario and the goal of providing mHealth/Digital 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^{TM} Smart Diabetes Management Solution is targeted at the mHealth app market currently estimated at $10 billion globally with expected annual growth of 15% to $31 billion by 2020.

Industry Background and the Dario™ Opportunity

From a competition perspective, four companies currently dominate the BGMS business, controlling more than 90% of the market: Roche Diagnostics (part of Hoffman-LaRoche), LifeScan (a Johnson & Johnson company), Bayer Healthcare Division, 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 BGMS market. The Dario™ solution, which features a compact all-in-one Smart Meter 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 Dario™ 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 Dario™ dongle (the part of the Smart Meter that attaches to the phone jack) and the similarity to our competitors' estimated cost of manufacturing the strips, when coupled with the 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. Dario™ 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 will seek to introduce and present Dario™ to the medical community through our participation in academic and professional conferences. Dario™ will mainly be marketed directly to our target users, who we believe are increasingly becoming the primary decision makers in choosing their glucose monitoring equipment.

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). 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. According to a publicly available 2016 study by Research2Guidance, smart mobile device applications will enable the mHealth industry to reach 551 million active users (at least once a month) by 2020. According to this report, in 2016, mHealth companies are estimated to generate $12.5 billion through mHealth apps related services mainly through service revenue, device revenue, consumable revenue, paid download revenue and advertising revenue. We believe that Dario™ is designed to play directly into this trend.

Currently more than 70% of the mHealth applications in major “app stores” are adhering to the paid business model according to Research2Guidance. With more and more traditional healthcare providers joining the mobile applications market, we expect the business models will broaden to include healthcare services, advertising and drug sales revenues. According to Research2Guidance, with the growing sophistication level of mHealth applications, only 14% of the total market revenue in the next 5 years will come from application download, advertisement and transaction revenue, whereas 76% of total mHealth application market revenue will come from related services and products. We believe that Dario™ is well-positioned to benefit from that trend.

The Dario™ diabetes management solution includes the Dario™ Smart Meter 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™ application provides knowledge and motivation with an 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 has been focused on the early adopter diabetics, and we expect to gradually broaden our marketing efforts (and benefitting from viral marketing) toward the entire diabetic population. We plan to initially focus on insulin dependent diabetic patients. While this population constitutes about 20-30% of the diabetic patient population, we estimate it to be responsible for over 60% of the revenue from blood glucose monitoring. Dario™’s ease of use and the lack of need for a special glucometer are also expected to be of major appeal to the entire Type 2 diabetes population.

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 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.

In the U.K., Dario^{TM} is a fully reimbursed product distributed by a new distributor since the second quarter of 2016. Dario 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 DarioHealth offers to people with diabetes. In addition, DarioHealth will be focusing on increasing its presence in the U.K. market via its direct to consumer strategy, utilizing the country wide availability of the strips in pharmacy and clinical awareness of the product via the healthcare providers.

In Canada, Dario is available through major pharmacy chains across Canada that include brands like Safeway and London Drugs. DarioHealth also offers 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^{TM} to the medical establishment via our distributor and expanding its awareness via our direct to consumer strategy which we have been ramping up.

Through our experience in the U.S., U.K., Canada, Australia and additional markets, we are poised to open up additional markets in 2017 that have a high diabetes penetration rate and fit our hybrid business model.

Dario™ is an Internet-driven product. Dario™ was designed for the mobile age and will be powered by the Internet as an effective route of launching and marketing new consumer products. We currently sell directly to consumers and also collaborate with distributorsin various jurisdictions. It is estimated that a typical Type 1 diabetes patient, who is testing his or her blood sugar 4 to 10 times a day, uses 120 to 300 strips each month, which creates the potential for a substantial and predictable revenue stream.

On the marketing side, primarily utilize online marketing in order to create awareness of Dario™. Rather than solely rely on 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.

In December 2014, we entered into an agreement with Israel's leading healthcare HMO, Maccabi Healthcare, to implement a comprehensive Dario™ digital suite for patients and professionals. The agreement with MOMA (Maccabi TeleCare unit) represents an additional channel of revenue stream for Dario™. We believe this channel for revenues indicates the huge potential available which is 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 Dario™'s clinical equivalence and usability superiority.

Manufacturing

As we do not engage in manufacturing activity ourselves, we have supply agreements with manufacturers for the Dario™ Smart Meter, glucose test strips, lancing devices and lancets. We have arrangements in place with commercial scale manufacturers for both the Dario™ Smart Meters 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™ Smart Meters.

During 2015, we commenced manufacturing of our Dario™ Smart Meter with a Chinese manufacturer as part of our efforts to further reduce manufacturing costs of the Dario™ Smart Meter. In the beginning of 2016 we have 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 this being obtained. In April 2014, we announced the receipt of reimbursement coverage for the use of the Dario™ Smart Meter 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™ Smart Meter. 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 Dario™ test strips 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™ Smart Meter in Israel with 161 diabetic patients. The aim of this study was to collect measurement data from capillary blood with 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 Dario™ strips are well within the 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 Dario™ compared to reference equipment (YSI 2300 STATPLUS) and to evaluate the ease of use of the Dario™ device by the first time user. This study was in connection with our regulatory submissions for the product in the U.S. and Canada and in accordance with ISO 15197:2013. The study was performed at Remington Davis Clinical Research in Columbus, Ohio with the Dario™ device and included 368 participants with varying demographics. As required by FDA, the study was approved by the institutional review board (IRB) which supervise the clinical studies performed in their institutions.

The purpose of the study was to demonstrate the accuracy of the Dario™ compared with the YSI reference standard and to evaluate how the first time users of the Dario™ (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™ device 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 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 Dario™ for the first time, as instructed at 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 were within BGMS range 43.0-477.0 mg/dL, and YSI range 42.3-435.5 mg/dL. There were no outliers. Accuracy for Dario™ 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 the 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 is 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™ 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 FDA. We evaluated the accuracy of blood glucose level results obtained from fingertip using Dario™ compared to reference equipment (YSI 2300 STATPLUS). We also assessed the usability of the Dario™ device by first time users. The study was performed at the University of Colorado Barbara Davis Center for Diabetes in Aurora, Colorado with the Dario™ device 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™ 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™ device 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.

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 the Dario's measurement at glucose concentrations < 75mg/dL and within ± 20% at glucose concentrations greater than or equal to 75mg/dL". The study evaluated 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 at 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 were 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 the 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.

Government Regulation

The principal markets that we are initially targeting for Dario™ are the United States, 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 be 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™ 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 a 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 bear 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 fulfil 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™ Smart Meter 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 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.

We are currently pursuing regulatory clearance in India. 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 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 Ethic 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, the 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 other 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 the nature and risks involved with the product.

Failure to comply with applicable regulatory requirements can result in enforcement action be 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 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 amount 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 is 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 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 Patent Cooperation Treaty (or 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) was 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 monitor draws power from and transmits data to a smart phone via the audio jack port. This patent was issued as U.S. Patent 8,797,180 in August 2014, and in September 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. We believe this represents a 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.

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

Furthermore, we filed 2 new U.S. Provisional applications, which are still pending, covering new features and functionalities related to future Dario™ generations.

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 Dario™ hardware and software with the goal of achieving enhanced functionality, user interface and data usability.

Design patents and patent applications on the Dario™ device

To further protect our market distinction and branding for Dario™, 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™ App

In addition, three U.S. Design Applications have been filed and granted covering our smart mobile device display screens with graphical user interface. These design application 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, as well as for the DARIO-LITE word mark, and our company's name DARIOHEALTH. The marks were granted and registered in the United States; national applications were filed in major territories, some of which are still pending.

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, 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 principally from two arenas:

Direct competition from existing companies in the blood based glucose monitors market. We compete directly and primarily with large pharmaceutical and medical device companies, including, but not limited to, Abbott Laboratories, Bayer Healthcare Division, Johnson & Johnson LifeScan, Roche Diagnostics and Sanofi. While the market is highly competitive, we believe that Dario™ has important comparative advantages versus other devices in the market. Some of these devices are now offered as connected devices to smart mobile devices, such as the Sanofi IBGStar, Medisana GlucoDock, Philosys Gmate Smart, One Drop, and iHealth Align.

The Dario™ Smart Meter offers 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, which enables Dario™ to offer features that are similar to or superior to the most advanced meters in the market (such as Sanofi IBGStar, Gmate Smart and iHealth Align) while having a smaller form factor than the compact meters in the market (Abbott FreeStyle Lite and OneTouch UltraMini). We believe this design will be attractive to diabetic patients.

Non-invasive and continuous blood glucose monitors. While there are numerous continuous blood glucose monitoring technologies in the market, we believe they are expensive to use and are therefore offered mainly for temporary usage and in medical settings (such as hospitals) or to limited population at high risk for hypoglycemia. There have been a wealth of attempts for noninvasive glucose monitors, but we are not aware of any that are available in the market or are expected to reach the market with significant presence over the next few years.

Gearing up for the expansion of DarioHealth and potential growth into the mHealth space, we are currently analyzing key players in the mobile health/digital health arena. Big Data and analytical insights are the key offerings for all segments of the market – patients, healthcare providers and payers. Our technology development focus and marketing efforts are all geared at placing us as a major player in this global market.

Employees

We currently have 30 full time employees and 1 part time employee. We have employment agreements with our two 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 Dario™, achieve market acceptance of Dario™ and respond to competition. We commenced a commercial launch of the free Dario™ application in the United Kingdom in late 2013 and commenced an initial soft launch of the full Dario™ solution (including the app and the Smart Meter) 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 revenue, and it is still too early to predict if we will be able to generate significant revenues over the next 12 months. 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 from Dario™ 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 heath 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 July 2017.

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 only recently entered the commercialization stage. We have financed our operations primarily through private placements of common stock and convertible debt and have incurred losses in each year since inception including net losses of $11,607,000 and $7,296,000 in 2016 and 2015, respectively. Our accumulated deficit at December 31, 2016 was approximately $55,000,000. 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 2016 audited 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 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 financial statements for December 31, 2016 a substantial doubt regarding our ability to continue as a going concern. Our 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.

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 Datio™ 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 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 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.

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 Dario™ and we lack the resources and the capability to manufacture Dario™ on a commercial scale. Therefore, we rely on a limited number of suppliers who manufacture and assemble certain components of Dario™. 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 Dario™ 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 Dario™;
- 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 mobile 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™ 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™ application compatible with these platforms, or if there is any deterioration in our relationship with either Apple or Google or others after our application is available, our business would be materially harmed.

We are subject to each of Apple's and Google's standard terms and conditions for application developers, which govern the promotion, distribution and operation of games and other applications on their respective storefronts. Each of Apple and Google has broad discretion to change its standard terms and conditions, including changes which could require us to pay to have our Dario™ application available for downloading. In addition, these standard terms and conditions can be vague and subject to changing interpretations by Apple or Google. We may not receive any advance warning of such changes. In addition, each of Apple and Google have 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™ application on its storefront, it would materially harm our business.

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

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

Our Dario™ Smart Meter 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™ Smart Meter that connects to an iPhone 7 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, New Zealand, Canada and Israel. 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 currency 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 currency 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 Meter, software application 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.

Dario™ (including the Smart Meter and software application) 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 Chairman of our Board of Directors, and Zvi Ben David, our Chief Financial Officer, Treasurer and Secretary. 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, the Netherlands, New Zealand, the United Kingdom and the United States and we are currently seeking approval in India.

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™ 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 ultimately commercialize Dario™ and generate 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 amount of resources, including 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 a 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 the 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 a significant number of other patent applications for aspects of both the Dario™ Smart Meter and software. We have also obtained numerous Web domains.

However, to date, we have only been issued two patents (which were issued in the United States) relating to how the Dario™ blood glucose monitor draws power from and transmits data to a smart phone 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 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, Bayer Healthcare Division, Johnson & Johnson LifeScan, Roche Diagnostics and Sanofi. The first four of these companies have more than 90% combined 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 technology 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 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. 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 governmental 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 is 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, and OurCrowd Digital Health, L.P.) collectively have an approximately 44.7% 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.

OurCrowd Digital Health L.P. has the right to appoint up to two members of our Board of Directors, which affords such investor the potential for control over our business.

OurCrowd Digital Health L.P., an investor that participated in our January 2017 private placement transaction, has the right, for so long as such investor holds 13% and 5% of our outstanding shares of common stock, to appoint, respectively, two or one member of our Board of Directors. To date, such investor has appointed two members of our Board of Directors (Allen Kamer and Yossi Bahagon). As a result, such investor has significant influence over the composition of our Board of Directors which, in turn, affords such investor the potential for material control over our business.

Our common stock has less liquidity than many other stocks listed on the NASDAQ Global 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, 2016, 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 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;
- failure to adequately manufacture Dario™ or any other products through third parties;
- 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 an important research, development or commercialization milestone or result by a publicly expected deadline, even if by only a small margin, there could be 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.

The right of the lead investor in our January 2017 Private Placement to participate in future financings of ours could impair our ability to raise capital.

Under the securities purchase agreement with the lead investor in our January 2017 private placement offering, in the event that we seek to raise money through the offer and sale of debt or equity securities, we must first offer such investor a right to participate in at least 13% of the securities we propose to offer in such funding. The existence of such right of participation, or the exercise of such rights, may deter potential investors from providing us needed financing, or may deter investment banks from working with, which would have a material adverse effect on our ability to finance our company which, in turn, could lead to our inability to continue our business.

As an "emerging growth company" under applicable law, we will be subject to lessened disclosure requirements, which could leave our stockholders without information or rights available to stockholders of more mature companies.

For as long as we remain an "emerging growth company" as defined in the JOBS Act, we have elected to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;
- taking advantage of an extension of time to comply with new or revised financial accounting standards;
- reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We expect to take advantage of these reporting exemptions until we are no longer an "emerging growth company". Because of these lessened regulatory requirements, our stockholders would be left without information or rights available to stockholders of more mature companies.

Because we have elected to use the extended transition period for complying with new or revised accounting standards for an "emerging growth company" our financial statements may not be comparable to companies that comply with public company effective dates.

We have elected to use the extended transition period for complying with new or revised accounting standards under Section 102(b)(1) of the JOBS Act. This election allows us to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. While we are not currently delaying the implementation of any relevant accounting standards, in the future we may avail ourselves of this rights, and as a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates. Because our financial statements may not be comparable to companies that comply with public company effective dates, investors may have difficulty evaluating or comparing our business, performance or prospects in comparison to other public companies, which may have a negative impact on the value and liquidity of our common stock.

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 9 Halamish Street, Caesarea Industrial Park, 3088900, Israel. On December 30, 2013, we signed a lease agreement for our headquarters facilities for a period of 3 years commencing January 1, 2014 for a monthly rent and management services of approximately $9,000. In December 2015, we signed a lease agreement for our U.S. headquarters facilities in Burlington, Massachusetts for a period of 1 year commencing February 1, 2016 for a monthly rent and management services of approximately $1,400, and our lease is currently in effect until the end of June 2017. We are planning to move to a new facility during the third quarter of 2017 that we believe will be adequate for our planned development of the business.

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 common stock began trading on Nasdaq on March 4, 2016. The following table sets forth the high and low sales prices per share of our common stock for the periods indicated as reported by Nasdaq. The share values reflected below have been adjusted to give effect to the 1-for-18 reverse split which we implemented on February 26, 2016.

Period	Price Range	
	High	Low
Year Ended December 31, 2015:		
First Quarter	$ 4.95	$ 2.70
Second Quarter	$ 9.54	$ 3.13
Third Quarter	$ 6.97	$ 4.52
Fourth Quarter	$ 11.67	$ 4.77
Year Ended December 31, 2016:		
First Quarter	$ 8.73	$ 3.30
Second Quarter	$ 5.90	$ 4.10
Third Quarter	$ 5.20	$ 3.03
Fourth Quarter	$ 4.30	$ 2.67
Year Ended December 31, 2017:		
First Quarter (through March 21, 2017)	$ 4.45	$ 3.08

As of March 21, 2017, the last reported price of our common stock quoted on the Nasdaq Capital Market was $4.476 per share.

Record Holders

As of March 21, 2017, we had 231 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, 2016:

The following table provides information as of December 31, 2016 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	510,163	$ 13.75	1,164,431
Equity compensation plans not approved by security holders *	13,974	$ 127.29	-
Equity compensation plans not approved by security holders **	4,225	$ 125.10	-
Equity compensation plans not approved by security holders ***	54,490	$ 5.76	-
Equity compensation plans not approved by security holders ****	2,778	$ 7.02	-
Total	585,630	$ 16,49	1,164,431

* 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. Following amendments, there are currently 676,637 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 June 22, 2016, we entered into a public relation services agreement with 5W Public Relations, LLC, or the Service Provider, which was amended on October 26, 2016, collectively referred to as the Service Provider Agreement. Pursuant to the Service Provider Agreement, we have the right, at our sole discretion, to issue shares of common stock in lieu of cash consideration. On January 26, 2017, we issued 6,553 shares of our common stock to the Service Provider, in lieu of cash consideration, pursuant to our Amended and Restated 2012 Equity Incentive Plan.

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. The share and per share numbers in the following discussion reflect a 1-for-18 reverse stock split that we effected on February 26, 2016.

Overview

We are 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. 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. Our flagship product, Dario™, 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 we call the Dario™ Smart Meter.

We commenced a commercial launch of the free Dario™ application in the United Kingdom in late 2013 and commenced an initial soft launch of the full Dario™ solution (including the app and the Smart Meter) 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. We currently have approximately 50,000 installs of our iOS app and over 10,000 installs of our Android app.

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 effort to include Australia as well. 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™ application, Smart Meters and test strips;
- continued product 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™ solution);
- continued work on registration of our patents worldwide;
- regulatory 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 July 2017 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 (or US 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 US 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™ Smart Meters through distributors or directly to end users. The Dario™ software 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 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.

We also generate revenues from arrangements with health care providers which include supply of Dario™ Smart Meters and software platform that requires certain customization followed by monthly service, support and maintenance.

When a sales arrangement contains multiple elements, such as software and non-software components, we allocate revenue to each element based on a selling price hierarchy as required according to ASC 605-25, "Multiple-Element Arrangements", or ASC 605-25. The selling price for a deliverable is based on its Vendor Specific Objective Evidence, or VSOE, or, if available, third party evidence, or TPE, if VSOE is not available, or estimated selling price, or 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 we offer our products. The determination of ESP is judgmental.

Revenues from software components in sales arrangements containing multiple elements are recognized when all criteria outlined in ASC 985-605, "Software Revenue Recognition", or ASC 985-605, are met (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).

For multiple element arrangements within ASC 985-605, revenues are allocated to the different elements in the arrangement under the "residual method" when VSOE of fair value exists for all undelivered elements and no VSOE exists for the delivered elements. Under the residual method, at the outset of the arrangement with the customer, we defer revenue for the fair value of its undelivered elements and recognize revenue for the remainder of the arrangement fee attributable to the elements initially delivered in the arrangement when the basic criteria in ASC 985-605 have been met. Any discount in the arrangement is allocated to the delivered element.

Since VSOE does not exist for undelivered elements, revenues are recognized as one unit of accounting, on a straight-line basis over the term of the last deliverable based on ASC 605-15 and ASC 985-605.

Liability Related to Certain Warrants

The fair value of the liability for certain warrants issued to investors and our previous placement agents in connection with our financings to date was calculated using the Binomial option-pricing model. We accounted for these warrants according to the provisions of ASC 815, "Derivatives and Hedging - Contracts in Entity's Own Equity" and, based on the anti-dilution protections contained in part of the warrants and net settlement cash feature contained in other warrants, we classified them as non-current liabilities, measured at fair value each reporting period until they will be exercised or expired, with changes in the fair values being recognized in our statement of comprehensive loss as financial income or expense. The anti-dilution protections feature for certain warrants was valued by calculating a put option. The value of these warrants was calculated using the call option value in addition with the put option value, which reflects the anti-dilution protection, multiplied by the probability that a down round will occur. The value of warrants with net settlement cash feature and liquidated damages penalties which do not include anti-dilution provision was calculated using a call option value.

Fair value for each reporting period was calculated based on the following assumptions:

(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 together with companies in the same industry 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.

Our net loss for the year ended December 31, 2016 and 2015 included finance income in the amount of $260,000 and $571,000, respectively, with connection to the above-mentioned warrants.

Inventories

Inventory write-down is also 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, 2016, total inventory write-off expenses amounted to $315,000.

Production Lines

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

Useful Lives of Assets. We are required to make subjective assessments as to the useful lives of our production lines for purposes of determining the amount of depreciation to record on an annual basis with respect to our construction of the production lines. These assessments have a direct impact on our net income (loss). Production lines are usually depreciated on a straight-line basis over a period of up to 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. During the year ended December 31, 2016, we recorded a non-cash charge with respect to an impairment of production equipment in the amount of $269,000.

Extended Transition Period for "Emerging Growth Companies"

We have elected to use the extended transition period for complying with new or revised accounting standards under Section 102(b)(1) of the JOBS Act. This election allows us to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. As a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates. Because our financial statements may not be comparable to companies that comply with public company effective dates, investors may have difficulty evaluating or comparing our business, performance or prospects in comparison to other public companies, which may have a negative impact on the value and liquidity of our common stock.

Results of Operations

Comparison of the Year Ended December 31, 2016 to Year Ended December 31, 2015

Revenues

Revenues for the year ended December 31, 2016 amounted to $2,803,000, compared to $823,000 during the year ended December 31, 2015.

Revenues generated during the year ended December 31, 2016 were derived mainly from the sales of Dario™'s components, including the Smart Meter itself, through direct sales to consumers located mainly in the United states through our on-line store and through distributors. This increase in revenues is attributable to additional commercialization and launch of sales in 2016.

Cost of Revenues and ramp up of manufacturing

During the years ended December 31, 2016 and 2015, we recorded costs related to revenues and ramp up of manufacturing in the amount of $3,364,000 and $1,678,000, respectively. The increase in cost of revenues and ramp up of manufacturing was mainly due to the increase in the quantities of products sold during 2016. In addition, in 2016 we recorded an amount of $269,000 in a separate line item due to an impairment of one of our production lines that we do not plan to use in the future, due to its high manufacturing costs.

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 decreased by $411,000 to $2,154,000 for the year ended December 31, 2016 compared to $2,565,000 for the year ended December 31, 2015. This decrease was mainly due to decreases in stock-based compensation expenses, development costs and other costs.

Research and development expenses consist mainly of payroll expenses to employees involved in research and development activities, expenses related to our Dario™ software application and related Smart Meter device, 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, Marketing and Pre-production Costs

Our sales, marketing and pre-production costs increased by $3,409,000 to $4,739,000 for the year ended December 31, 2016 compared to $1,330,000 for the year ended December 31, 2015. This increase was mainly due to the increase in our expenses on digital marketing campaigns primarily in the U.S. since we commenced sales in the U.S. in March 2016.

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 $430,000 to $3,378,000 for the year ended December 31, 2016 compared to $2,948,000 for the year ended December 31, 2015. The increase is mainly due to an increase in payroll expenses, patent registration expenses and professional expenses offset partially by a reduction in stock-based compensation 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 income, net, decreased by $342,000 to $214,000 for the year ended December 31, 2016 compared to $556,000 for the year ended December 31, 2015. Finance income includes mainly the results of revaluation of warrants to investors and a former placement agent, which are recorded as a liability and presented as fair value for each reporting period.

Net loss

Net loss for the year ended December 31, 2016 was $10,887,000. Net loss for the year ended December 31, 2015 was $7,142,000. The increase from 2015 was mainly due to the increase in our sales and marketing effort in the United States through our digital marketing campaigns.

Net operating loss carryforwards

We had U.S. federal net operating loss carryforwards of approximately $9,756,000 at December 31, 2016. This loss carryforwards expire principally beginning in 2031 through 2035.

Our Israeli subsidiary has accumulated net operating losses for Israeli income tax purposes as of December 31, 2016 in the amount of approximately $6,961,000. The net operating losses may be carried forward and offset against taxable income in the future for an indefinite period.

In accordance with 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.

Liquidity and Capital Resources

As of December 31, 2016, we had approximately $1,093,000 in cash and cash equivalents compared to $2,671,000 at December 31, 2015.

We have experienced cumulative losses of $55,000,000 from inception (August 11, 2011) through December 31, 2016, and have a stockholders' deficiency of $6,541,000 at December 31, 2016. 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 is 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 of our common stock and warrants to purchase shares of our common stock, receiving aggregate net proceeds totaling $38,800,000 as of December 31, 2016, approximately $2,000,000 of which was raised during February and March 2015 pursuant to a private placement, or the February 2015 Private Placement, pursuant to which we issued 627,035 shares of our common stock and warrants to purchase an aggregate of 313,538 shares of our common stock, $453,000 which was raised following the entry on May 15, 2015 into warrant exercise and replacement agreements, or the Exercise and Replacement Agreements, with certain of the investors and the placement agent, or the Buyers, in our February 2015 Private Placement. The purpose of the Exercise and Replacement Agreements was to induce the exercise of the warrants issued in the February 2015 Private Placement, or the Warrants, into 106,881 shares of our common stock at an exercise price of $4.32 per share. In connection with the Exercise and Replacement Agreements and the exercise of the Warrants, we issued to the Buyers additional warrants to purchase an aggregate of 106,881 shares of our common stock at an exercise price of $4.32 per share. In connection with the issuance of the Warrants to purchase an aggregate of 106,881 shares of our common stock we recorded in the second quarter of 2015 a deemed dividend in the amount of $154,000.

In July and August 2015, we consummated a private placement, or the July 2015 Private Placement, pursuant to which we issued 463,960 shares of our common stock, Series A Warrants to purchase 231,987 shares of our common stock at an exercise price of $6.30 per share and Series B Warrants to purchase 231,987 shares of our common stock at an exercise price of $7.20 per share for an aggregate gross consideration of approximately $2,500,000. With respect to the July 2015 Private Placement our issuance costs were approximately $181,000 ($122,000 out of which related to commissions and fees of the placement agent). In addition, we agreed to grant to the placement agent 2,778 restricted shares of our common stock, to the placement agent and a selected dealer an aggregate of 49,910 warrants at exercise prices of $5.40, $6.30 and $7.20 per share, and to certain finders that assisted with the July 2015 Private Placement 13,630 restricted shares of our common stock, 20,793 non-plan stock options to purchase 20,793 shares of common stock and 34,424 warrants at exercise prices of $6.30 and $7.20 per share.

On November 19, 2015, we consummated a private placement, or the November 2015 Private Placement, pursuant to which we issued 424,919 shares of common stock and warrants exercisable for an aggregate of 424,919 shares of common stock for an aggregate gross consideration of approximately $2,300,000. The warrants issued in the November 2015 Private Placement consisted of a Series A warrant to purchase 0.7 shares of our common stock, immediately exercisable at an exercise price of $6.66 per share and expiring 16 months from the date of the closing and a Series B warrant to purchase 0.3 shares of common stock, immediately exercisable at an exercise price of $7.74 per share and expiring 36 months from the date of the closing. In connection with the November 2015 Private Placement we agreed to issue to certain finders 21,304 restricted shares of common stock, 24,424 non-plan stock options to purchase 24,424 shares of common stock and 45,730 warrants subject to the same terms as those issued to investors.

On December 24, 2015, we consummated a private placement, or the December 2015 Private Placement, pursuant to which we issued 81,222 shares of common stock and a warrant exercisable for an aggregate of 81,222 shares of common stock for an aggregate gross consideration of approximately $500,000. The warrant issued in the December 2015 Private Placement consisted of a warrant to purchase shares of our common stock, immediately exercisable at an exercise price of $6.16 per share and expiring 6 months from the date of the closing.

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 $3,100,000. 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.

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 July 2017 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 Meter and its related application and data storage components, (2) our efforts to obtain regulatory clearances or approvals necessary to be able to commercially launch Dario™, (3) expenses which will be required in order to start and 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™ 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,	
	2016	2015
	$	$
Cash used in operating activities:	(8,379,000)	(6,277,000)
Cash used in investing activities:	(947,000)	(113,000)
Cash provided by financing activities:	7,748,000	7,608,000
	(1,578,000)	1,218,000

Net cash used in operating activities

Net cash used in operating activities was $8,379,000 for the year ended December 31, 2016 compared to $6,277,000 used in operations for the same period in 2015. Cash used in operations increased mainly due to increase in our sales and marketing activities in promoting our product sales.

Net cash used in investing activities

Net cash used in investing activities was $947,000 for the year ended December 31, 2016 compared to $113,000 for the year ended December 31, 2015. Cash used in investing activities increased mainly due to investment in manufacturing facilities to support the increase in sales.

Net cash provided by financing activities

Net cash provided by financing activities was $7,748,000 for the year ended December 31, 2016 compared to $7,608,000 for the year ended December 31, 2015. During the year ended December 31, 2016, we raised net proceeds in an amount of $7,748,000, of which $7,538,000 was raised through our March 2016 Public and Private offerings. In addition, we raised $210,000 in January 2016 through our Warrant Exercise.

Contractual Obligations

Set forth below is a summary of our current obligations as of December 31, 2016 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**	**1-3 years**
Operating Lease Obligations	$ 360	$ 250	$ 110
Purchasing Obligations	1,356	1,356	-
Total contractual cash obligations	$ 1,716	$ 1,606	$ 110

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, or FASB, issued Accounting Standards Update ("ASU") No. 2014-09, "Revenue from Contracts with Customers", which will replace most of the existing revenue recognition guidance under U.S. Generally Accepted Accounting Principles. The core principle of the ASU is that an entity should recognize revenue for the transfer of goods or services equal to the amount that it expects to be entitled to receive for those goods or services. The ASU requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments. In August 2015, the FASB issued ASU 2015-14, "Revenue from Contracts with Customers (Topic 606)," which defers the effective date of ASU 2014-09 by one year to fiscal years beginning after December 15, 2018, and interim reporting periods within annual reporting periods beginning after December 15, 2019 with early adoption permitted. We are in the process of determining the method of adoption and assessing the impact of this ASU on our consolidated financial position, results of operations and cash flows.

In August 2014, the FASB issued Accounting Standards Update No. 2014-15 (ASU 2014-15), "Presentation of Financial Statements-Going Concern" (Subtopic 205-40): "Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern", which defines management's responsibility to assess an entity's ability to continue as a going concern, and to provide related footnote disclosures if there is substantial doubt about its ability to continue as a going concern. ASU 2014-15 is effective for annual reporting periods ending after December 15, 2016 with early adoption permitted. The adoption of this guidance did not have a material impact on our financial statements.

In July 2015, the FASB issued ASU No. 2015-11, "Inventory (Topic 330): Simplifying the Measurement of Inventory." Under this accounting guidance, inventory will be measured at the lower of cost and net realizable value and other options that currently exist for market value will be eliminated. ASU No. 2015-11 defines net realizable value as the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. No other changes were made to the current guidance on inventory measurement. ASU 2015-11 is effective for fiscal years beginning after December 15, 2016, and interim periods within fiscal years beginning after December 15, 2017 with early adoption permitted. The adoption of this guidance did not have a material impact on the Company's financial statements.

In November 2015, the FASB issued ASU No. 2015-17, "Income Taxes – Balance Sheet Classification of Deferred Taxes." The purpose of the standard is to simplify the presentation of deferred taxes on a classified balance sheet. Under current GAAP, deferred income tax assets and liabilities are separated into current and noncurrent amounts in the balance sheet. The amendments in ASU 2015-17 require that all deferred tax assets and liabilities be classified as noncurrent in the balance sheet. ASU 2015-17 is effective for interim and annual periods beginning after December 15, 2017. Early application is permitted and should be applied prospectively. We do not expect the adoption of ASU 2015-17 to have a material impact on its consolidated financial statements or presentation.

In February 2016, the FASB issued ASU No. 2016-02, "Leases (Topic 842)," which is intended to increase the transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. In order to meet that objective, the new standard requires recognition of the assets and liabilities that arise from leases. A lessee will be required to recognize on the balance sheet the assets and liabilities for leases with lease terms of more than 12 months. Accounting by lessors will remain largely unchanged from current U.S. generally accepted accounting principles. The new standard is effective for public companies for fiscal years beginning after December 15, 2019, and interim periods within those years, with early adoption permitted. We are currently evaluating the effect that adopting this standard will have on our financial statements and related disclosures.

In March 2016, the FASB issued ASU No. 2016-09, "Compensation – Stock Compensation (Topic 718)," which changes the accounting for certain aspects of share-based payments to employees. The new guidance requires excess tax benefits and tax deficiencies be recorded in the income statement when the awards vest or are settled. In addition, cash flows related to excess tax benefits will no longer be separately classified as a financing activity apart from other income tax cash flows. The standard also allows us to repurchase more of each employee's shares for tax withholding purposes without triggering liability accounting, clarifies that all cash payments made on an employee's behalf for withheld shares should be presented as a financing activity on our cash flows statement, and provides an accounting policy election to account for forfeitures as they occur.

The new standard is effective for us beginning January 1, 2017. 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-39 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, 2016, 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, 2016 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, 2016. 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, 2016.

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	44	Chairman of the Board of Directors and Chief Executive Officer
Zvi Ben David	56	Chief Financial Officer, Treasurer and Secretary
Malcolm Hoenlein	73	Director
Dennis M. McGrath	60	Director
Prof. Richard B. Stone	74	Director
Rami Yehudiha	47	Director
Hila Karah	48	Director
Yalon Farhi	55	Director
Allen Kamer	46	Director
Yossi Bahagon	47	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 has served as Chairman of the Board of Directors since November 2014. He previously and since 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.

Malcolm Hoenlein has been a director of our company since August 31, 2011. Since 1986, Mr. Hoenlein has served as Chief Executive Officer and Executive Vice Chairman of the Conference of Presidents of Major American Jewish Organizations, the coordinating body on international and national concerns for 52 national American Jewish organizations. Previously, he served as the founding Executive Director of the Jewish Community Relations Council of Greater New York. Prior to that, he was the founding Executive Director of the Greater New York Conference on Soviet Jewry. A National Defense Fellow at the Near East Center of the University of Pennsylvania, Mr. Hoenlein taught International Relations in the Political Science Department and served as a Middle East specialist at the Foreign Policy Research Institute. In addition, he served on the editorial staff of ORBIS, the Journal of International Affairs. He serves as a director of several companies, Coronado Biosciences Inc. (NASDAQ: CNDO), Nanox Technologies, Data to Life, Nuvo Corp and WellSense Technologies. Mr. Hoenlein has a B.A. in Political Science from Temple University and a Master's Degree in International Relations from the University of Pennsylvania, as well as an honorary Doctorate of Laws from Touro College and an honorary Doctorate of Humane Letters from Yeshiva University. He was appointed by Presidents Clinton and Bush as a U.S. delegate to the Organization for Security and Cooperation in Europe. In 2013, he received the highest civilian decoration from King Mohamad VI of Morocco. We believe Mr. Hoenlein is qualified to serve on our Board of Directors because of his extensive experience serving on the boards of public and private companies.

Dennis M. McGrath has been a director of our company since November 12, 2013. Mr. McGrath is the President and Chief Financial Officer, and a member of the Board of Directors, of PhotoMedex, Inc. (NASDAQ: PHMD), a global medical device and specialty pharmaceutical company. Upon completion of the PhotoMedex's 2011 merger with Radiancy, Inc., Mr. McGrath reassumed his role of Chief Financial Officer in addition to President and director of PhotoMedex, to which he was appointed in July 2009. Mr. McGrath was the Chief Executive Officer of PhotoMedex from July 2009 through December 2011, the date of the merger. He had previously served as Chief Financial Officer and vice president, finance and administration of PhotoMedex from January 2000 through June 2009. He has held several senior-level positions in prior endeavors of public companies, including, from February 1999 to January 2000, serving as the Chief Operating Officer of Internet Practice, the largest division for AnswerThink Consulting Group, Inc., a company specializing in business consulting and technology integration. Concurrently, from August 1999 until January 2000, Mr. McGrath served as Chief Financial Officer of Think New Ideas, Inc., a company specializing in interactive marketing services and business solutions. In addition to the financial reporting responsibilities, he was responsible for the merger integration of Think New Ideas, Inc. and AnswerThink Consulting Group, Inc. Prior to that, from September 1996 to February 1999, Mr. McGrath was Chief Financial Officer and executive vice-president of operations of TriSpan, Inc., an internet commerce solutions and technology consulting company that was acquired by AnswerThink Consulting Group, Inc. in 1999. Mr. McGrath is currently a director of Noninvasive Medical Technologies, Inc., Cagent Vascular, LLC and serves on the Board of Advisors of Taylor University and the Board of Trustees of Manor College. 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. Mr. McGrath began his career at the accounting firm Arthur Andersen in Philadelphia, PA. Upon graduating maxima cum laude with a B.S. in accounting from LaSalle University in 1979 he became a certified public accountant in 1981.

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. We believe Prof. Stone is qualified to serve on our Board of Directors because of his legal expertise and experience with life sciences companies. He is a graduate of Harvard College and Harvard Law School.

Rami Yehudiha has been a director of our company since September 23, 2014. Mr. Yehudiha is a marketing and advertising executive with a particular expertise in developing and implementing campaigns utilizing cutting edge technologies and methods. From 2004 to the present, he has served as the Founder and Chief Executive Officer of LEAD, a top ten Israeli advertising firm. From 1997 to 2003, he served as the Chief Executive Officer at Ogilvy One Israel, a part of the WPP Group. We believe Mr. Yehudiha is qualified to serve on our Board of Directors because of his experience in technology-based marketing. Mr. Yehudiha received his B.A. in Political Science and Economics from Tel Aviv University and an M.B.A. in Marketing from Manchester University.

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.

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. form 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.

Yossi Bahagon has been a director of our company since February 28, 2017. Since July 2016, Mr. Bahagon has served as a managing partner at OurCrowd, a digital health fund. From March 2013 until June 2016 he served as the CEO of Luminox Health Ltd., a consulting and management company in the field of digital health. From September 2008 until August 2012, he founded and served as manager of the digital health wing of Clalit Health Services the largest HMO in Israel, and prior to that, from August 2005 until September 2008 he founded and managed the medical informatics department of Clalit health services. From April 2007 until 2012, he also served as a lecturer in the field of evidence based medicine and biomedical informatics at the at the Hadassah University Medical School and at the Ben Gurion University medical school. Mr. Bahagon has an M.D. degree from the Hebrew University, Hadassah Medical School, and a diploma from the Oregon Health & Science University, Department of Medical Information & Clinical Epidemiology. We believe Mr. Bahagon is qualified to serve on our Board of Directors because of his business 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.

Dr. William Polonsky, PhD, CDE is an internationally recognized expert in the behavioral aspects of diabetes management. Dr. Polonsky is the Founder of the Behavioral Diabetes Institute and serves as its Chief Executive Officer. Dr. Polonsky is also an Associate Clinical Professor of Psychiatry at University of California, San Diego. He served as Senior Psychologist at the Joslin Diabetes Center in Boston, faculty member at Harvard Medical School and Chairman of the National Certification Board for Diabetes Educators. Dr. Polonsky serves as a Member of Advisory Board at SweetSpot Diabetes Care, Inc. He has served on the editorial boards of numerous professional and lay publications, including Diabetes Care, Diabetes Forecast, Clinical Diabetes, Diabetes Self-Management and Diabetes Health. In addition to his professional publications, he is the author of *Diabetes Burnout: What to Do When You Can't Take it Anymore*, a popular book for patients published by the American Diabetes Association. In addition, he was co-editor of A CORE Curriculum for Diabetes Education and Diabetes Education Goals. Dr. Polonsky received his PhD in clinical psychology from Yale University.

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.

Mr. Erez Levy attended the Technion Institution in Haifa and graduated with a B.Sc. degree in Industrial Engineering and Management in 1996. He then started to work as a Manufacturing Program Manager, Missile Division in Rafael, Israel. He joined GE Healthcare in 2000 as a Material Site Manager in Haifa, Israel and became a certified Six Sigma Green belt in 2001. In 2003, he became certified Lean Manufacturing Leader. During 2004 he relocated with his family to Cleveland, Ohio as an Operation manager in GE Coils. In 2006, he returned to Israel as VCP leader in Nuclear Medicine, Engineering drive design for cost in NPI process. During 2008 to 2010 he led the evaluation, due diligence and negotiation process the acquisition of Orbotech by GE and become the integration manager after deal closing. In 2011, he was appointed as General Manager of Global Direct Conversion Detector, CZT solid-state Center of Excellence located in Rehovot, Israel. Mr. Levy brings with him 18 years of broad leadership experience with growing responsibilities, and strong leadership background in medical device design, process engineering, manufacturing and supply chain. He has completed his M.B.A. studies at the Technion institution, Haifa, Israel.

Dr. Paolo Pozzilli is a Professor of Endocrinology and Metabolic Diseases, Head of Department at the University Campus Bio-Medico in Rome, Italy where he is in charge of the Post-Graduate School and PhD program in Endocrinology and Diabetes. He is also Professor of Diabetes Research at St. Bartholomew's and the London School of Medicine, Queen Mary, University of London.

Hope Warchaw, MMSc, RD, CDE, BC-ADM is a dietitian and diabetes educator for thirty-five years and is author of professional articles in leading diabetes journals and co-author of several American Diabetes Association books for healthcare professionals. Among diabetes educators, Ms. Warshaw is a leading promoter of the Diabetes Online Community and its value to people with diabetes and their caregivers.

Dr. Paul Rosman, DO FACP FACE FACOI has served roles in industry, academia and non-profit leadership. He was Former Senior Medical Advisor at Eli Lilly & Company, has held teaching positions at Ohio University and Northeastern Ohio Universities College of Medicine, as well as served as President or Chair of American Diabetes Association, Ohio Chapter, American Association of Clinical Endocrinologists, Ohio River Chapter, and the Ohio Diabetes Prevention and Control Program at Ohio Department of Health.

Gary Scheiner, CDE MS has dedicated his professional life to improving the lives of people with insulin-dependent diabetes. Scheiner has authored six books: You Can Control Diabetes (1997), Think Like A Pancreas (2004), The Ultimate Guide to Accurate Carb Counting (2007), Get Control of Your Blood Sugar (2009), Think Like A Pancreas, 2nd edition (2011), and Until There's A Cure (2012). Mr. Scheiner holds a B.A. in Psychology, an M.S. in Exercise Physiology, and is a Certified Diabetes Educator who trained at the Joslin Diabetes Center.

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.

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., is entitled 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.

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.

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.

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. Hoenlein, 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. Hoenlein, McGrath and Yehudiha and Ms. Karah. Mr. Hoenlein is the Chairman of the Compensation Committee. Under the terms of the Securities Purchase Agreement in our September 2014 Private Placement, we agreed to appoint two nominees of our lead investor, David Edery, to the Compensation Committee. Both Mr. Yehudiha and Ms. Karah are nominees of Mr. Edery.

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, Bahagon and Yehudiha. Prof. Stone is the Chairman of the Nominating and Corporate Governance Committee.

Under the terms of the Securities Purchase Agreement in our September 2014 Private Placement, we agreed to appoint two nominees of our lead investor, David Edery to the Nominating and Corporate Governance Committee. Mr. Yehudiha is the current nominee of Mr. Edery serving on this committee. In addition, 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., is entitled 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.

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. Hoenlein, Yehudiha, Kamer, Bahagon 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 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 (i) the Form 4 filed by Erez Raphael on August 17, 2016, (ii) the Form 4 filed by Zvi Ben-David on March 14, 2016 and August 17, 2016, (iii) the Form 4s filed by Richard Stone on March 14, 2016, March 30, 2016 and August 17, 2016, (iv) the Form 4s filed by Hila Karah on March 14, 2016 and August 17, 2016, (v) the Form 3s filed by Shmuel Farhi on April 28, 2016, (vi) the Form 4 filed by Dennis McGrath on August 17, 2016, (vii) the Form 4 filed by Rami Yehudiha on August 17, 2016, and (viii) the Form 4 filed by Malcolm Hoenlein on August 17, 2016, we believe that during fiscal year ended December 31, 2016, 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, 2016 and 2015.

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 (Chairman and Chief Executive Officer)***	2016	$ 128,953(1)	$ 100,000(2)	$ 118,828(3)				$ 72,642(5)	$ 420,423
	2015	$ 113,802(1)	—	$ 541,813(3)	$ 608,053(4)	—	—	$ 69,388(5)	$ 1,333,057
Zvi Ben David (Chief Financial Officer)	2016	$ 110,978(6)		$ 76,649(7)				$ 32,279(9)	$ 219,907
	2015	$ 89,769(6)	—	$ 32,146(7)	$ 155,060(8)	—	—	$ 27,688(9)	$ 304,663

* 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, 2016, 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.

*** Since August 2013, Mr. Raphael has served as Chief Executive Officer and since November 2014 as Chairman of the Board of Directors.

(1) In accordance with his second amendment to the employment agreement with our company effective August 11, 2013, Mr. Raphael is was entitled to a monthly salary of NIS 44,000, commencing April 1, 2016 his monthly salary was increased to NIS 80,000 (approximately $20,834 per month). During 2015 and 2016, Mr. Raphael agreed to a waiver of 16% and 42% respectively, of his cash salary according to our salary program (see further details in “Employment and Related Agreements” below).

(2) On March 2016, Mr. Raphael was paid a bonus of $100,000 following the successful completion of the public offering.

(3) On August 27, 2015, Mr. Raphael was granted 2,924 shares of our common stock under our 2012 Equity Incentive Plan against waiver of cash salary for the period from April to September 2015. On October 7, 2015, Mr. Raphael was granted 1,889 shares of our common stock under our 2012 Equity Incentive Plan against waiver of cash salary for the period from October to December 2015, on September 3, 2015, Mr. Raphael was granted 84,452 shares of our common stock under our 2012 Equity Incentive Plan, and

On January 27, 2016, Mr. Raphael was granted 1,364 shares of our common stock under our 2012 Equity Incentive Plan against waiver of cash salary for the period from January to March 2016. On June 23, 2016, Mr. Raphael was granted 7,089 shares of our common stock under our 2012 Equity Incentive Plan against waiver of cash salary for the period from April to June 2016, On August 1, 2016, Mr. Raphael was granted 7,688 shares of our common stock under our 2012 Equity Incentive Plan against waiver of cash salary for the period from July to September 2016, 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.

(4) Mr. Raphael, upon his nomination as the Chief Executive Officer of our company, was granted 3,334 options pursuant to our 2012 Equity Incentive Plan. The options granted vested as follows: 1,667 vested on August 29, 2013 (grant date) and 1,667 vested on August 30, 2014. During 2014, Mr. Raphael was granted an additional 889 and 4,667 options which vest over a period of 2 years commencing January 7, 2014 and July 7, 2014, respectively. During 2015, Mr. Raphael was granted 168,904 options to purchase shares of our common stock. 56,302 of such options are immediately vested and the balance shall vest in eight equal quarterly installments from the grant date during a two 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 $7,996) 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 $9,995) per month, and commencing April 1, 2016 his monthly salary was updated to NIS 60,000 (approximately $15,625). During 2015 and 2016, Mr. Ben David agreed to a waiver of 21.9% and 35.2% respectively of his cash salary according to our salary program (see further details in “Employment and Related Agreements” below).

(7) On August 27, 2015, Mr. Ben David was granted 3,801 shares of our common stock under our 2012 Equity Incentive Plan against waiver of cash salary for the period from April to September 2015. On October 7, 2015, Mr. Ben David was granted 1,717 shares of our common stock under our 2012 Equity Incentive Plan against waiver of cash salary for the period from October to December 2015. On January 27, 2016, Mr. Ben David was granted 1,736 shares of our common stock under our 2012 Equity Incentive Plan against waiver of cash salary for the period from January to March 2016.

On June 23, 2016, Mr. Ben David was granted 4,135 shares of our common stock under our 2012 Equity Incentive Plan against waiver of cash salary for the period from April to June 2016, On August 1, 2016, Mr. Ben David was granted 4,485 shares of our common stock under our 2012 Equity Incentive Plan against waiver of cash salary for the period from July to September 2016, 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 March 31, 2016 Mr. Ben David was granted 20,000 shares of our common stock under our 2012 Equity Incentive Plan as bonus for the successful completion of the public offering in march 2016.

(8) During 2015, Mr. Ben David was granted 43,073 options to purchase shares of our common stock. 14,358 of such options are immediately vested and the balance shall vest in eight equal quarterly installments from the grant date during a two 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".

All compensation awarded to our executive officers were 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 Chairman of our 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 80,000 (approximately $20,834 per month). During 2015 and 2016, Mr. Raphael agreed to a waiver of 16% and 42% respectively of his cash salary according to our salary program pursuant to which Mr. Raphael shall receive compensation shares of restricted common stock as consideration for cash salary waived. Mr. Raphael's employment agreement may be terminated by either party at will upon 180 days prior written notice or terminated by us or for cause, as defined under the employment agreement. In the event the employment agreement is terminated by us at will, Mr. Raphael 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 for cause, Mr. Raphael will only be entitled to severance payment 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 to us. 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 August 27, 2015, the Compensation Committee of our Board of Directors approved the issuance to Mr. Raphael of 2,924 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $17,091 salary otherwise payable to Mr. Raphael from April to September 2015.

On September 3, 2015, our Board of Directors approved the issuance to Mr. Raphael of 84,452 shares of our common stock under our 2012 Equity Incentive Plan and to grant to Mr. Raphael 168,904 options to purchase shares of our common stock for an exercise price of $5.76 per share. 56,302 of such options are immediately vested and the balance will vest in eight equal quarterly installments from the grant date during a two year period.

On October 7, 2015, the Compensation Committee of our Board of Directors approved the issuance to Mr. Raphael of 1,889 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $10,917 salary otherwise payable to Mr. Raphael from October to December 2015.

On January 27, 2016, the Compensation Committee of our Board of Directors approved the issuance to Mr. Raphael of 1,364 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $10,637 salary otherwise payable to Mr. Raphael from January to March 2016.

On June 23, 2016, the Compensation Committee of our Board of Directors approved the issuance to Mr. Raphael of 7,089 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $36,185 salary otherwise payable to Mr. Raphael from April to June 2016.

On August 1, 2016, the Compensation Committee of our Board of Directors approved the issuance to Mr. Raphael of 7,688 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $36,045 salary otherwise payable to Mr. Raphael from July to September 2016.

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.

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 $7,996) 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 $9,995) . Commencing April 1, 2016 Mr. Ben David's Salary was updated to NIS 60,000 (approximately $15,625) per month. During 2015 and 2016 , Mr. Ben David agreed to a waiver of 21.9% and 35.2% respectively of his cash salary according to our salary program pursuant to which Mr. Ben David shall receive 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 severance payment 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 August 27, 2015, the Compensation Committee of our Board of Directors approved the issuance to Mr. Ben David of 3,801 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $22,222 salary otherwise payable to Mr. Ben David from March to September 2015.

On September 3, 2015, the Board of Directors approved a grant to Mr. Ben David of 43,073 options to purchase shares of our common stock for an exercise price of $5.76 per share. 14,358 of such options are immediately vested and the balance will vest in eight equal quarterly installments from the grant date during a two year period.

On October 7, 2015, the Compensation Committee of our Board of Directors approved the issuance to Mr. Ben David of 1,717 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $9,925 salary otherwise payable to Mr. Ben David from October to December 2015.

On January 27, 2016, the Compensation Committee of our Board of Directors approved the issuance to Mr. Ben David of 1,736 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $13,538 salary otherwise payable to Mr. Ben David from January to March 2016.

On March 31, 2016, the Compensation Committee of our Board of Directors approved the issuance to Mr. Ben David of 20,000 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued as a bonus for the successful completion of the public offering in March 2016.

On June 23, 2016, the Compensation Committee of our Board of Directors approved the issuance to Mr. Ben David of 4,135 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $21,108 salary otherwise payable to Mr. Ben David from April to June 2016.

On August 1, 2016, the Compensation Committee of our Board of Directors approved the issuance to Mr. Ben David of 4,485 shares of our common stock under our 2012 Equity Incentive Plan. Such shares were issued in lieu of the waiver of $21,026 salary otherwise payable to Mr. Ben David from July to September 2016.

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.

Outstanding Equity Awards at December 31, 2016

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 (Chairman and Chief Executive Officer)	2,001	-	-	$ 121,50	March 14, 2023
	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
	140,754	28,150(1)		$ 5.76	September 3, 2021
Zvi Ben David (Chief Financial Officer, Secretary and Treasurer)	35,894	7,179(2)		$ 5.76	September 3, 2021
Total Option Shares	187,762	35,329			

(1) Following vesting of 56,302 options on September 3, 2015, vests in 8 equal quarterly installments commencing December 3, 2015.

(2) Following vesting of 14,358 options on September 3, 2015, vests in 8 equal quarterly installments commencing December 3, 2015.

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. Hoenlein, McGrath and Yehudiha, 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

Up through September 2015, both the Annual Directors Options as well as the one-time options granted were not issued under our 2012 Equity Incentive Plan.

On April 3, 2015, our Board of Directors approved a compensation plan under which the executive officers have been granted the authority (in their discretion from time to time with the concurrence of the impacted individuals, and subject to applicable laws, rules and regulations) to cause the issuance of shares of common stock to our directors, officers and employees as consideration for a reduction in cash salary or fees owed to such individuals. For that purpose a pool of up to 122,222 shares of common stock is reserved under a shares for salary program.

On April 20, 2015, 4,931, 4,975 and 12,323 shares were respectively issued to Prof. Stone, Mr. McGrath and Mr. Hoenlein in lieu of $23,988, $24,201 and $61,500 fees otherwise payable to each of Prof. Stone for the period from July 7, 2014 to March 31, 2015, Mr. McGrath for the period from November 12, 2013 to March 31, 2015 and Mr. Hoenlein for the period from October 1, 2013 to March 31, 2015.

On August 13, 2015, 1,707 shares were issued to each of Prof. Stone, Mr. Hoenlein and Mr. McGrath in lieu of $10,250 in fees otherwise payable to each of them for the period from April 1, 2015 to June 30, 2015.

On August 27, 2015, the Compensation Committee of our Board of Directors approved the issuance to Ms. Karah and Mr. Yehudiha 3,507 and 5,397 shares of our common stock under our 2012 Equity Incentive Plan, respectively. Such shares were issued in lieu of $20,500 and $31,549 of fees, respectively, otherwise payable to each of Ms. Karah for the period from January 2015 to June 2015 and Mr. Yehudiha, for the period from September 23, 2014 to June 30, 2015.

On September 3, 2015, our Board of Directors approved a grant of an aggregate of 76,000 options to our non-employee directors. These options have an exercise price of $5.76 per share. 25,335 of such options are immediately vested and the balance shall vest in quarterly arrears.

On October 6, 2015, 1,781 shares were issued to each of Prof. Stone, Mr. Hoenlein and Mr. McGrath, in lieu of $10,250 in fees otherwise payable to each of them for the period from July 1, 2015 to September 30, 2015.

On October 7, 2015, the Compensation Committee of our Board of Directors approved the issuance to each of Ms. Karah and Mr. Yehudiha of 1,773 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 Ms. Karah and Mr. Yehudiha for the period from July 1, 2015 to September 30, 2015.

On January 3, 2016, 1,349 shares were issued to each of Prof. Stone, Mr. Hoenlein and Mr. McGrath in lieu of $10,250 in fees otherwise payable to each of them for the period from October 1, 2015 to December 31, 2015 (this grant included a correction to the grant made on October 6, 2015).

On January 3, 2016, the Compensation Committee of our Board of Directors approved the issuance to each of Ms. Karah and Mr. Yehudiha of 1,351 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 Ms. Karah and Mr. Yehudiha for the period from October 1, 2015 to December 31, 2015.

On June 19, 2016, 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 2,008 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, 2016 to March 31, 2016.

On July 27, 2016, 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 2,186 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, 2016 to June 30, 2016.

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 inliew of $14,583.33 in fees otherwise payable to Mr. Farhi for the period June 1, 2016 to December 31, 2016*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, 2016:

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 ($)	Total ($)
Malcolm Hoenlein	2016	$ -	$ 41,000(1)	$ -(2)	$ -	$ -	$ -	$ 41,000
Dennis McGrath	2016	$ -	$ 41,000(3)	$ -(4)	$ -	$ -	$ -	$ 41,000
Prof. Richard B. Stone	2016	$ -	$ 41,000(5)	$ -(6)	$ -	$ -	$ -	$ 41,000
Rami Yehudiha	2016	$ -	$ 41,000(7)	$ -(8)	$ -	$ -	$ -	$ 41,000
Yalon Farhi	2016	$ -	$ 14,583(9)	$ -(10)	$ -	$ -	$ -	$ 14,583
Hila Karah	2016	$ -	$ 41,000(11)	$ -(12)	$ -	$ -	$ -	$ 41,000

* Amount shown does not reflect dollar amount actually received. Instead, this amount reflects the aggregate grant date fair value of each stock option granted in the fiscal year ended December 31, 2016, 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.

** On February 23, 2015, Dr. Kash resigned from the Board of Directors.

(1) 21,354 stock awards are outstanding as of December 31, 2016.
(2) 19,646 option awards are outstanding as of December 31, 2016.
(3) 14,006 stock awards are outstanding as of December 31, 2016.
(4) 17,145 option awards are outstanding as of December 31, 2016.
(5) 13,962 stock awards are outstanding as of December 31, 2016.
(6) 16,867 option awards are outstanding as of December 31, 2016.
(7) 12,715 stock awards are outstanding as of December 31, 2016.
(8) 15,200 option awards are outstanding as of December 31, 2016.
(9) No stock awards are outstanding as of December 31, 2016.
(10) No option awards are outstanding as of December 31, 2016.
(11) 10,825 stock awards are outstanding as of December 31, 2016.
(12) 15,200 option awards are outstanding as of December 31, 2016.

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 14, 2017 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., 9 Halamish Street, Caesarea 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]	1,896,805	21.7%
Zvi Ben David [3]	579,913	7.1%
Malcolm Hoenlein [4]	46,188	*
Dennis M. McGrath [5]	36,339	*
Prof. Richard B. Stone [6]	221,896	2.8%
Rami Yehudiha [7]	33,103	*
Hila Karah [8]	36,991	*
Yalon Farhi[9]	7,144	*
Allen Kamer[10] [12]	892,858	11.2%
Yossi Bahagon[11] [12]	892,858	11.2%
All Executive Officers and Directors as a group (9 persons)	3,751,237	44.7%
5% Stockholders		
OurCrowd Digital Health L.P.[12]	892,858	11.2%
Shmuel Farhi [13]	690,870	8.5%
Ben Farhi[14]	474,446	5.8%
Shehnee Lawrence Farhi[15]	507,444	6.2%

* Less than 1%.

(1) Percentage ownership is based on 7,976,521 shares of our common stock outstanding as of March 22, 2017 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 163,798 vested options and 2,224 warrants to purchase Common Stock. Excludes 159,384 options which are not vested. Also includes 757,509 shares of our Common Stock and 611,943 warrants to purchase 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 38,545 vested options to purchase common stock and 168,753 warrants to purchase common stock. Excludes 36,351 options which are not vested.

(4) Includes 18,446 vested options to purchase common stock. Excludes 17,207 options which are not vested.

(5) Includes 15,945 vested options to purchase common stock. Excludes 17,207 options which are not vested.

(6) Includes 51,545 warrants to purchase common stock, and 15,667 vested options to purchase common stock. Excludes 17,207 options which are not vested.

(7) Includes 14,000 vested options to purchase common stock. Excludes 17,207 options which are not vested.

(8) Includes 14,000 vested options to purchase common stock. Excludes 17,207 options which are not vested.

(9) Includes 2,600 vested options to purchase common stock. Excludes 28,607 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) Mr. Bahagon 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. Bahagon. Mr. Bahagon disclaims beneficial ownership of the securities owned by OurCrowd Digital Health L.P. except to the extent of his pecuniary interest therein.

(12) Based solely on information contained in the filed Schedule 13G filed with the SEC on January 27, 2017, reporting beneficial ownership of OurCrowd Digital health L.P.. Includes 892,858 warrants to purchase Common Stock issued to OurCrowd Digital health L.P. OurCrowd Digital health L.P address is 28 Hebron Rd., Jerusalem 918001, Israel.

(13) Based on information contained in the filed Schedule 13D filed with the SEC on June 3, 2016, reporting beneficial ownership of Mr. Shmuel Farhi and the Securities Purchase Agreement executed by and between Mr. Shmuel Farhi dated January 9, 2017. Includes 111,127 warrants to purchase Common Stock issued to Mr. Shmuel Farhi. Mr. Shmuel Farhi's address is 484 Richmond St., London, England, N6A 3E6.

(14) Based solely on information contained in the filed Schedule 13G filed with the SEC on June 14, 2016, reporting beneficial ownership of Mr. Ben Farhi. Includes 213,334 warrants to purchase common stock issued to Mr. Ben Farhi. Mr. Ben Farhi's address is 90 St. Bees St., London, Ontario, Canada

(15) Based solely on information contained in the filed Schedule 13G filed with the SEC on June 14, 2016, reporting beneficial ownership of Ms. Farhi. Includes 195,689 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 the 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.

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, 2016 and December 31, 2015 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, 2016	December 31, 2015
Audit Fees	$ 83,000	$ 83,000
Audited Related Fees	$ -	$ -
Tax Fees (1)	$ 16,000	$ 8,000
All Other Fees (2)	$ 55,000	$ 12,000
Total	$ 154,000	$ 103,000

(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 (19)
3.2	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock of the Company (2)
3.3	Bylaws (3)
4.1	Form of Warrant issued to investors in the Company's 2011-2012 Private Placement (3)
4.2	Warrant for shares of common stock issued to Spencer Trask Ventures, Inc. (3)
4.3	Warrant for shares of common stock issued to Spencer Trask Ventures, Inc. (3)
4.4	Form of Warrant issued to investors in the Company's August 2012 Private Placement (3)
4.5	Form of Finder Warrant issued in connection with the Company's October 2012 Private Placement (3)
4.6	Form of Warrant issued to investors in the Company's May 2013 Private Placement (4)
4.7	Registration Rights Agreement, dated as of February 12, 2014, by and among the Company and the Buyers named therein in connection with the Company's February 2014 Private Placement (5)
4.8	Form of Warrant issued to investors in the Company's September 2014 Private Placement (6)
4.9	Registration Rights Agreement, dated as of September 24, 2014, by and among the Company and the Purchasers named therein in connection with the Company's September 2014 Private Placement (6)
4.10	Form of Series A Warrant issued to investors in the Company's February 2015 Private Placement (14)
4.11	Form of Series B Warrant issued to investors in the Company's February 2015 Private Placement (14)
4.12	Registration Rights Agreement, dated as of February 25, 2015, by and among the Company and the Purchasers named therein in connection with the Company's February 2015 Private Placement (14)
4.13	Form of Warrant issued in connection with warrant exercise and replacement agreement (15)
4.14	Form of Series A Warrant issued to investors in the Company's July 2015 Private Placement (1)
4.15	Form of Series B Warrant issued to investors in the Company's July 2015 Private Placement (1)
4.16	Form of placement agent common stock warrant issued in the Company's July 2015 Private Placement (1)
4.17	Form of placement agent Series A warrant issued in the Company's July 2015 Private Placement (1)
4.18	Form of placement agent Series B warrant issued in the Company's July 2015 Private Placement (1)
4.19	Form of Warrant issued in connection with warrant replacement agreement (18)
4.20	Form of Series A Warrant issued to investors in the Company's November 2015 Private Placement (18)
4.21	Form of Series B Warrant issued to investors in the Company's November 2015 Private Placement (18)
4.22	Form of Warrant issued to investors in the Company's December 2015 Private Placement (7)
4.23	Warrant Agent Agreement, dated as of March 8, 2016, between LabStyle Innovations Corp. and VStock Transfer, LLC (21)
4.24	Form of Representatives' Warrant (21)
4.25	Form of Series A Warrant (21)
4.26	Warrant dated January 9, 2017 issued to OurCrowd Digital Health L.P. (22)
4.27	Form of Warrant issued in January 2017 Private Placement (22)
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+ (8)
10.3	Amendment to Employment Agreement, dated August 30, 2013, between LabStyle Israel and Erez Raphael+ (8)
10.4	Form of Securities Purchase Agreement for the Company's August 2012 Private Placement (3)
10.5	Addendum to Securities Purchase Agreement, dated February 11, 2013, for the Company's August 2012 Private Placement (9)

10.6	Form of Subscription Agreement for the Company's October 2012 private placement (3)
10.7	Distribution Agreement, dated April 25, 2013, by and between the Labstyle Innovation Ltd. and Farla Medical Limited (10)
10.8	Form of Subscription Agreement for the Company's May 2013 Private Placement (4)
10.9	Securities Purchase Agreement, dated as of February 12, 2014, by and among the Company and the Buyers named therein in connection with the Company's February 2014 Private Placement (5)
10.10	Amendment, dated as of March 20, 2014, by and among the Company and the Buyers named therein in connection with the Company's February 2014 Private Placement (11)
10.11	Form of Amendment and Exchange Agreement, dated August 15, 2014, entered into between the Company and the several investors in the Company's February 2014 Private Placement (12)
10.12	Securities Purchase Agreement, dated as of September 24, 2014, by and among the Company and the Purchaser named therein in connection with the Company's September 2014 Private Placement (2)
10.13	Personal Employment Agreement, dated January 8, 2015, between the Company and Zvi Ben David+ (13)
10.14	Securities Purchase Agreement, dated as of February 25, 2015, by and among the Company and the Purchaser named therein in connection with the Company's February 2015 Private Placement (14)
10.15	Form of Warrant Exercise and Replacement Agreement (15)
10.16	Amended and Restated 2012 Equity Incentive Plan of the Company+(16)
10.20	Form of Securities Purchase Agreement by and among the Company and the Purchasers named therein in connection with the Company's July 2015 Private Placement (1)
10.21	Form of Warrant Replacement Agreement (17)
10.22	Form of Securities Purchase Agreement by and among the Company and the Purchasers named therein in connection with the Company's November 2015 Private Placement (18)
10.23	Form of Securities Purchase Agreement by and among the Company and the Purchasers named therein in connection with the Company's December 2015 Private Placement(7)
10.24	Agreement between the Company, Dicilyon Consulting and Investment Ltd. and David Edery, dated August 10, 2016 (19)
10.25	Form of Warrant Amendment Agreement (20)
10.26	Form of Securities Purchase Agreement for March 2016 Private Placement (21)
10.27	Securities Purchase Agreement between the Company and OurCrowd Digital Health L.P., dated January 9, 2017 (22)
10.28	Form of Registration Rights Agreement by and between the Company and OurCrowd in connection with the Company's January 2017 Private Placement (22)
10.29	Securities Purchase Agreement between the Company and Shmuel Farhi, dated January 9, 2017 (22)
10.30	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 (22)
10.31	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 (22)
21.1	List of Subsidiaries of the Company (7)
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 12, 2015.

(2) Incorporated by reference to the Company's Current Report on Form 8-K, filed with the Securities and Exchange Commission on September 24, 2014.

(3) Incorporated by reference to the Company's Registration Statement on Form S-1, filed with the Securities and Exchange Commission on January 16, 2013.

(4) Incorporated by reference to the Company's Current Report on Form 8-K, filed with the Securities and Exchange Commission on May 13, 2013.
(5) Incorporated by reference to the Company's Current Report on Form 8-K, filed with the Securities and Exchange Commission on February 13, 2014.
(6) Incorporated by reference to the Company's Current Report on Form 8-K, filed with the Securities and Exchange Commission on September 24, 2014.
(7) Incorporated by reference to the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on on February 8, 2016.
(8) Incorporated by reference to the Company's Current Report on Form 8-K, filed with the Securities and Exchange Commission on September 6, 2013.
(9) Incorporated by reference to the Company's Registration Statement on Form S-1, filed with the Securities and Exchange Commission on February 12, 2013.
(10) Incorporated by reference to the Company's Current Report on Form 8-K, filed with the Securities and Exchange Commission on April 30, 2013.
(11) Incorporated by reference to the Company's Registration Statement on Form S-1, filed with the Securities and Exchange Commission on March 20, 2014.
(12) Incorporated by reference to the Company's Current Report on Form 8-K, filed with the Securities and Exchange Commission on August 18, 2014.
(13) Incorporated by reference to the Company's Current Report on Form 8-K, filed with the Securities and Exchange Commission on January 9, 2015.
(14) Incorporated by reference to the Company's Current Report on Form 8-K, filed with the Securities and Exchange Commission on February 26, 2015.
(15) Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 20, 2015.
(16) Incorporated by reference to the Company's Definitive Proxy Statement filed with the Securities and Exchange Commission on October 19, 2016.
(17) Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 2, 2015.
(18) Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on November 19, 2015.
(19) Incorporated by reference to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 10, 2016.
(20) Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 28, 2016.
(21) Incorporated by reference to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 9, 2016.
(22) Incorporated by reference to the Company's Registration Statement on Form S-3, filed with the Securities and Exchange Commission on March 10, 2017.

Item 16. Form 10-K Summary.

None.

DARIOHEALTH CORP. AND ITS SUBSIDIARIES
(Formerly: LABSTYLE INNOVATIONS CORP.)

CONSOLIDATED FINANCIAL STATEMENTS

AS OF DECEMBER 31, 2016

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of

DARIOHEALTH CORP.

We have audited the accompanying consolidated balance sheets of DarioHealth Corp. (the "Company") and its subsidiaries as of December 31, 2016 and 2015, and 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, 2016. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above, present fairly, in all material respects, the consolidated financial position of the Company and its subsidiaries at December 31, 2016 and 2015, and the consolidated results of their operations and their cash flows for each of the two years in the period ended December 31, 2016, in conformity with U.S. generally accepted accounting principles.

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 consolidated financial statements, the Company has recurring losses from operations and has limited liquidity resources that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1c. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Tel-Aviv, Israel
March 22, 2017

/s/ KOST FORER GABBAY & KASIERER
A Member of Ernst & Young Global

DARIOHEALTH CORP. (FORMERLY LABSTYLE INNOVATIONS CORP.) AND ITS SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands

	December 31,	
	2016	**2015**
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 1,093	$ 2,671
Short-term bank deposits	225	80
Trade Receivables	226	-
Inventories	888	601
Other accounts receivable and prepaid expenses	504	935
Total current assets	2,936	4,287
LEASE DEPOSITS	35	41
PROPERTY AND EQUIPMENT, NET	901	749
Total assets	$ 3,872	$ 5,077

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

DARIOHEALTH CORP. (FORMERLY LABSTYLE INNOVATIONS CORP.) AND ITS SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

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

	December 31,	
	2016	**2015**
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIENCY)		
CURRENT LIABILITIES:		
Trade payables	$ 1,812	$ 978
Deferred revenues	-	31
Other accounts payable and accrued expenses	1,113	681
Total current liabilities	2,925	1,690
LIABILITY RELATED TO WARRANTS	7,488	2,610
COMMITMENTS AND CONTINGENT LIABILITIES		
CONVERTIBLE PREFERRED SHARES:		
Series A Preferred Stock of $0.0001 par value - Authorized: 60,000 shares at December 31, 2016 and 2015; Issued and Outstanding: None and 1,984 shares at December 31, 2016 and December 31, 2015, respectively	-	2,357
STOCKHOLDERS' EQUITY (DEFICIENCY)		
Common Stock of $0.0001 par value - Authorized: 160,000,000 shares at December 31, 2016 and 2015; Issued and Outstanding: 5,713,383 and 2,911,788 shares at December 31, 2016 and 2015, respectively	6	5
Preferred Stock of $0.0001 par value - Authorized: 5,000,000 shares at December 31, 2016 and 2015; Issued and Outstanding: None at December 31, 2016 and December 31, 2015	-	-
Additional paid-in capital	48,413	41,769
Accumulated deficit	(54,960)	(43,354)
Total stockholders' equity (deficiency)	(6,541)	(1,580)
Total liabilities and stockholders' equity (deficiency)	$ 3,872	$ 5,077

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

DARIOHEALTH CORP. (FORMERLY LABSTYLE INNOVATIONS CORP.) AND ITS SUBSIDIARIES

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

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

	Year ended December 31,	
	2016	**2015**
Revenues	$ 2,803	$ 823
Cost of revenues	3,364	1,678
Impairment of production line	269	-
Gross loss	830	855
Operating expenses:		
Research and development	$ 2,154	$ 2,565
Sales and marketing	4,739	1,330
General and administrative	3,378	2,948
Total operating expenses	10,271	6,843
Operating loss	11,101	7,698
Financial expenses (income), net:		
Revaluation of warrants	(260)	(571)
Other financial expense, net	46	15
Total financial expenses (income), net	(214)	(556)
Net loss	$ 10,887	$ 7,142
Deemed dividend related to May 2015 exchange agreement	-	154
Deemed dividend related to Series A Preferred Stock exchange agreement	455	-
Deemed dividend related to extension of July 2015 Series A warrants in July 2016	265	-
Net loss attributable to holders of Common Stock	$ 11,607	$ 7,296
Net loss per share:		
Basic and diluted loss per share	$ 2.09	$ 3.84
Weighted average number of Common Stock used in computing basic and diluted net loss per share	5,202,974	1,897,755

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

DARIOHEALTH CORP. (FORMERLY LABSTYLE INNOVATIONS CORP.) AND ITS SUBSIDIARIES

STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIENCY)

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

	Common Stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity (deficiency)
	Number	Amount			
Balance as of December 31, 2014	902,068	$ 2	$ 30,761	$ (36,058)	$ (5,295)
Issuance of Common Stock and warrants in February 2015 at $3.24 per unit, net of issuance cost	627,035	1	1,955	-	1,956
Issuance of Common Stock in July and August 2015 at $5.40 per unit, net of issuance cost	480,368	1	2,324	-	2,325
Issuance of Common stock in November 2015 at $5.40 per unit, net of issuance cost	446,223	1	2,293	-	2,294
Issuance of Common stock in December 2015 at $6.16 per unit, net of issuance cost	81,222	*)-	500	-	500
Issuance of Common Stock in April, August and December 2015 to service provider	16,668	*)-	118	-	118
Issuance of Common Stock in September 2015 to employees as compensation	97,121	*)-	591	-	591
Issuance of Common Stock in September 2015 to service provider	2,778	*)-	16	-	16
Payment for executives and directors under Salary Program	55,474	*)-	304	-	304
Exercise of warrants into Common Stock in May 2015, net of issuance cost	106,881	*)-	453	-	453
Deemed dividend related to inducement of warrant exercise in May 2015	-	-	154	(154)	-
Issuance of warrants related to warrant replacement agreement in November and December 2015	-	-	822	-	822
Receipts on account of shares	-	-	20	-	20
Conversion of Series A Preferred Stock into Common Stock	84,812	*)-	400	-	400
Exercise of warrants	10,804	*)-	60	-	60
Exercise of options	334	*)-	*)-	-	*)-
Stock-based compensation	-	-	998	-	998
Net loss	-	-	-	(7,142)	(7,142)
Balance as of December 31, 2015	2,911,788	$ 5	$ 41,769	$ (43,354)	$ (1,580)
Issuance of Common Stock in March 2016 Public Offering, net of issuance cost	1,333,333	1	1,571	-	1,572
Issuance of Common Stock in March 2016 Private Placement, net of issuance cost	599,999	*) -	828	-	828
Issuance of Common Stock in January 2016 to service provider	5,556	*) -	37	-	37
Payment for executives, employee and directors under Salary Program	57,910	*) -	310	-	310
Issuance of Common Stock in March 2016 to officer	20,000	*) -	86	-	86
Exercise of warrants into Common Stock, net of issuance cost	77,019	*) -	210	-	210
Exercise of non plan options	84,106	*) -	*) -	-	*) -
Deemed dividend related to Series A Preferred Stock exchange agreement into Common Stock in March 2016	124,737	-	455	(455)	-
Deemed dividend related to extension of July 2015 Series A warrants in July 2016	-	-	265	(265)	-
Conversion of Series A Preferred Stock into Common Stock	498,935	*) -	2,277	-	2,277
Stock-based compensation	-	-	605	-	605
Net loss	-	-	-	(10,887)	(10,887)
Balance as of December 31, 2016	5,713,383	$ 6	$ 48,413	$ (54,960)	$ (6,541)

*) Represents an amount lower than $1.

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

DARIOHEALTH CORP. (FORMERLY LABSTYLE INNOVATIONS CORP.) AND ITS SUBSIDIARIES

CONSOLIDATED STATEMENT OF CASH FLOWS

U.S. dollars in thousands

	Year ended December 31,	
	2016	**2015**
Cash flows from operating activities:		
Net loss	$ (10,887)	$ (7,142)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Stock-based compensation and Common Stock to service providers	1,038	1,723
Depreciation	387	335
Write-off of a production line	269	-
Increase in trade receivables	(226)	-
Increase (decrease) in deferred revenues	(31)	7
Decrease (increase) in other accounts receivable and prepaid expenses	406	(649)
Increase in inventories	(287)	(366)
Increase in trade payables	834	292
Increase in other accounts payable and accrued expenses	378	102
Change in the fair value of warrants to purchase shares of Common Stock	(260)	(571)
Loss from disposal of fixed assets	-	(8)
Net cash used in operating activities	(8,379)	(6,277)
Cash flows from investing activities:		
Investment in short-term bank deposits	(145)	(282)
Proceeds of maturities of short-term bank deposit	-	285
Investment in lease deposit, net	6	(6)
Purchase of property and equipment	(808)	(110)
Net cash used in investing activities	(947)	(113)
Cash flows from financing activities:		
Proceeds from issuance of Common Stocks and warrants, net of issuance cost	7,538	7,075
Proceeds from exercise of options and warrants	210	533
Net cash provided by financing activities	7,748	7,608
Increase (decrease) in cash and cash equivalents	(1,578)	1,218
Cash and cash equivalents at beginning of year	2,671	1,453
Cash and cash equivalents at end of year	$ 1,093	$ 2,671
Non-cash investing and financing activities:		
Purchase of property and equipment	$ -	$ 27
Classification of liability related to warrants as a result of September 2014 round Replacement Agreement	$ -	$ 822
Conversion of Series A Preferred Stock to Common stock	$ 2,277	$ 400
Payment for executives and directors under Salary Program	$ 154	$ 304

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

NOTE 1:- GENERAL

a. DarioHealth Corp. (formerly LabStyle Innovations 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 we call 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.

c. During the year ended December 31, 2016, the Company incurred operating losses and negative cash flows from operating activities amounting to $11,101 and $8,379, 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. According to management estimates, the Company has sufficient liquidity resources to continue its planned activity into July 2017.

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.

NOTE 1:- GENERAL (Cont.)

e. On February 17, 2016, the Company's Board of Directors approved approved a reverse split in a ratio of one-to-eighteen (the "2016 Reverse Split"). The 2016 Reverse Split was implemented on February 26, 2016. The amount of authorized Common Stock as well as the par value for the Common Stock were not affected. All issued and outstanding share and per share amounts included in the accompanying consolidated financial statements have been adjusted to reflect this reverse stock split for all periods presented.

f. 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. generally accepted accounting principles ("GAAP") and the Company's discussion and analysis of its financial condition and operating results require 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.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

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, its Subsidiary and LabStyle US. 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 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 0.1% and 0.01% as of December 31, 2016 and 2015, respectively. The short-term bank deposits are presented at their cost, including accrued interest.

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, 2016 and 2015 amounted to $315 and $193, respectively.

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

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

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.

During the year ended December 31, 2016, the Company decided to cease the operation of one of its production lines and performed a recoverability test for such long-lived assets. Based on its analysis, the Company recorded a non-cash charge with respect to impairment of its production line in the amount of $268. This charge was recorded as a separate line in the consolidated statements of comprehensive loss. During the year ended December 31, 2015, no impairment loss has been recorded.

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 Dario™ Smart Meter 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.

Commencing July 1, 2016, product sales to distributors are recognized as revenues upon delivery, when the fee is fixed or determinable and collectability is probable.

The Company also generates revenues from arrangements with health care providers which include supply of Dario™ Smart Meters and software platform that requires certain customization followed by monthly service, support and maintenance.

When a sales arrangement contains multiple elements, such as software and non-software components, 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. The determination of ESP is judgmental.

Revenues from software components in sales arrangement contains multiple elements are recognized when all criteria outlined in ASC 985-605, “Software Revenue Recognition” (“ASC 985-605”), are met. Revenue from services is 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.

For multiple element arrangements within ASC 985-605, revenues are allocated to the different elements in the arrangement under the “residual method” when VSOE of fair value exist for all undelivered elements and no VSOE exists for the delivered elements. Under the residual method, at the outset of the arrangement with the customer, the fair value of the undelivered elements is deferred and the remaining portion of the arrangement fee is allocated to the delivered elements and is recognized as revenue when the basic criteria in ASC 985-605 have been met. Any discount in the arrangement is allocated to the delivered element.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

Revenue recognition (Cont.):

Since VSOE does not exist for undelivered elements, revenues are recognized as one unit of accounting, on a straight-line basis over the term of the last deliverable based on ASC 605-15, “Products” and ASC 985-605.

Deferred revenues include advances and payments received from customers, for which revenue has not yet been recognized.

k. Cost of revenues and ramp up of manufacturing:

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.

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, 2016 and 2015, a full valuation allowance was provided by the Company.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

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, 2016 and 2015, 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. Series A Preferred Stock:

In 2015, the Company classified the Series A Preferred Stock (as defined in Note 9b) outside of Stockholders' deficiency because certain features of the COI would require redemption of some or all of the Series A Preferred Stock upon events not solely within the control of the Company.

p. Warrants:

The Company accounts for certain warrants held by investors and the Company’s previous placement agent and its permitted designees which include priced-based anti-dilution protection or certain net settlement cash features and liquidated damages penalties 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 Binomial 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.

q. 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.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

Accounting for stock-based compensation (Cont.):

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 volatilities of similar entities in the related sector index until the Company's own volatility data will be reliable. 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.

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

Until the Company received a ticker symbol for its Common Stock and caused the Common Stock to be eligible for trading on April 9, 2013, The fair value of the shares of Common Stock underlying the options and warrants granted through such date, had been determined by the Company's management with assistance of an independent valuation firm by applying of market approach using recent third-party transactions in the equity of the Company.

r. 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.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

Fair value of financial instruments (Cont.):

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 are 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.

s. 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 weighted average 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 3,208,430 and 1,026,661 for the year ended December 31, 2016 and 2015, respectively.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

t. 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

u. 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.

v. Impact of recently issued accounting pronouncements:

In May 2014, the Financial Accounting Standards Board (“FASB”) issued ASU 2014-09, “Revenue from Contracts with Customers” (“ASU 2014-09”), which will replace most of the existing revenue recognition guidance under U.S. GAAP. The core principle of ASU 2014-09 is that an entity should recognize revenue for the transfer of goods or services equal to the amount that it expects to be entitled to receive for those goods or services. ASU 2014-09 requires additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments. In August 2015, the FASB issued ASU 2015-14, "Revenue from Contracts with Customers (Topic 606)," which defers the effective date of ASU 2014-09 by one year to fiscal years beginning after December 15, 2018, and interim reporting periods within annual reporting periods beginning after December 15, 2019, with early adoption permitted. The Company is in the process of determining the method of adoption and assessing the impact of ASU 2014-09 on the Company’s consolidated financial position, results of operations and cash flows.

In March 2016, the Financial Accounting Standards Board issued Accounting Standards Update No. 2016-09, “Compensation – Stock Compensation (Topic 718),” which changes the accounting for certain aspects of share-based payments to employees. The new guidance requires excess tax benefits and tax deficiencies be recorded in the income statement when the awards vest or are settled. In addition, cash flows related to excess tax benefits will no longer be separately classified as a financing activity apart from other income tax cash flows. The standard also allows us to repurchase more of each employee’s shares for tax withholding purposes without triggering liability accounting, clarifies that all cash payments made on an employee’s behalf for withheld shares should be presented as a financing activity on our cash flows statement, and provides an accounting policy election to account for forfeitures as they occur.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

Impact of recently issued accounting pronouncements (Cont.):

The new standard is effective for us beginning January 1, 2017. The adoption of this guidance is not expected to have a material impact on the Company's financial statements.

In February 2016, the FASB issued ASU No. 2016-02, "Leases (Topic 842)," which is intended to increase the transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements. In order to meet that objective, the new standard requires recognition of the assets and liabilities that arise from leases. A lessee will be required to recognize on the balance sheet the assets and liabilities for leases with lease terms of more than 12 months. Accounting by lessors will remain largely unchanged from current U.S. generally accepted accounting principles. The new standard is effective for public companies for fiscal years beginning after December 15, 2019, and interim periods within those years, with early adoption permitted. The Company is currently evaluating the effect that adopting this standard will have on the financial statements and related disclosures.

In August 2014, the FASB issued ASU 2014-15, "Presentation of Financial Statements-Going Concern" (Subtopic 205-40): "Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern" ("ASU 2014-15"), which defines management's responsibility to assess an entity's ability to continue as a going concern, and to provide related footnote disclosures if there is substantial doubt about its ability to continue as a going concern. ASU 2014-15 is effective for annual reporting periods ending after December 15, 2016 with early adoption permitted. The adoption of this guidance did not have a material impact on the Company's financial statements.

In July 2015, the FASB issued ASU No. 2015-11, "Inventory (Topic 330): Simplifying the Measurement of Inventory." Under this accounting guidance, inventory will be measured at the lower of cost and net realizable value and other options that currently exist for market value will be eliminated. ASU No. 2015-11 defines net realizable value as the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. No other changes were made to the current guidance on inventory measurement. ASU 2015-11 is effective for fiscal years beginning after December 15, 2016, and interim periods within fiscal years beginning after December 15, 2017, with early adoption permitted. The adoption of this guidance did not have a material impact on the Company's financial statements.

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

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

Impact of recently issued accounting pronouncements (Cont.):

In November 2015, the FASB issued ASU No. 2015-17, "Income Taxes – Balance Sheet Classification of Deferred Taxes" ("ASU 2015-17"). The purpose of the standard is to simplify the presentation of deferred taxes on a classified balance sheet. Under current GAAP, deferred income tax assets and liabilities are separated into current and noncurrent amounts in the balance sheet. The amendments in ASU 2015-17 require that all deferred tax assets and liabilities be classified as noncurrent in the balance sheet. ASU 2015-17 is effective for interim and annual periods beginning after December 15, 2017, and interim periods within annual periods beginning after December 15, 2018. Companies can adopt the guidance either prospectively or retrospectively. The Company does not expect the adoption of ASU 2015-17 to have a material impact on its consolidated financial statements or presentation.

NOTE 3:- OTHER ACCOUNTS RECEIVABLE AND PREPAID EXPENSES

	December 31,	
	2016	**2015**
Prepaid expenses	$ 440	$ 622
Government authorities	64	22
Deferred costs (*)	-	291
	$ 504	$ 935

(*) Inventory delivered to customers for which revenue criteria have not been met.

NOTE 4:- INVENTORIES

	December 31,	
	2016	**2015**
Raw materials	$ 431	$ 469
Finished products	457	132
	$ 888	$ 601

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

NOTE 5:- PROPERTY AND EQUIPMENT, NET

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

	December 31,	
	2016	2015
Cost:		
Computers and peripheral equipment	$ 244	$ 209
Office furniture and equipment	74	62
Production lines	817	903
Leasehold improvement	52	7
	1,187	1,181
Accumulated depreciation:		
Computers and peripheral equipment	175	140
Office furniture and equipment	15	12
Production lines	92	276
Leasehold improvement	4	4
	286	432
Property and equipment, net	$ 901	$ 749

Depreciation expenses for the year ended December 31, 2016 and 2015 amounted to $ 387 and $335, respectively.

NOTE 6:- OTHER ACCOUNTS PAYABLE AND ACCRUED EXPENSES

	December 31,	
	2016	2015
Employees and payroll accruals	$ 491	$ 247
Accrued expenses	622	434
	$ 1,113	$ 681

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

NOTE 7:- COMMITMENTS AND CONTINGENT LIABILITIES

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

Ltd. is party to a lease agreement in Israel for a period of 60 months that is expected to commence towards the third quarter of 2017 when the facility will be available to Ltd., in the meantime the landlord has extended Ltd.'s stay in the current premises.

Commencing November 13, 2011 and through the year ended 2016, Ltd. also entered into several motor vehicle lease agreements for a period of 36 months. As of December 31, 2016 the Company maintains 10 leased cars.

b. In December 2015 the Company entered into a lease agreement in the United States for its offices for a period of 12 months commencing February 1, 2016 and scheduled to expire on January 31, 2017.

c. As of December 31, 2016, the future minimum aggregate lease commitments under non-cancelable operating lease agreements are as follows:

As of ended December 31,	Facilities	Motor vehicles	Total
2017	120	130	250
2018	1	73	74
2019	-	36	36
	$ 121	$ 239	$ 360

Facility and motor vehicle lease expenses for the year ended December 31, 2016 and 2015 were $280 and $232, respectively.

d. As of December 31, 2016, Ltd. established guarantees to cover rent agreements and credit cards commitments that amounted to $153.

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

NOTE 8:- TAXES ON INCOME

a. The Company and Ltd. are separately taxed under the domestic tax laws of the state of incorporation of each entity. LabStyle US is a pass through entity for U.S. income tax purposes.

b. Tax rates applicable to Ltd.:

Corporate tax rate in Israel in 2015 26.5% and 2016 is 25%.

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.

c. Net operating loss carryforward:

Ltd. has accumulated net operating losses for Israeli income tax purposes as of December 31, 2016 in the amount of approximately $6,961. The net operating losses may be carried forward and offset against taxable income in the future for an indefinite period.

As of December 31, 2016, the Company had a U.S. federal net operating loss carryforward of approximately $9,756 that can be carried forward and offset against taxable income and that expires during the years 2031 to 2035. Utilization of U.S. loss carryforward may be subject to substantial annual limitation due to the "change in ownership" provisions of the Internal Revenue Code of 1986 and similar state provisions. The annual limitations may result in the expiration of losses before utilization.

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,	
	2016	**2015**
Deferred tax assets:		
Net operating loss carry forward	$ 9,944	$ 6,900
Temporary differences	445	713
Deferred tax assets before valuation allowance	10,389	7,613
Valuation allowance	(10,389)	(7,613)
Net deferred tax asset	$ -	$ -

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

NOTE 8:- TAXES ON INCOME (Cont.)

Deferred income taxes (Cont.):

The deferred tax balances included in the financial statements as of December 31, 2016 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.

The net change in the total valuation allowance for the year ended December 31, 2016 was an increase of $2,776 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,	
	2016	**2015**
Domestic	$ 3,972	$ 783
Foreign	6,915	6,359
	$ 10,887	$ 7,142

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' DEFICIT AND CONVERTIBLE PREFERRED SHARES

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 September 23, 2014, the Company consummated the final closing of a private placement with existing and new institutional and accredited investors (the "September 2014 Private Placement") pursuant to which the Company raised $4,096 in net proceeds by issuance of aggregate 2,359 units which consist of 2,359 shares of newly designated Series A Convertible Preferred Stock (the "Series A Preferred Stock") which are convertible into up to an aggregate of 593,546 shares of Common Stock, and warrants to purchase 296,775 shares of Common Stock with an exercise price of $8.56 per share which is subject to a standard anti-dilution protection clause. Such warrants contain a net settlement cash feature and liquidated damages penalties and therefore accounted as a liability according to the provisions of ASC 815-40 "Contracts in entity's own equity".

The holders of Series A Preferred Stock have rights, preferences and privileges, as follows:

Liquidation preference - Based on preference of distribution, the holders of Series A Preferred Stock shall be entitled to receive, out of funds legally available thereof, as determined by the Company's Board of Directors, dividends at an amount per share which is equal (on an as converted to Common Stock basis) to and in the same form as dividends actually paid on shares of Common Stock, as and if such dividends are paid on shares of Common Stock.

Based on preference of any distribution, liquidation, dissolution or winding up of the Company, whether voluntary or involuntary, including, without limitation, upon any deemed liquidation as determined in the COI, the Company's assets or surplus funds legally available for distribution shall be distributed to the holders of Series A Preferred Stock pursuant to which each Series A Preferred Stock will be entitled to receive the original issue price paid by each Series A Preferred stockholder, plus all accrued but unpaid dividends for each share of Common Stock.

NOTE 9:- STOCKHOLDERS' DEFICIT AND CONVERTIBLE PREFERRED SHARES (Cont.)

Preemptive rights - One Series A Preferred Stockholder has a preemptive right to participate in future financings for a period of two years in an amount necessary to maintain such investor's fully-diluted percentage interest in the Company.

Voting - Each stockholder shall have one vote for each share of Common Stock held by such stockholder of record of such Common Stock as would be held by each holder of Series A Preferred Stock if all shares of Series A Preferred Stock were converted to Common Stock at the then effective conversion rate, on every resolution.

Conversion - Each holder of a Series A Preferred Stock shall be entitled to convert, at any time and from time to time, and without payment of additional consideration, into such number of fully paid and non-assessable shares of Common Stock in ratio as determined in the COI. The conversion price shall be subject to standard anti-dilution adjustments as described in the COI.

Upon the written election of the holders of a majority of the outstanding Series A Preferred Stock, all shares of Series A Preferred Stock shall automatically be converted into fully paid and non-assessable shares of Common Stock.

During 2015, 335 shares of Series A Preferred Stock have been converted into 84,812 shares of Common Stock and therefore an amount of $400 was credited to additional paid in capital in the Company's statement of changes in stockholders' deficiency.

On February 18, 2016, the Company entered into a Preferred Stock Conversion Agreement (the "Preferred Stock Conversion Agreement") with the holders of the Series A Preferred Stock according to which the then currently outstanding 1,984 shares of the Series A Preferred Stock would be converted into 623,672 shares of our Common Stock, reflecting an increase of 25% in the original number of shares of Common Stock issuable upon conversion of the Series A Preferred Stock. Accordingly, in March 2016 the Company issued to the remaining Purchasers 623,672 shares of Common Stock and recorded an increase of $2,277 to additional paid in capital, net of issuance costs. The increase of 25% in the original number of shares of Common Stock issued to holders of the Series A Preferred Stock was accounted for as change in the conversion terms in the Company's financial statements and a deemed dividend in the amount of $455 was recorded to the Statement of Changes in Equity (Deficiency).

c. On February 25, 2015 and March 16, 2015, the Company completed two closings of a private placement (the "February 2015 Private Placement") with existing and new institutional and accredited investors and raised $1,956 in net proceeds through the issuance of 627,035 shares of Common Stock, and series A warrants to purchase 156,769 shares of Common Stock (the "Series A Warrants") and series B warrants to purchase 156,769 shares of Common Stock (the "Series B Warrants"). Out of the above issuance, 63,889 shares of Common Stock, 15,973 Series A Warrants and 15,973 Series B Warrants were purchased by the Chief Financial Officer of the Company for gross proceeds of $207 and 61,729 shares of Common Stock, 15,433 Series A Warrants and 15,433 Series B Warrants were purchased by one of the directors of the Company for gross proceeds of $200.

NOTE 9:- STOCKHOLDERS' DEFICIT AND CONVERTIBLE PREFERRED SHARES (Cont.)

The Series A Warrants are immediately exercisable at an exercise price of $4.32 per share and expire 9 months from the closing of the February 2015 Private Placement in which such warrants were purchased. The Series B Warrants are immediately exercisable at an exercise price of $5.40 per share and expire 36 months from the closing of the February 2015 Private Placement in which such warrants were purchased. The Series A Warrants and the Series B Warrants contain a standard anti-dilution protection clause.

The Series B Warrants are callable by the Company for nominal consideration in the event that the share price of the Common Stock trades over $14.40 (adjusted for splits and the like) for 20 consecutive trading days.

With respect to the February 2015 Private Placement the Company entered into a finder’s fee agreement with a finder according to which the finder shall receive a cash fee of approximately $43 and immediately exercisable warrants to purchase: i) 13,415 shares of Common Stock with an exercise price of $3.24, with a “cashless exercise” feature and which are exercisable by February 25, 2018; ii) 3,355 shares of Common Stock with an exercise price of $4.32 which expired on November 25, 2015; and iii) 3,355 shares of Common Stock with an exercise price of $5.40 and which are exercisable by February 25, 2018. All finders' warrants contain a standard anti-dilution protection clause.

d. On April 3, 2015, the Company's Board of Directors approved the following:

1. To reserve 22,224 shares of Common Stock under the terms of an engagement agreement with a service provider (“Service Provider Agreement”) dated March 15, 2015 (the “Effective Date”) offering investor relations services (“Services”) to the Company. The Service Provider Agreement is for a period of one year beginning with the Effective Date (the “Term”), pursuant to which in addition to monthly retainer Company shall issue 5,556 shares of Common Stock on a quarterly basis over the Term in consideration for the Services. The Company recorded General and Administrative expenses amounting to $37 and $118 in connection with 5,556 and 16,668 shares of Common Stock that have been issued during the years ended December 31, 2016 and 2015, respectively.

NOTE 9:- STOCKHOLDERS' DEFICIT AND CONVERTIBLE PREFERRED SHARES (Cont.)

2. A salary program pursuant to which the Company will issue up to 122,223 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 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, 2016 and 2015, the Company issued 57,910 and 55,474, respectively, Compensation Shares to certain members of the Board of Directors and officers as consideration for a waiver of cash owed to such individuals amounting to $310 and $304, respectively.

e. On May 5, 2015 (the "Commitment Date"), the Company's Board of Directors approved a warrant exercise and replacement agreement according to which upon the Company's request for a period of eight business days the holders of warrants from the February 2015 Private Placement were able to exercise for cash their outstanding 160,123 warrants. Upon such exercise, the Company issued the participating holders additional warrants to purchase the same number of additional shares of Common Stock, for an exercise price of $4.32 per share, having the same terms and conditions of the exercised warrants.

   The transaction was accounted for in accordance with ASC 470-20 "Debt with Conversion and Other Options" ("ASC 470"), pursuant to which the induced conversion privileges are exercisable only for a limited period of time and includes the issuance of all of the equity securities issuable pursuant to conversion privileges included in the terms of the warrants at issuance for each warrant instrument that is converted. Therefore, the induced conversion was accounted for as a deemed dividend and measured at the Commitment Date in a total amount of $154.

   Under this offer, 106,881 warrants were exercised into 106,881 shares of Common Stock for a total net consideration of $453.

f. On July 23, 2015 and August 28, 2015, the Company completed two closings of a private placement (the "July 2015 Private Placement") with existing and new institutional and retail investors and raised approximately $2,325 in net proceeds through the issuance of 480,368 shares of Common Stock, and series A warrants to purchase 261,677 shares of Common Stock (the "2015 Series A Warrants") and Series B Warrants to purchase 261,677 shares of Common Stock (the "2015 Series B Warrants") and 24,954 shares of Common Stock underlying Placement Agent Warrants. Out of the above issuance, 41,667 shares of Common Stock, 20,834 2015 Series A Warrants and 20,834 2015 Series B Warrants were purchased by the Chief Financial Officer of the Company for gross proceeds of $225 and 2,223 shares of Common Stock, 1,112 2015 Series A Warrants and 1,112 2015 Series B Warrants were purchased by the Chief Executive Officer of the Company for gross proceeds of $12. Out of the above issuances, 13,630 and 2,778 restricted shares of Common Stock were issued to finders and to a placement agent, respectively. In addition, the Company also issued to a finder 20,793 non-plan stock options.

NOTE 9:- STOCKHOLDERS' DEFICIT AND CONVERTIBLE PREFERRED SHARES (Cont.)

The 2015 Series A Warrants are immediately exercisable at an exercise price of $6.30 per share and expire 12 months from the closing date. The 2015 Series B Warrants are immediately exercisable at an exercise price of $7.20 per share and expire 36 months from the closing date. The 2015 Series A and Series B Warrants are exercisable for cash or on a cashless basis if a registration statement covering the shares issuable upon exercise of the Warrants is unavailable. The non-plan stock options issued to the finder are fully vested and exercisable after the lapse of four months from the grant date in December 2015.

With respect to the July 2015 Private Placement, the Company entered into finder's fee agreements with certain finders according to which the finders received 13,630 restricted shares of Common Stock and 34,424 warrants, evenly divided between “Series A Finders Warrants” and “Series B Finders Warrants”. The Series A Finders Warrants are exercisable at an exercise price of $6.30 per share and expire 12 months from the date of the closing of the July 2015 Private Placement at which such warrants were issued. The Series B Finders Warrants are exercisable at an exercise price of $7.20 per share and expire 3 years from the date of the closing of the July 2015 Private Placement at which such warrants were issued.

Issuance costs related to the July 2015 Private Placement were approximately $181 ($122 out of which related to the placement agent). In addition, the Company issued to the placement agent 2,778 restricted shares of Common Stock and an aggregate of 49,910 warrants to the placement agent and to a selected dealer (the “Placement Agent Warrants”). The Company issued three types of Placement Agent Warrants, of which (i) the first will have an exercise price of $5.40 per share exercisable over a period of three years, (ii) the second will have an exercise price of $6.30 per share, exercisable over a period of one year; and (iii) the third will have an exercise price of $7.20 per share, exercisable over a period of three years. The Placement Agent Warrants are exercisable for cash or on a cashless basis and have similar registration rights as the shares but also include piggyback registration rights.

The July 2015 Private Placement triggered the anti-dilution mechanism of the warrants issued in the 2011-2012 Private Placement by adjusting the current exercise price of the warrants for the investors and placement agent from $11.52 to $8.10 per share and an additional 128,173 and 24,409 shares became subject to such warrants, respectively. In addition, the exercise price of the placement agent's warrants in the 2011-2012 Private Placement, was adjusted from $9.54 to $6.84 per share and an additional 17,327 warrants were issued.

g. On September 3, 2015, the Company's Board of Directors approved the issuance of 97,121 shares of Common Stock under the 2012 Equity Incentive Plan to certain employees according to the Israeli sub-plan. Consequently, the Company recorded in 2015 General and Administrative and Research and Development expenses amounting to $514 and $77, respectively.

NOTE 9:- STOCKHOLDERS' DEFICIT AND CONVERTIBLE PREFERRED SHARES (Cont.)

h. On September 17, 2015, the Company's Board of Directors approved the issuance of 2,778 shares of Common Stock to a service provider. Consequently, the Company recorded in 2015 General and Administrative expenses amounting to $16 in the statements of comprehensive loss.

i. On November 19, 2015 the Company completed a closing of a private placement (the "November 2015 Private Placement") with existing shareholders and private investors and raised approximately $2,924 in net proceeds through the issuance of 446,223 shares of Common Stock, 329,455 Series A Warrants (the "November 2015 Series A Warrants") and 141,205 Series B Warrants (the "November 2015 Series B Warrants"). Out of the above issuances, 21,304 restricted shares of Common Stock, 32,010 November 2015 Series A Warrants and 13,720 November 2015 Series B Warrants were issued to finders. In connection with the November 2015 Private Placement the Company also issued to a finder 24,424 non-plan stock options.

The November 2015 Series A Warrants are immediately exercisable at an exercise price of $6.66 per share and expire 16 months from the closing date. The November 2015 Series B Warrants are immediately exercisable at an exercise price of $7.74 per share and expire 36 months from the closing date. The November 2015 Series A Warrants and November 2015 Series B Warrants are eligible also for “cashless exercise” only if the underlying shares of Common Stock are not registered for resale.

With respect to the November 2015 Private Placement the Company entered into a finder’s fee agreements with certain finders according to which the finders received 21,304 restricted shares of Common Stock, 32,010 November 2015 Series A Warrants, 13,720 November 2015 Series B Warrants and 24,424 fully vested non-plan stock options having an exercise price of $0.0018. The non-plan stock options are fully vested and exercisable after the lapse of four months from the grant date in December 2015. The warrants issued to the finders are subject to the same terms as those issued to the investors.

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

NOTE 9:- STOCKHOLDERS' DEFICIT AND CONVERTIBLE PREFERRED SHARES (Cont.)

The November 2015 Private Placement triggered the anti-dilution mechanism of the warrants issued in the 2011-2012 Private Placement by adjusting the current exercise price of the warrants for the investors and placement agent from $8.10 to $6.48 per share and an additional 107,224 and 20,419 shares became subject to such warrants, respectively. In addition, the exercise price of the placement agent's warrants in the 2011-2012 Private Placement, was adjusted from $6.48 to $5.58 per share and an additional 13,888 warrants were issued.

On October 22 2015, the Company's Board of Directors approved a warrant replacement agreement (the "September 2014 round Replacement Agreement") with the September 2014 Private Placement Purchasers pursuant to which up to 296,775 outstanding warrants that contain a net settlement cash feature will be replaced by new warrants to acquire up to an aggregate of 326,454 shares of common stock at an exercise price of $8.559 per share, which warrants are subject to standard anti-dilution protections. Consequently, certain investors replaced 240,010 outstanding warrants that contain certain net settlement cash features by 264,012 new warrants to acquire an aggregate of 264,012 shares of Common Stock at an exercise price of $8.559 per share which are subject to standard anti-dilution protections and do not contain a net settlement cash feature. As of December 31, 2015 the Company's offer to the warrant holders expired.

The above replacement is considered as a modification of the warrants' terms of the September 2014 Private Placement. As a result, and in accordance with ASC 470 the incremental value that was generated to the particular Purchasers from the aforementioned exchanged warrants was recorded in 2015 as financial expenses in the amount of $75 in the consolidated statement of comprehensive loss.

The September 2014 round Replacement Agreement triggered the anti-dilution mechanism of the warrants issued in the 2011-2012 Private Placement and an additional 4,547 and 866 shares became subject to such warrants, respectively. In addition, 732 additional shares became subject to the warrants issued to the placement agent of the 2011-2012 Private Placement.

The table below presents the September 2014 Private Placement carrying value of the warrants issued in such placement:

	Year ended December 31, 2015
Fair value of warrants at beginning of year	$ 101
Revaluation of warrants during the year	1,099
Reclassification of warrants to additional paid-in capital upon warrant replacement agreement in November and December 2015	(822)
Fair value of warrants at the end of the year	$ 378

NOTE 9:- STOCKHOLDERS' DEFICIT AND CONVERTIBLE PREFERRED SHARES (Cont.)

j. On December 24, 2015, the Company completed a private placement (the “December 2015 Private Placement”) with a new investor and raised $500 in net proceeds through the issuance of 81,222 shares of Common Stock and warrants to purchase 81,222 shares of Common Stock (the "December 2015 Warrants"). The December 2015 Warrants are immediately exercisable at an exercise price of $6.16 per share and expire 6 months from the closing of the December 2015 Private Placement. The December 2015 Warrants are eligible also for “cashless exercise” only if the underlying shares of Common Stock are not registered for resale.

The December 2015 Private Placement triggered the anti-dilution mechanism of the warrants issued in the 2011-2012 Private Placement to the investors and placement agent by adjusting the current exercise price of the warrants from $6.48 to $6.30 per share and an additional 15,726 and 2,995 shares became subject to such warrants, respectively.

k. 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".

In addition, the Company granted to the underwriters 200,000 additional shares of Common Stock and 200,000 warrants (the “Option Warrants”) each to purchase one share of Common Stock at a purchase price of $4.185 per Share and $0.0093 per Warrant. In connection with the Public Offering, the Company agreed to issue to the representatives of the underwriters five-year warrants (the “Representatives’ Warrants”) to purchase up to 143,333 shares of Common Stock. In connection with the Public Offering, the Representatives’ Warrants are exercisable at a per share exercise price equal to $5.625 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 Representatives’ Warrants is available.

NOTE 9:- STOCKHOLDERS' DEFICIT AND CONVERTIBLE PREFERRED SHARES (Cont.)

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".

In connection with the Private Offering, the Company agreed to issue to two non-U.S. finders an aggregate of 44,444 restricted shares of Common Stock, 73,333 warrants to purchase Common Stock at an exercise price of $4.50 per share which expire 5 years from the date of issuance, and 38,889 non-plan stock options which have an exercise price of $0.0001 per share and are fully vested and exercisable after the lapse of four months from the grant date.

The Public Offering and Private Offering triggered the anti-dilution mechanism of the warrants issued in the 2011-2012 Private Placement to investors and placement agent by adjusting the current exercise price of the warrants from $6.30 to $3.59 per share and an additional 415,316 and 78,662 shares became subject to such warrants, respectively. In addition, the exercise price of the placement agent's warrants in the 2011-2012 Private Placement, was adjusted from $5.58 to $3.33 per share and an additional 48,054 warrants were issued.

l. In March 2016, the Company's Board of Directors approved the issuance of 20,000 shares of Common Stock under the 2012 Equity Incentive Plan to an officer according to the Israeli sub-plan. Consequently, the Company recorded General and Administrative expenses amounting to $86.

m. On July 23, 2015 and August 28, 2015, the Company completed two closings of a private placement (the "July 2015 Private Placement"). The Company issued in the July 2015 Private Placement series A warrants to purchase 261,677 shares of Common Stock (the "2015 Series A Warrants"). The 2015 Series A Warrants were immediately exercisable at an exercise price of $6.30 per share and expire 12 months from the closing date.

NOTE 9:- STOCKHOLDERS' DEFICIT AND CONVERTIBLE PREFERRED SHARES (Cont.)

In July 2016, following the request of substantially all of the buyers to amend the term of the existing warrants, the Company's Board of Directors approved a Warrant Amendment Agreement, according to which the term of the 2015 Series A Warrants were extended by one year and the exercise price was amended to $6.66 per share. This modification is considered a modification of the original terms of the 2015 Series A Warrants and therefore the Company recorded a deemed dividend in the amount of approximately $265 in the third quarter of 2016.

n. 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 our 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 has 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.

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

NOTE 9:- STOCKHOLDERS' DEFICIT AND CONVERTIBLE PREFERRED SHARES (Cont.)

o. The table below summarizes the outstanding warrants as of December 31, 2016:

	Warrants outstanding as of December 31, 2016	Exercise price $	Expiration date
September 2014 PPM	56,764	8.56	September 23, 2018
September 2014 PPM-Warrant Replacement Agreement	264,012	8.56	September 23, 2018
February 2015 PPM A (*)	4,630	4.32	November 25,2015
February 2015 PPM B	125,903	5.40	February 25,2018
February 2015 PPM A-Finders	13,415	3.24	February 25,2018
February 2015 PPM - C Finders	3,355	5.40	February 25,2018
February 2015 PPM - B 2nd closing	30,866	5.40	March 16, 2018
July 2015 PPM - 2015 Series A Warrants - 1st Closing	131,966	6.66	July 23, 2017
July 2015 PPM - 2015 Series B Warrants - 1st Closing	138,910	7.20	July 23, 2018
July 2015 PPM - 2015 Series A Warrants (Finder's warrants)	17,213	6.66	August 28, 2017
July 2015 PPM - 2015 Series B Warrants (Finder's warrants)	17,213	7.20	August 28, 2018
July 2015 PPM - 2015 Series A Warrants-2nd Closing	93,077	6.66	August 28, 2017
July 2015 PPM - 2015 Series B Warrants-2nd Closing	93,077	7.20	August 28, 2018
July 2015 PPM (PA) - 1st Closing	23,613	5.40	July 23, 2018
July 2015 PPM (PA) - 2015 Series A Warrants - 1st Closing	11,807	6.66	July 23, 2017
July 2015 PPM (PA) – 2015 Series B Warrants – 1st Closing	11,807	7.20	July 23, 2018
July 2015 PPM (PA) - 2nd Closing	1,341	5.40	August 28, 2018
July 2015 PPM (PA) - 2015 Series A Warrants - 2nd Closing	671	6.66	August 28, 2017
July 2015 PPM (PA) - 2015 Series B Warrants - 2nd Closing	671	7.20	August 28, 2018
November 2015 PPM - 2015 Series A Warrants (Finder's warrants)	32,010	6.66	March 19, 2017
November 2015 PPM - 2015 Series B Warrants (Finder's warrants)	13,720	7.74	November 19, 2018
November 2015 PPM - Series A Warrants	297,445	6.66	March 19, 2017
November 2015 PPM - Series B Warrants	127,485	7.74	November 19, 2018
March 2016 PPM – Warrants	1,528,333	4.50	March 8, 2021
March 2016 PPM – (Finder’s Warrants)	73,333	4.50	March 8, 2021
March 2016 Public Offering - Warrants	666,666	4.50	March 8, 2021
March 2016 Public Offering – Banker Warrants	143,333	5.625	March 8, 2021
August 2016 – Settlement - Warrants	300,000	4.50	March 8, 2021
Total outstanding	4,222,637		

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

NOTE 9:- STOCKHOLDERS' DEFICIT AND CONVERTIBLE PREFERRED SHARES (Cont.)

During the year ended December 31, 2015, proceeds from warrants exercised amounted to $513 following the issuance of 117,685 shares of Common Stock out of which none were issued utilizing a cashless exercise feature.

During the year ended December 31, 2016, proceeds from warrants exercised amounted to $210 following the issuance of 77,019 shares of Common Stock out of which 27,236 were issued utilizing a cashless exercise feature.

p. Stock-based compensation:

1. 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 up to 31,778 shares of Common Stock have been reserved. Under the 2012 Plan, options to purchase shares of Common Stock may be granted to employees and non-employees of the Company or any affiliate, each option granted can be exercised to one share of Common Stock.

   On January 23, 2012, the 2012 Israeli equity sub plan (the "Sub Plan") was adopted by the Board of Directors of the Company, which set 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 Plan and subject to the same terms and conditions.

   During February 2013, the Board of Directors and majority stockholders of the Company approved an increase in the size of the 2012 Plan from 31,778 shares of Common Stock to 55,556 shares of Common Stock.

   On June 17, 2014, the Board of Directors and majority stockholders of the Company approved an increase in the size of the 2012 Plan from 55,556 shares of Common Stock to 83,334 shares of Common Stock.

   On June 15, 2015, the Company held its 2015 Annual Meeting of Stockholders in which, among other matters, Company stockholders approved an amendment to the 2012 Plan to increase the number of shares authorized for issuance under the 2012 Plan by 662,500 shares from 83,334 to 745,834 shares of Common Stock.

   On November 30, 2016, the Company held its 2016 Annual Meeting of Stockholders in which, among other matters, Company stockholders approved to amend the Company’s 2012 Equity Incentive Plan, and to increase the number of shares authorized for issuance under such Plan by 1,127,166 shares from 745,834 to 1,873,000.

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

NOTE 9:- STOCKHOLDERS' DEFICIT AND CONVERTIBLE PREFERRED SHARES (Cont.)

2. On September 3, 2015, the Company's Compensation Committee of the Board of Directors approved the grants of 350,753, 76,015 and 36,153 options to employees, directors and consultants of the Company, respectively, at an exercise price of $5.76 per share. 127,541 of such stock options are vested upon grant and the remainder shall vest over a period of two to three years commencing on the grant date. All of the aforementioned options have six year term. 408,232 options were issued under the 2012 Plan and 54,209 options are non-plan.

   On December 17, 2015, the Company's Compensation Committee of the Board of Directors approved the grants of 36,279, and 36,540 options to employees and consultants of the Company, respectively, at an exercise price of $7.02 per share. The options shall vest over a period of three years commencing on the grant date. All of the aforementioned options have a six year term. 70,037 options were issued under the 2012 Plan and 2,782 options were issued to a member of the Company's Scientific Advisory Board which are non-plan.

   On June 19, 2016, the Company's Compensation Committee of the Board of Directors approved the grants of 67,667 options to employees of the Company, at an exercise price of $4.80 per share. The options shall vest over a period of three years commencing on the grant date. All of the aforementioned options have a six year term. All options were issued under the 2012 Plan.

   Transactions related to the grant of options to employees, directors and non-employees under the above plans during the year ended December 31, 2016 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	587,678	16.87	5.8	1,264
Options granted	67,667	4.80		
Options exercised	-	-		
Options expired	60,218	6.23		
Options forfeited	11,973	18.29		
Options outstanding at end of year	583,334	16.53	4.87	7
Options vested and expected to vest at end of year	529,514	17.42	4.27	7
Exercisable at end of year	362,560	23.12	4.81	7

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

NOTE 9:- STOCKHOLDERS' DEFICIT AND CONVERTIBLE PREFERRED SHARES (Cont.)

Weighted average fair value of options granted during the year ended December 31, 2016 and 2015 is $2.86 and $5.94, 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 2016 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, 2016. This amount is impacted by the changes in the fair market value of the Common Stock.

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

	Year ended December 31,	
	2016	**2015**
Volatility	82.36%-86.03%	82.39%-87.28%
Risk-free interest rate	0.91%-0.99%	1.00%-1.54%
Dividend yield	0%	0%
Expected life (years)	3.5-4.06	5.68-8.51

As of December 31, 2016, the total unrecognized estimated compensation cost related to non-vested stock options granted prior to that date was $498, which is expected to be recognized over a weighted average period of approximately 1.1 years.

The total compensation cost related to all of the Company's equity-based awards, recognized during year ended December 31, 2016 and 2015 were comprised as follows:

	Year ended December 31,	
	2016	**2015**
Cost of revenues	$ 73	$ 183
Research and development	91	185
Sales, Marketing and pre-production costs	97	111
General and administrative	777	1,244
Total stock-based compensation expenses	$ 1,038	$ 1,723

NOTE 10:- LIABILITY RELATED TO WARRANTS

a. On March 30, 2012, the Company consummated the final closing of the 2011-2012 Private Placement pursuant to which certain accredited investors purchased an aggregate of 27,345 shares of Common Stock and warrants to purchase 27,345 shares of Common Stock at an exercise price of $135 per share for total consideration of $2,461.

The placement agent for the 2011-2012 Private Placement and its permitted designees were granted warrants to purchase an aggregate of (i) 5,358 shares of Common Stock at the exercise price of $90.00 per share and (ii) 5,358 shares of Common Stock at the exercise price of $135 per share.

Subsequent to the issuance of the 2011-2012 Private Placement warrants the original exercise price of the warrants for the investors and placement agent was adjusted from $135 per share to $3.59 per share and an additional 950,177 and 180,556 warrants were issued, respectively. In addition, the exercise price for the placement agent warrants of the 2011-2012 Private Placement, with an original exercise price of $90.00 per share was adjusted to $3.33 per share and an additional 119,705 warrants were issued.

As of December 31, 2016, the 2011-2012 Private Placement warrants expired unexercised.

b. On September 23, 2014, the Company consummated the September 2014 Private Placement (see also Notes 9b).

c. On March 8, 2016, the Company consummated the final closing of a Public Offering and a concurrent Private Placement (see also Note 9k).

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 (see also Note 9n).

The warrants of the 2011-2012 Private Placement, the warrants of the September 2014 Private Placement, the warrants of the March 2016 Public Offering and Private Placement and the Warrants of the August 2016 agreement, contain certain net settlement cash features and liquidated damages penalties and therefore the Company accounts for such warrants as a liability according to the provisions of ASC 815-40 and re-measured using the Binomial option-pricing model as described below.

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

NOTE 10:- LIABILITY RELATED TO WARRANTS (Cont.)

In estimating the warrants' fair value, the Company used the following assumptions:

Investors' warrants in 2011-2012 Private Placement:

	December 31, 2016	December 31, 2015
Risk-free interest rate (1)	-	0.60%
Expected volatility (2)	-	74.64%
Expected life (in years) (3)	-	0.82
Expected dividend yield (4)	-	0%
Fair value per warrant	-	$ 3.06

Placement agent's warrants 2011-2012 Private Placement:

	December 31, 2016	December 31, 2015
Risk-free interest rate (1)	-	0.19%
Expected volatility (2)	-	86.65%
Expected life (in years) (3)	-	0.27
Expected dividend yield (4)	-	0%
Fair value per warrant	-	$ 2.52-3.24

Investors' warrants in September 2014 Private Placement:

	December 31, 2016	December 31 2015
Risk-free interest rate (1)	1.11%	1.24%
Expected volatility (2)	91.65%	158.68%
Expected life (in years) (3)	1.73	2.73
Expected dividend yield (4)	0%	0%
Fair value per warrant	$ 0.70	$ 6.66

Investors' warrants in March 2016 Public Offering and Private Placement:

	December 31, 2016	Issuance date
Risk-free interest rate (1)	0.48%-1.74%	0.68%-1.34%
Expected volatility (2)	71.99%-74.72%	76.3%-109.54%
Expected life (in years) (3)	0.18-4.18	1-5
Expected dividend yield (4)	0%	0%
Fair value per warrant	$ 2.90	$ 2.26

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

NOTE 10:- LIABILITY RELATED TO WARRANTS (Cont.)

Investors' warrants in August 2016 agreement:

	December 31, 2016	Issuance date
Risk-free interest rate (1)	0.48%-1.74%	0.45%-1.01%
Expected volatility (2)	71.99%-74.72%	73.36%-102.36%
Expected life (in years) (3)	0.18-4.18	0.57-4.57
Expected dividend yield (4)	0%	0%
Fair value per warrant	$ 2.90	$ 2.34

(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 and other companies in the same industry 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 2011-2012 Private Placement, the September 2014 Private Placement warrants, the March 2016 Public Offering and Private Placement and the August 2016 Private Placement, are 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, 2016:

	Fair value of liability related to warrants
Balance at December 31, 2015	$ 2,610
Fair value of warrants to investors that were issued in March 2016	5,138
Fair value of warrants to investor that were issued in August 2016	702
Change in fair value of warrants during the period	(962)
Balance at December 31, 2016	$ 7,488

As of December 31, 2016, there were outstanding warrants to purchase 2,625,096 shares of Common Stock from the above issuances which were recorded as a liability.

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

NOTE 11:- SELECTED STATEMENTS OF OPERATIONS DATA

Financial expenses, net:

	Year ended December 31,	
	2016	2015
Bank charges	$ 20	$ 22
Foreign currency adjustments losses (gain)	26	(7)
Change in the fair value of warrants	(260)	(571)
Total Financial expenses (income), net	$ (214)	$ (556)

NOTE 12:- SUBSEQUENT EVENTS

a. On Januaty 9, 2017, the Company commenced a private placement offering of up to $5,100 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, 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 $3,100. On January 11, 2017, the Company 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 obtaining stockholder approval, pursuant to Nasdaq rules.
Stockholders approval was obtained on March 9, 2017

b. In January 2017, 77,891 Compensation Shares of Common Stock 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 owed to such individuals. The shares were issued under the 2012 Plan.

c. In January 10, 2017, 6,553 Compensation Shares of Common Stock were issued to certain service provider instead of cash owed to him for services provided during the fourth quarter of 2016. The shares were issued under the 2012 Plan. In February 6, 2017, 34,050 options were granted to a certain service provider of Ltd., under the 2012 plan, instead of cash owed to the service provider for services provided during the period July – December of 2016. The options are fully vested, and exercisable at an exercise price of $0.0001 per share.

d. In January and February, 2017, the Company's Compensation Committee of the Board of Directors approved the grants of 367,257 share to officers, employees and consultants of the Company, and the grant of 111,242, 386,029 and 21,000 options to employees, directors and consultants of the Company, respectively, at exercise prices of between $3.202 to $3.829 per share. The stock options shall vest over a period of three years commencing on the grant date. All of the aforementioned options have six year term. All options were issued under the 2012 Plan.

e. On March 8, 2017 the March 2016 Warrants and August 2016 Warrants exercise price adjustment feature expired, and therefore the warrants are no longer accounted for as a liability (See also Note 9k, Note 9n and Note 10).

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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 22, 2017

DARIOHEALTH CORP.

By: /s/ Erez Raphael
Name: Erez Raphael
Title: President and 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	President, Chief Executive Officer and Chairman of the Board (Principal Executive Officer)	March 22, 2017
/s/ Zvi Ben David Zvi Ben David	Chief Financial Officer, Secretary and Treasurer (Principal Financial and Accounting Officer)	March 22, 2017
/s/ Richard B. Stone Richard B. Stone	Director	March 22, 2017
/s/ Malcolm Hoenlein Malcolm Hoenlein	Director	March 22, 2017
/s/ Rami Yehudiha Rami Yehudiha	Director	March 22, 2017
/s/ Dennis M. McGrath Dennis M. McGrath	Director	March 22, 2017
/s/ Hila Karah Hila Karah	Director	March 22, 2017
/s/ Yossi Bahagon Yossi Bahagon	Director	March 22, 2017
/s/ Allen Kamer Allen Kamer	Director	March 22, 2017
/s/ Yalon Farhi Yalon Farhi	Director	March 22, 2017

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. 333-211417 and 333-215829) and the Registration Statements on Form S-3 (File No. 333-211396, 333-212644, 333-214849 and 333-216607), of DarioHealth Corp. ("the Company"), of our report dated March 22, 2017 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, 2016.

Tel-Aviv, Israel
March 22, 2017

/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 22, 2017

/s/ Erez Raphael
Erez Raphael
President, 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 22, 2017

/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, 2016 (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 22, 2017

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

Date: March 22, 2017

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