

DarioHealth Corp.

(DRIO - NASDAQ)

Chronic Care Through AI App

Based on our discounted multiple of earnings model DarioHealth is valued at approximately \$10.50 per share. Our model assumes rapid revenue growth and positive EPS by 2024. We apply a 20x multiple to 2024 EPS and discount to present using a 25% discount rate.

Current Price (7/14/2020) **\$6.40**
Valuation \$10.50

SUMMARY DATA

52-Week High **13.13**
 52-Week Low **3.02**
 One-Year Return (%) **1,473**
 Beta **2.22**
 Average Daily Volume (sh) **278,933**

Shares Outstanding (mil) **8.08**
 Market Capitalization (\$mil) **52.1**
 Short Interest Ratio (days) **9.47**
 Institutional Ownership (%) **19.6**
 Insider Ownership (%) **13.0**

Annual Cash Dividend **\$0.00**
 Dividend Yield (%) **0.00**

5-Yr. Historical Growth Rates
 Sales (%) **N/A**
 Earnings Per Share (%) **N/A**
 Dividend (%) **N/A**

P/E using TTM EPS **N/A**
 P/E using 2020 Estimate **N/A**
 P/E using 2021 Estimate **N/A**

Zacks Rank **N/A**

INITIATION

DarioHealth is a global digital therapeutics (DTx) company that provides digital management of chronic conditions. Dario offers a blood sugar monitor and associated smartphone application which provides diabetes monitoring and advice to prompt behavioral change and disease improvement. Dario recently launched a hypertension module and will expand into other disease states including obesity.

The DTx platform is targeting multiple parties, including retail, provider, employer and health plan customers. The company's new strategy is to shift primary marketing efforts towards large health care providers which should yield greater subscriber growth and higher PMPM. Dario will also add multiple chronic conditions to its offering which is also expected to increase the PMPM total.

This move to target large healthcare providers is complemented by a shift from the previous B2C model to a high margin SaaS model and B2B2C approach addressing multiple chronic conditions.

Dario has conducted numerous studies leveraging its user data which have demonstrated improvement in clinical parameters. We expect additional studies to be conducted supporting the use of the device on a wide scale by payors and health plans.

Risk Level Above Average
Type of Stock Small-Growth
Industry Diagnostic/Research

ZACKS ESTIMATES

Revenue

(In millions of USD)

	Q1	Q2	Q3	Q4	Year
	(Mar)	(Jun)	(Sep)	(Dec)	(Dec)
2019	\$2.2 A	\$1.7 A	\$1.9 A	\$1.8 A	\$7.6 A
2020	\$1.7 A	\$1.7 E	\$2.0 E	\$2.2 E	\$7.6 E
2021					\$13.4 E
2022					\$25.8 E

Earnings per Share

	Q1	Q2	Q3	Q4	Year
2019	-\$2.92 A	-\$2.53 A	-\$1.11 A	\$2.86 A	-\$9.22 A
2020	-\$3.61 A	-\$1.54 E	-\$1.19 E	-\$1.03 E	-\$6.91 E
2021					-\$3.96 E
2022					-\$2.22 E

INITIATING COVERAGE

We are initiating coverage of DarioHealth, Corp. (NASDAQ: DRIO) with a current valuation of \$10.50 per share. This present value is based on our estimates for a successful expansion of the business-to-business-to-consumer (B2B2C) initiative and penetration into health plans, provider networks and employer sponsored care. Dario's primary offering is a system to improve diabetes. It consists of a blood glucose meter (BGM), consumables and a smartphone application that leverages an artificial intelligence (AI) algorithm to encourage positive behavior change guided by data. The product is primarily intended for individuals with diabetes or pre-diabetes, although it can be used by anyone that wants to improve their health behaviors related to blood sugar. Dario recently added hypertension along with a blood pressure monitoring system to its plan and is in the process of expanding the product offering to include management of other chronic conditions that can be changed through behavior, such as obesity.

Dario's foray into application-based diabetes management is part of a larger trend in digital therapeutics (DTx). The ubiquity of smartphones and wireless connectivity has provided the necessary infrastructure to monitor health and continuously guide a subscriber. In the past, the primary methods to treat chronic disease were medication, physical interventions and behavioral therapy but the management of chronic conditions is a continuous endeavor whereas physician visits are periodic. The availability of smartphones provides an alternative that can help patients adhere to medication requirements and enact durable behavioral change. Digital therapeutics can also gather real-time diagnostic data and provide instant feedback using artificial intelligence-based best practices. Dario has employed its user data to demonstrate clinical improvements for users on its platform. Proof of efficacy is an important asset to present to healthcare providers as they allocate their resources.

According to the National Health Council, chronic diseases affect 40% of the population, which is about 131 million Americans. The Center for Disease Control finds that six in 10 adults have a chronic disease and four in 10 have two or more chronic diseases. These patients are responsible for the majority of the United States' \$3.5 trillion in annual health care costs.¹ The chronic conditions include cardiovascular disease, diabetes, chronic kidney disease and many others that arise from tobacco use, poor nutrition, lack of exercise and excessive alcohol intake. One of the most prevalent chronic diseases, diabetes, now affects over 460 million individuals around the world and is projected to rise to 700 million by 2045. These human and financial impact clarify the need for proven approaches that can address both health and cost.

Dario has an international presence; however, the majority of its revenues are generated in the United States. The company serves 50,000 active users on its platform which represent a loyal customer base that rates the product highly. The majority of these individuals have been added through the consumer initiative where acquisition costs are high and revenue per user is low. To improve these critical financial metrics, management will shift its primary marketing focus towards the provider, health plan and employer markets. These prospects serve large populations, require evidence of efficacy and demand a return on their investment. The addition of several new executives with experience and relationships in the healthcare provider market is expected to catalyze the acquisition of new clients that should drive up both number of subscribers and revenue per user at a lower cost. The company is transforming itself from a retail-only DTx company, generating the majority of its revenues from retail product sales, to a software as a service (SaaS) and platform as a service (PaaS) enterprise with a diversified revenue base.

On March 31, 2020 Dario held \$15.8 million in cash after a recent \$21.3 million private placement in the fourth quarter 2019. The company posted quarterly revenues of \$1.7 million and registered a net loss of (\$11.2) million including the deemed dividend related to the Series A Preferred Stock. Dario is wholly financed with equity and equity-like instruments and has no debt on its balance sheet. With the addition of several new key executives and board members, DarioHealth is positioned to accelerate the growth of its subscriber base using personalized technology and the science of behavior modification to make durable improvements in chronic disease.

¹ Center for Disease Control and Prevention. National Center for Chronic Disease Prevention and Health Promotion. Chronic Diseases in America. <https://www.cdc.gov/chronicdisease/resources/infographic/chronic-diseases.htm>

INVESTMENT THESIS

Digital Therapeutics (DTx) is an emerging, revolutionary approach to health care that combines behavioral health with artificial intelligence and connected devices to help patients improve chronic conditions through their actions rather than through medications or invasive treatments. The near universal availability of smartphones and their ability to connect with a variety of diagnostic devices provides a recipe for a personalized, real-time experience which can improve the course of chronic disease. There are many statistics that illuminate the potential size of the DTx market. In 2018, US health care spending was \$3.6 trillion, of which 75%, or \$2.7 trillion, was estimated to be spent on chronic diseases. One of the leading chronic conditions that adds to this total is diabetes, which is estimated to cost \$13,000 per year, per patient.² Medications spent on diabetes and hypertension are over \$60 billion and combined expenditures on these maladies reach almost \$300 billion in the United States.

DarioHealth has capitalized on the opportunity to improve health and reduce cost through the launch of its glucose blood meter platform that combines a meter, testing kit and smartphone application. The platform monitors glucose levels and provides the guidance that diabetics need to control their condition through behavior rather than medication. The company's early days were spent refining their product and application, accumulating retail active users and generating data and analysis demonstrating the efficacy of the platform. Now that the pieces are in place, Dario is moving away from a product sales model and moving towards a subscription-only model in populations managed by large healthcare providers. These providers demand services that can help them lower cost and improve health and are backed up by reliable data. Dario can provide these features and expects to enter this important market with a higher revenue per user and lower cost of acquisition. The addition of several new management team members with substantial experience growing revenues in the health plan market will provide the necessary expertise to partner with these groups to provide a tailored product that adapts to the needs of the client. The improved profile of the incremental subscriber in health plan markets is expected to have a dramatic positive impact on revenues and margins, leading to profitability in the next few years.

We see a near term inflection in revenues as large health plans are added to the platform. Our forecasts call for a revenue pickup in 2H:20 and high double digit growth in subsequent years, the result of a combination of rising revenue per subscriber and large subscriber additions from health plans. Pricing will increase as a result of additional services and conditions covered. While our target price is generated based solely on new subscribers in the retail and health plan market, Dario has launched its remote patient monitoring program which could prove to be lucrative if it catches on. We will reflect value for this opportunity upon further confirmation of success and quantification of results.

Key reasons to own DarioHealth shares:

- **AI-driven behavioral change platform that is personalized and scalable**
- **Immense untapped market in Digital Therapeutics**
- **High and expanding gross margins**
- **Clinically-proven patient outcomes**
- **DTx market size forecast of almost \$10 billion by 2026**
- **Existing and growing partnerships with health plans, employers, providers and retailers**
- **Membership-based SaaS with recurring revenue**
- **Opportunity to address multiple chronic conditions in diabetes, hypertension & obesity**
- **Cash position of \$15.8 million with no debt on balance sheet**
- **Leadership and management team with experience in healthcare and technology**

In the following sections we review the DTx industry, the regulatory pathway required for DTx and provide a primer on diabetes illustrating the importance of behavioral change on the disease. We then review Dario's clinical evaluations of the glucose monitoring system and the major findings. A detailed discussion of the company's strategy is given, emphasizing the opportunity in the healthcare provider space. General and specific risks are listed as is a summary of peers competing for share in the chronic disease DTx market. We end our report with a thorough discussion of our financial model assumptions and provide our appraisal of DarioHealth generating a valuation of \$10.50 per share.

² National Association of Chronic Disease Directors. <https://www.chronicdisease.org/page/whyweneedph2imphc>

Digital Therapeutics

The ubiquity of smartphones and wireless connectivity has provided the infrastructure to continuously monitor and guide a patient's health; however, we are only in the early stages of developing the applications that provide the breadth of services that are possible. In the past, the primary methods to treat chronic disease were medication, physical interventions and behavioral therapy. While these approaches worked for some, adherence to behavioral prescriptions proved challenging; many did not take their medications as directed and others failed to follow a prescribed diet, increase exercise or follow directed physical therapy. With the omnipresence of smartphones there is now an alternative that can help patients adhere to medication requirements and behavioral change. Digital therapeutics can gather diagnostic measurements and provide instant feedback using artificial intelligence-influenced best practices to provide the next generation of health care. A DTx company can track and learn from behavior to improve the health of its users.

For the uninitiated, the breadth of wellness applications, from step counters to heart rate monitors to sleep trackers and fitness apps may all seem to fall into the same digital health bucket. However, digital therapeutics is a distinct subset of digital health which uses evidence-based therapeutic interventions to prevent, manage or treat a medical disorder or disease. The research conducted to support the utility of the digital therapeutic and efforts to prove it is safe and effective differentiates DTx from other health-related digital applications.

According to the National Health Council, chronic diseases affect 40% of the population or 131 million Americans. The Center for Disease Control finds that six in 10 adults have a chronic disease and four in 10 have two or more chronic diseases. These adults are responsible for the majority of the United States' \$3.5 trillion in annual health care costs.³ These include cardiovascular disease, diabetes, chronic kidney disease and many others that arise from tobacco use, poor nutrition, lack of exercise and excessive alcohol intake. All of these conditions stem from lifestyle and behaviors that can be modified with the right stimulus.

Evaluate Pharma estimates sales of diabetes and hypertension medications were more than \$46 billion and \$15 billion in 2019, highlighting just one component of the savings that could be realized with behavior change. Looking more broadly, diabetes is the fourth most expensive chronic disease for health care payors according to an article by HealthPayer Intelligence. It is estimated to cost \$245 billion in 2016, with 71% of this total attributable to direct healthcare expenses. Other sources find that one in four health care dollars in the U.S. is spent on diabetes.⁴ Serious health complications can arise from diabetes if it is not treated, including blindness, kidney disease, amputations and heart disease. An article by OnHealth finds that hypertension is the eighth most costly medical condition with 15.8 million hospital stays and \$50 billion in costs. The author notes that only half of the individuals with hypertension are able to keep it under control.⁵ As for the size of the DTx market itself, we have seen a variety of estimates, two of which provide a representative sample. Grandview Research estimates a DTx market size of around \$10 billion in 2025 and Allied Market Research forecasts a magnitude of \$10 billion in 2026 propelled by a compound annual growth rate of 21% and 20% respectively.

This brief review of the expenditures for two of the most prevalent chronic diseases and opportunities for DTx show the incentives that are available for companies that are able to successfully employ DTx. Before spending on new technology, payors demand proof that the digital interventions work. Health providers want to see real-world data in the populations that can benefit most. One advantage that DTx has over other therapies is the availability of data. The companies providing these services collect information that is used to both build and refine platform efficacy.

Industry trade groups have created standards so consumers and health care providers know what to expect in terms of privacy, reliability, user engagement and other elements. Recommendations from the trade groups call for the completion of multiple independent studies on the target population that are published in peer-reviewed journals. Many times, sponsors will pursue FDA clearance for the digital therapeutic and in other cases, real-world evaluations that demonstrate improved health outcomes is sufficient. Consumers and providers want to see tangible benefits from DTx such as better control of diabetes or hypertension, a reduction in serious health claims and a positive return on investment (ROI).

There are a variety of health conditions that are appropriate for DTx, including opioid use disorder, mental health, asthma, obesity, hypertension and diabetes. Diseases that are driven by behavior and lifestyle are most

³ Center for Disease Control and Prevention. National Center for Chronic Disease Prevention and Health Promotion. Chronic Diseases in America. <https://www.cdc.gov/chronicdisease/resources/infographic/chronic-diseases.htm>

⁴ American Diabetes Association. The Cost of Diabetes Care – An Elephant in the Room. Matthew C. Riddle and William H. Herman.

⁵ The 18 Most Expensive U.S. Medical Conditions, Reviewed by Charles Patrick Davis, MD, PhD. August 23, 2017.

appropriate. Diseases that can be monitored and measured using digital tools and diagnostics that are able to track a patient's status are also superb candidates for DTx. Outputs from a DTx platform to a user can range from a notification to change behavior or a recommendation to exercise or take medication. In some cases, connected devices can deliver a drug based on patient readings. If a patient has a condition that requires assistance, a connected device can alert caregivers of an emergency. In the case of disorders such as depression and mental health, the patient can enter a virtual session with a counsellor or be connected with a specialist to provide additional help.

To help align the industry's goals, provide standards and increase education, advocacy and research, the trade group [Digital Therapeutics Alliance](#) (DTA) was founded in 2017. It has set foundational principles for the industry and has expanded access to evidence-based digital therapeutics for patients, providers and payors to support desired outcomes. The DTA has categorized DTx treatments into groups that have four distinct objectives: 1) Address a medical condition; 2) Manage or prevent a medical disorder or disease; 3) Optimize medication; 4) Treat a medical disease or disorder. The categorization of the digital treatment determines the associated requirements for delivery. The DTA is international, and includes members from the US, Europe, Australia, Japan and other countries. The alliance has defined a digital therapeutic as a product that increases remote access to clinically demonstrated safe and effective therapies, provide scalable and accessible services and generate actionable, real world data that can guide data-driven care management and clinical decision making.

Diagnostic Tests and Regulatory Paths to Market

The FDA, under the Food, Drug & Cosmetic Act, provides regulatory oversight for all medical devices in the US, including blood glucose monitoring systems and digital products. Medical devices include everything from hip implants to bandages and are placed into three groups ascending based on their risk: Class I, II and III. Digital products are cleared by the FDA as class II medical devices, and are regulated by the Center for Devices and Radiological Health (CDRH) at the FDA. To obtain clearance for a DTx device, a company makes a *de novo* request to the FDA. Tests are used in a wide variety of environments but must meet regulatory standards so that providers and patients can rely on them to make proper recommendations and diagnoses.

A blood glucose monitoring system is considered a Class II device by the FDA and requires the filing of a 510(k) application to obtain clearance. The FDA will evaluate the intended use, performance and labeling of the device as part of its review. The approval is only intended to support monitoring activity and not for diagnosis and screening. Precision of the device must be repeatable across several devices using multiple strip lots. Accuracy thresholds require that 95% of the results should be within +/- 15 mg/dL of a reference measurement below 75 mg/dL and within +/-20% of 75 mg/dL and greater.⁶

By far, the most stringent, lengthy and capital-intensive medical device regulatory approval process is the premarket approval⁷ (PMA). If a device (typically Class III) is first-in-class, and there are no other devices that have preceded it that have already been granted marketing approval, then the device must substantiate its safety and efficacy. To manage the risk associated with first-in-class high-risk medical devices, the PMA requires substantial scientific evidence that the health benefits of the device outweigh the risks.

To avoid the time and expense associated with a PMA, most sponsors apply for 510(k) market approval. It is an accelerated path to market that relies on a medical device being considered substantially equivalent to one or more legally marketed predicate devices. If a substantially equivalent predicate is not identified, the FDA will require a PMA. A 510(k) is required by a sponsor introducing a device for the first time without substantial equivalence to a predicate, by a sponsor required to register (regardless of the device meeting criteria) and for a device already in the market but about to undergo significant change either in its design and manufacture or its intended use.

Diabetes

With advancements in agriculture and supply chain, more food is available than ever before. While a victory over starvation, humans are unable to adapt to this surplus of fast calories and medicine is struggling to catch up. According to the World Health Organization, global prevalence of diabetes in adults was an estimated 463 million between 2014 and 2019 and is rising quickly.⁸ Type 1 diabetes is characterized by the inability for the pancreas to produce insulin whereas type 2 is marked by the body's resistance to insulin.⁹ Prediabetes is identified by elevated

⁶ FDA Evaluation of Point of Care Blood Glucose Meters. Denise Johnson-Lyles, Ph.D., Office of In Vitro Diagnostic Device Evaluation and Safety.

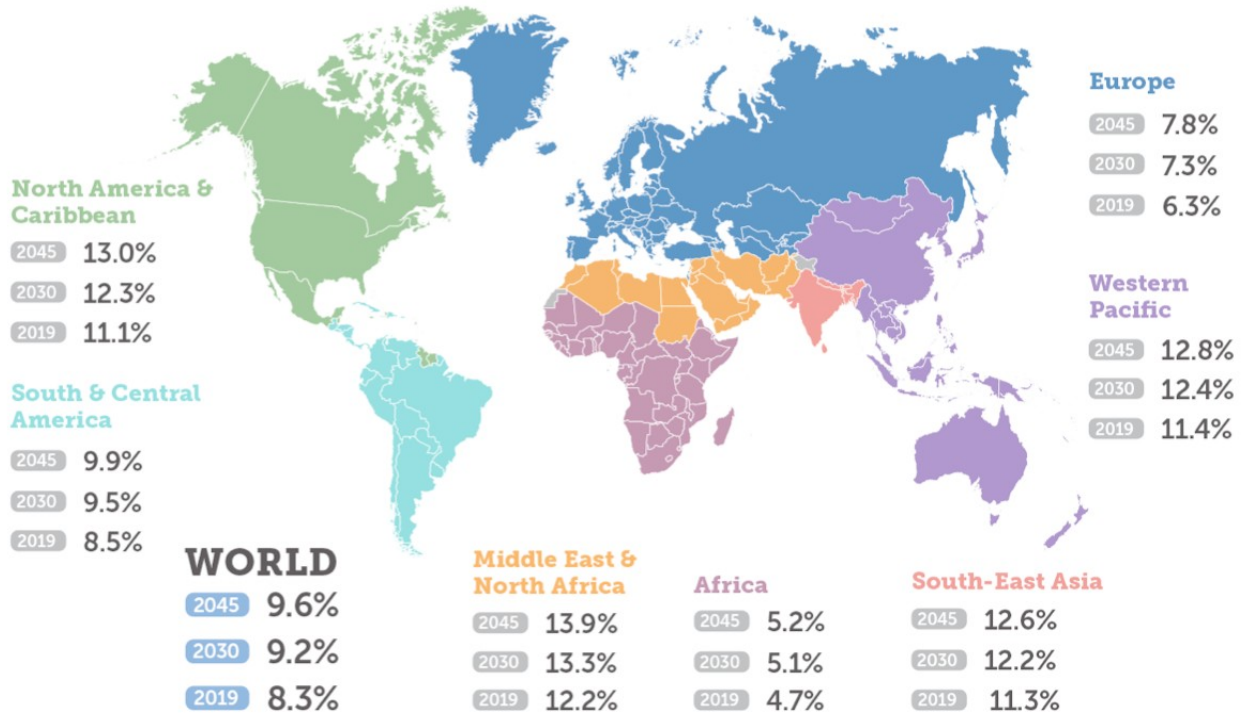
⁷ <https://www.fda.gov/medical-devices/premarket-submissions/premarket-approval-pma>

⁸ <https://www.idf.org/aboutdiabetes/what-is-diabetes/facts-figures.html>

⁹ <https://www.who.int/news-room/fact-sheets/detail/diabetes>

blood glucose, but not to the threshold of diagnosis.¹⁰ Diabetes can also occur in pregnant women, known as gestational diabetes, but it is frequently temporary. In 2017, the total cost of diagnosed diabetes was \$327 billion in the US and \$760 billion^{11,12} around the globe.

Exhibit I – Prevalence of diabetes in adults in IDF Regions, age adjusted¹³



Prevalence & Incidence

Global prevalence of diabetes in adults was 422 million in 2014, or approximately 8.5% of the population, almost double the relative prevalence in 1980.¹⁴ Between 2014 and 2019, prevalence increased again to an estimated 463 million adults living with diabetes and is projected to rise to 700 million by 2045. Prevalence has risen rapidly in low- and middle-income countries versus high income countries. An estimated 79% of adults living with diabetes were living in low- and middle-income countries.¹⁵ Prevalence of both type 1 and type 2 diabetes outpaces genetic variation, suggesting that environmental factors and behavior play a key role.¹⁶

Research conducted by Abyassin and Laher in 2016 attribute the rise in diabetes to rapid urbanization, obesity, an increasingly sedentary lifestyle and dietary habits.¹⁷ A statistical analysis finds significant correlation with sugar exposure.¹⁸ The region with the lowest prevalence of diabetes is in Africa, likely attributed to low urbanization and undernutrition.¹⁹ The largest population of diabetics is in China, with approximately 116.4 million Chinese with the disease in 2019, followed by India, with a population of 77 million, and the United States at over 31 million.²⁰

¹⁰ <https://www.webmd.com/diabetes/what-is-prediabetes>

¹¹ <https://www.diabetes.org/resources/statistics/statistics-about-diabetes>

¹² <https://www.diabetesatlas.org/en/>

¹³ <https://www.diabetesatlas.org/en/sections/demographic-and-geographic-outline.html>

¹⁴ <https://www.who.int/news-room/fact-sheets/detail/diabetes>

¹⁵ <https://www.idf.org/aboutdiabetes/what-is-diabetes/facts-figures.html>

¹⁶ Skyler et al. 2017. Differentiation of Diabetes by Pathophysiology, Natural History, and Prognosis. *Diabetes*

¹⁷ Al-Khudairy L, Stranges S, Kumar S, Al-Daghri N, Rees K. Dietary factors and type 2 diabetes in the Middle East: what is the evidence for an association?—a systematic review. *Nutrients*. 2013;5(10):3871-3897. Published 2013 Sep 26. doi:10.3390/nu5103871

¹⁸ Basu S, Yoffe P, Lustig R. 2013 The Relationship of Sugar to Population-Level Diabetes Prevalence: An Econometric Analysis of Repeated Cross-Sectional Data. *PLOS ONE*

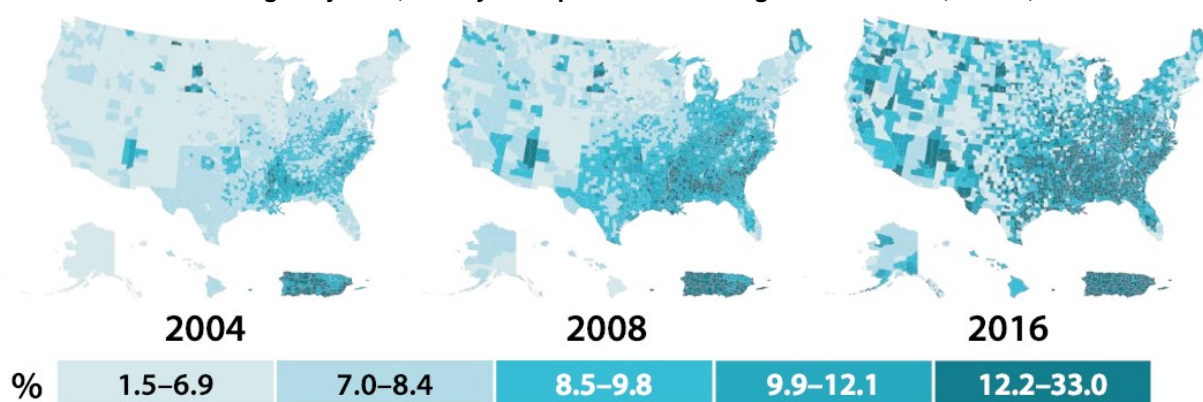
¹⁹ Basu S, Yoffe P, Lustig R. 2013 The Relationship of Sugar to Population-Level Diabetes Prevalence: An Econometric Analysis of Repeated Cross-Sectional Data. *PLOS ONE*

²⁰ <https://www.diabetesatlas.org/en/sections/demographic-and-geographic-outline.html>

United States

In 2018, it was estimated that 10.5% of the US population, or 34.2 million people had diabetes. US Adults with diabetes totaled 34.1 million or 13.0% of the population, 21.4% of which were undiagnosed. At the regional level in the US, the highest level of diabetes prevalence began in the southeast in 2004 and increased in prevalence across the rest of the nation by 2016.²¹

Exhibit II - Age-adjusted, county-level prevalence of diagnosed diabetes, adults, US²²



According to 2018 Centers for Disease Control and Prevention (CDC) estimates of US diabetes prevalence, of those 18-44 years of age, 4.9% had diabetes while those aged 45-64 had much higher prevalence at 14.8%. The proportion of people age 65 and older with diabetes is also above 14%. The age-adjusted prevalence of diabetes rose significantly between 1999 and 2002, from 9.5% to 12%. Men are more likely to have diabetes than women, with 14% of men and 12% of women presenting the disease. In addition to diabetes, an estimated 34.5% of US adults had prediabetes, measured using their HbA1c (A1C) level. Men had a higher percentage prevalence than women, at 37.4% and 29.2% respectively.²³

Incidence

New cases of diabetes in the US were estimated to be 1.5 million cases, or 6.9 per 1000 persons in 2018. Incidence in adults age 45 and older was higher than in younger adults. Incidence in men is higher than women at 7.3 and 6.6 per thousand. US incidence in adults has remained largely unchanged since 2000 versus 2018, although incidence of type 2 diabetes in youth, age 10-19, has climbed.²⁴

Diabetes is comorbid with obesity²⁵, hypertension, and cardiovascular disease. Diabetes induced complications include blindness, kidney failure, heart attacks, stroke and amputation.²⁶ As diabetes and obesity are exacerbated by lack of sleep, sleep apnea, also a function of obesity, can reduce sleep in a cyclically worsening manner.²⁷ Through the diabetic weakening of the immune system and restricted blood circulation, small cuts and blisters can fester into advanced infections requiring amputation of the limb. It is not uncommon to see foot amputations resulting from foot ulcers.²⁸ Another result of the compromised immune system is risk to tuberculosis (TB).²⁹ Diabetes increases the risk of developing TB three-fold, and also increases the risk of relapse or death; it is estimated that 15% of TB cases may be attributable to diabetes, and a large portion of those with concurrent diabetes and TB are diagnosed too late or not at all.³⁰

Risks

Prevalence of both type 1 and type 2 diabetes outpaces genetic variation, suggesting that environmental factors and behavior play a key role. Environmental factors that increase the risk of both types are diet, endocrine disruptors, environmental pollutants, and even gut microbiome composition. It has been long accepted that diet and exercise are key behaviors that can affect blood sugar and A1C levels and that adjusting environmental factors can

²¹ CDC National Diabetes Statistics Report 2020

²² CDC National Diabetes Statistics Report 2020

²³ CDC National Diabetes Statistics Report 2020

²⁴ CDC National Diabetes Statistics Report 2020

²⁵ Barnes AS. The epidemic of obesity and diabetes: trends and treatments. *Tex Heart Inst J.* 2011;38(2):142-144.

²⁶ <https://www.who.int/news-room/fact-sheets/detail/diabetes>

²⁷ Skyler et al. 2017. Differentiation of Diabetes by Pathophysiology, Natural History, and Prognosis. *Diabetes*

²⁸ <https://www.mayoclinic.org/diseases-conditions/diabetes/in-depth/amputation-and-diabetes/art-20048262>

²⁹ https://www.who.int/tb/publications/diabetes_tb.pdf

³⁰ https://www.who.int/tb/publications/diabetes_tb.pdf

affect these critical inputs.³¹ While there is a clear correlation between environmental factors and diabetes risk, causality remains to be established.³²

Type 1: Factors related to the risk of type 1 diabetes are largely genetic, though trends in prevalence outpace that expected by genetic variation alone; discordance rates in twins, variation in geographic prevalence and urban migration also support the role of the environment in type 1 diabetes risk. The variability in onset age obscures the role of environment on childhood-onset type 1, but exposure to hazardous environments, even in the first few years, may contribute.³³ Other relevant environmental exposures include enteroviral infections, cereal/gluten, and low vitamin D serum concentration; perinatal exposure of nitrosamine has been implicated as well. Children with family history of type 1 diabetes, or have certain genes have increased risk of diabetes. Type 1 diabetes can appear at any age; however, the two most common age ranges are between 4-7 and 10-14 years old. While typically considered risk factors for type 2 diabetes, obesity and insulin resistance is now thought to be an accelerator of type 1 diabetes.³⁴

Type 2: Risk factors related to type 2 diabetes mellitus include smoking, being overweight, insulin resistance, physical inactivity, family history, prediabetes, elevated A1C, high blood pressure, and high cholesterol.^{35,36,37} Fat distribution throughout the body is correlated with type 2 diabetes risk. Those who store fat predominantly in the abdomen versus the hips and thighs are at higher risk.³⁸ Obesity and diabetes are related to abnormal sleep. Obstructive sleep apnea, often a result of obesity, can also shorten sleep duration and cyclically exacerbate the condition. Type 2 diabetes risk is also correlated with age, especially after age 45.³⁹ Race plays a role, with Black, Hispanic, American Indian and Asian-Americans at increased risk. While type 2 diabetes onset occurs at varying levels of obesity, Asians and Asian-Americans can acquire type 2 diabetes at a lower body mass index.⁴⁰

Symptoms & Diagnosis

Type 1: After losing β -cell function, type 1 diabetics experience hyperglycemia, symptoms of which include frequent urination, thirst, blurred vision, fatigue, irritability, hunger, and difficulty concentrating. Prolonged high blood glucose is implicit in the aforementioned risk to renal, neural, ocular, and cardiovascular systems. Metabolic markers, such as occurrence of dysglycemia can be used to monitor onset in at-risk individuals, and prediction accuracy can be further improved by tracking glucose and C-peptide.⁴¹

Type 2: The American Diabetes Associations recommends routine screening starting at the age of 45, especially if risk factors such as obesity, family history, or high blood pressure are present. Symptoms of type 2 diabetes, like type 1, include thirst, frequent urination, hunger, unexpected weight loss, fatigue, blurred vision, slow-healing sores, frequent infections and darkened areas of the skin around the armpits and neck. If left unchecked, type 2 diabetes can be deadly with atherosclerotic, neuropathic, renal, and ocular consequences. Also common is impaired healing that can render small cuts and blisters into infections that can require amputation. Auditory impairment, skin conditions and sleep apnea are all common, though obesity is thought to drive both sleep apnea and diabetes. Finally, patients with type 2 diabetes also are at increased risk of Alzheimer's disease, though the underlying mechanism is not understood. Type 2 diabetes is diagnosed the same way it is monitored, via glycated hemoglobin (A1C) test, which is an indicator of average blood sugar levels for the past few months. Other tests include the random blood sugar test, fasting blood sugar test, and oral glucose tolerance test. The three are variants of common blood glucose testing. Blood glucose testing is also used in the day-to-day management of diabetes.

Management & Treatments (DTx)

Type 1: Management of Type 1 diabetes involves the injection of insulin to supplement the body's inability to produce its own. Under the care of a physician, an A1C goal is set and through insulin and meal-planning the condition is managed. Exercise and weight management are encouraged. Nutritional recommendations base the diet on higher levels of nutritious, low-fat, high-fiber foods and fewer animal products and refined carbohydrates. In addition to A1C, frequent blood-glucose monitoring is required in day-to-day management.⁴²

³¹ Wang, R.R., *et al.* Behavioral Science Research in Diabetes. *Diabetes Care* 2001 Jan; 24(1): 117-123.

³² Skyler et al. 2017. Differentiation of Diabetes by Pathophysiology, Natural History, and Prognosis. *Diabetes*

³³ Skyler et al. 2017. Differentiation of Diabetes by Pathophysiology, Natural History, and Prognosis. *Diabetes*

³⁴ <https://www.mayoclinic.org/diseases-conditions/type-1-diabetes/diagnosis-treatment/drc-20353017>

³⁵ CDC National Diabetes Statistics Report 2020

³⁶ <https://www.mayoclinic.org/diseases-conditions/type-2-diabetes/symptoms-causes/syc-20351193>

³⁷ Skyler et al. 2017. Differentiation of Diabetes by Pathophysiology, Natural History, and Prognosis. *Diabetes*

³⁸ <https://www.mayoclinic.org/diseases-conditions/type-2-diabetes/symptoms-causes/syc-20351193>

³⁹ <https://www.mayoclinic.org/diseases-conditions/type-2-diabetes/symptoms-causes/syc-20351193>

⁴⁰ Skyler et al. 2017. Differentiation of Diabetes by Pathophysiology, Natural History, and Prognosis. *Diabetes*

⁴¹ Skyler et al. 2017. Differentiation of Diabetes by Pathophysiology, Natural History, and Prognosis. *Diabetes*

⁴² <https://www.mayoclinic.org/diseases-conditions/type-1-diabetes/diagnosis-treatment/drc-20353017>

Type 2: Disease progression can be retarded through medication and lifestyle intervention, and early therapy has demonstrated reduction in retinopathy, cardiopathy, and mortality. Insulin secretion deficiency can be partially rectified with caloric restriction and weight loss in early stages; it is difficult to reverse prolonged diabetes, even with dramatic intervention such as bariatric surgery, likely due to deterioration of β -cell function. Thus, early diagnosis and intervention is key to preserving β -cells. However, most patients, even after diagnosis of type 2 diabetes, are still exposed to years of hyperglycemia due to incomplete control.⁴³

Diabetes type 2 is managed and treated through monitoring blood glucose and A1C, changes in lifestyle, taking drugs and supplementing insulin. Typically, the first line of defense for pre- and type 2 diabetes is change in lifestyle. Both aerobic and resistance training are recommended. Eating foods lower in fat and calories and higher in fiber, such as vegetables and fruits, daily aerobic activity and losing weight are encouraged.⁴⁴ Weight loss has been shown to improve insulin sensitivity in liver and skeletal muscle and may reduce fat accumulation in the pancreas.⁴⁵ Cessation of smoking is also supported.⁴⁶ All of these factors can be guided by automated coaching and support.

Diabetes medication and insulin therapy are options as well. As foot ulcers and are notably common, and can fester to require amputation, management of type 2 diabetes also requires consistent hygiene and inspection of the feet. Physicians advise professional removal of foot-lesions, careful toenail trimming, avoiding going barefoot, and buying shoes that fit properly. Signs to be vigilant for are ingrown toenails, blisters, plantar warts, bleeding/open sores, general inflammation, pain and foul odor.⁴⁷ Management of the risks of concurrent Diabetes and TB involve screening, if either is suspected or diagnosed.

Conclusion

Exercise and diet have changed for the worse over the last decades which has led to a high and increasing prevalence of diabetes resulting in treatment costs that run into the billions of dollars. Diabetes is frequently comorbid with obesity, hypertension and cardiovascular disease. Complications include blindness, kidney failure, heart attacks, stroke and amputation. As both type 1 and type 2 diabetes manifest as hyperglycemia, the symptoms and effect on the body are similar even though treatment and management differ. Treatment for type 1 is insulin supplementation, while type 2 typically centers on lifestyle and weight management, followed by medication. For type 1 patients, constant blood glucose monitoring and administration of insulin is vital. For type 2, lifestyle, drug and insulin-based therapy are prescribed.

⁴³ Skyler et al. 2017. Differentiation of Diabetes by Pathophysiology, Natural History, and Prognosis. *Diabetes*

⁴⁴ <https://www.mayoclinic.org/diseases-conditions/type-2-diabetes/diagnosis-treatment/drc-20351199>

⁴⁵ Skyler et al. 2017. Differentiation of Diabetes by Pathophysiology, Natural History, and Prognosis. *Diabetes*

⁴⁶ CDC National Diabetes Statistics Report 2020

⁴⁷ <https://www.mayoclinic.org/diseases-conditions/diabetes/in-depth/amputation-and-diabetes/art-20048262>

Clinical Evaluation of Dario Blood Glucose Monitoring System

Dario is able to access numerous data points over time from its active users which enables retrospective analysis of the data to determine the efficacy of the Dario digital solution. Analysis of the data can not only help see whether or not the intervention is working but can also guide future design of the application to be even more effective. The combination of digital monitoring, data analytics and artificial intelligence and coaching help members make better decisions regarding their health. These improvements can be quantified. The company has conducted several analyses that have identified a reduction in A1C, lower fluctuations in glucose readings and fewer glycemic events as a result of using the Dario blood glucose monitoring system. Below we summarize a selection of studies and outcomes produced by Dario. Future studies will likely measure outcomes health plan partners want to quantify and control and include hypertension and obesity to the assessment.

Exhibit III – Dario Blood Glucose Meter⁴⁸



In a poster entitled “Reducing A1C Levels in Individuals with High-Risk Diabetes Using Mobile Glucose Meter Technology” researchers found an improvement in glucose and Hemoglobin A1C levels over time, linked to user engagement levels. The study screened for a group of high-risk, engaged users, with a baseline A1C of greater than 8% that measured data at least three times per day over a nine month period. 276 users were included in the analysis which found an improvement of 1.3% for 64% of the population at the nine month mark. The analysis also determined that there was a direct correlation between the number of measurements per day and the proportion of users that improved A1C levels.

Exhibit IV – Results of A1C Study⁴⁹

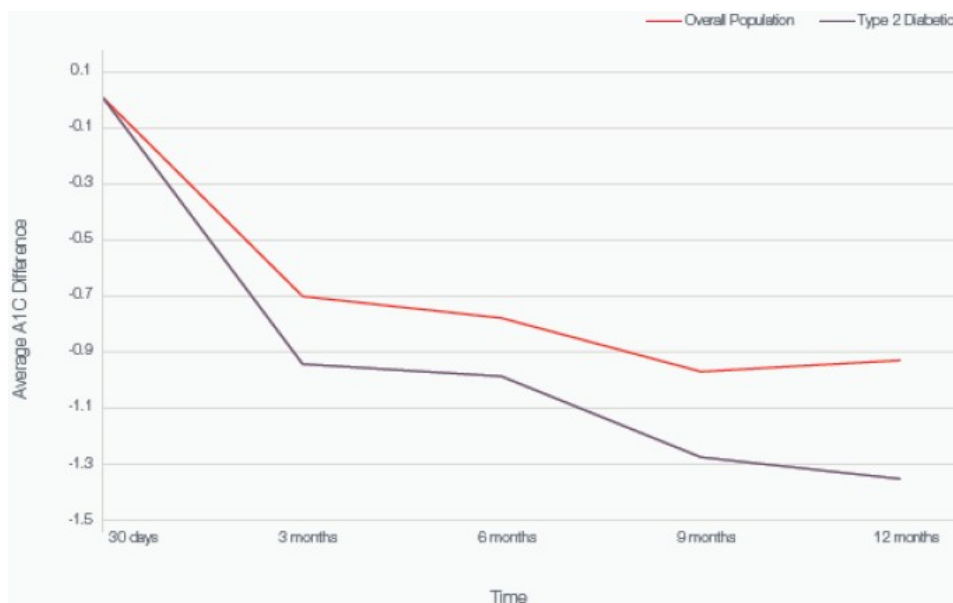
Baseline A1C	Improvement by	3-months	6-months	9-months
>8	At least 1.0%	178/276 (64%)	174/276 (63%)	179/276 (65%)
>9	At least 1.3%	90/120 (75%)	89/120 (74%)	89/120 (74%)
>10	At least 1.7%	36/47 (77%)	39/47 (83%)	38/47 (81%)

⁴⁸ Source: Dario company website.

⁴⁹ Data summarized from Moeshe, K. *et al.* Reducing A1C Levels in Individuals with High-Risk Diabetes Using Mobile Glucose Meter Technology.

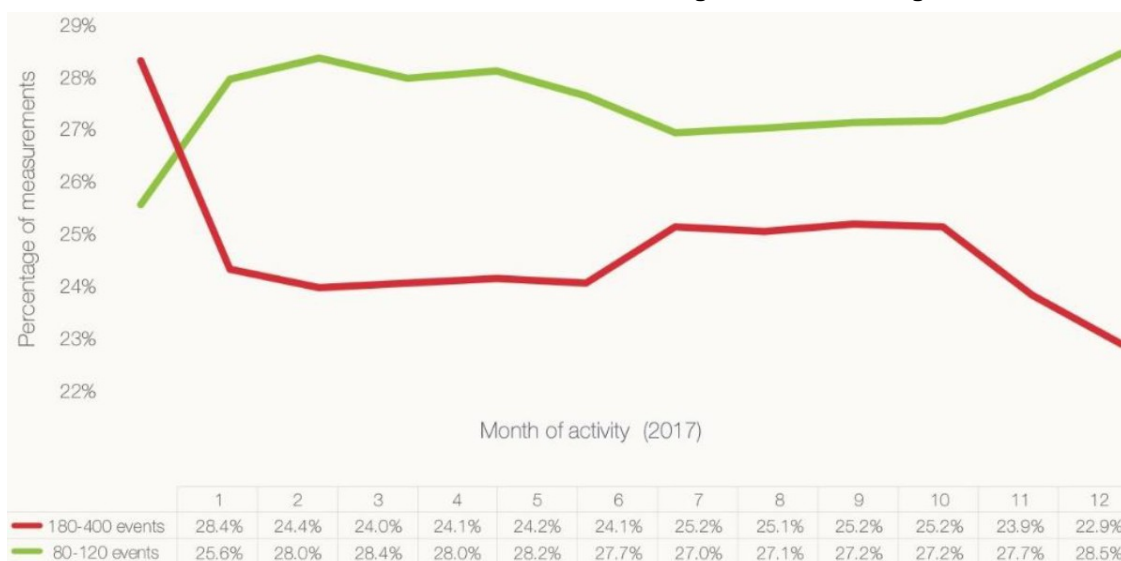
Another A1C study examined high-risk users of the Dario diabetes management system over a full year and was presented at the American Association of Diabetes Educators (AADE) 2018. The study measured A1C value for a high risk population with A1C greater than 7.5 percent and for the overall population of diabetes management system users. The results of the 363-subject study demonstrated a (1.4%) reduction in A1C for high-risk users after 12 months and a (0.9%) reduction in A1C for the overall population.

Exhibit V – Reduction in A1C⁵⁰



A poster presentation at the 2018 American Diabetes Association examined the benefit of the Dario system in a population of users with type 2 diabetes glucose levels above 180 mg/dL. The study found that the proportion of in-range readings for over 17,000 observations increased by 11.3% (from 25.6% to 28.5%) and the proportion of high glucose readings declined by 19.3% (28.4% to 22.9%) over a 12-month period. A later analysis which combined 2017 and 2018 data and included over 3.3 million measurements found a 14.3 decrease in high readings (180-400 mg/dL) and a 9.2% increase in in-range (80-120 mg/dL) readings. A majority of the benefit that was observed at 12 months was achieved after only one month of use.

Exhibit VI – Reduction and Sustainment of High Glucose Readings⁵¹



⁵⁰ Hershcovitz, Y., et al. Decrease in Estimated A1C for people in High-risk over a Full Year of Users Monitoring with a Digital Diabetes Management System. AADE 2018. Graph represents the difference in estimated A1C values over a year in high-risk Dario users.

⁵¹ Hershcovitz, Y., et al. T2D Users of a Digital Diabetes Management System Experience a Shift from Greater than 180 mg/dL to Normal Glucose Levels with Sustainable Results. ADA 2018.

The diabetes monitoring system enables patients to self-manage and control their condition. A retrospective study using the Dario database of type 2 diabetes users measured the averages of high and hyperglycemic readings on a monthly basis over a twelve month period compared to baseline. 225 type 2 diabetes users were included in the analysis and high blood glucose events were reduced by 19.6% (from 23.4% to 18.8%) for the group by the end of the measurement period. Severe hyperglycemic events were also reduced.

Exhibit VII – Reduction of Glycemic Events⁵²

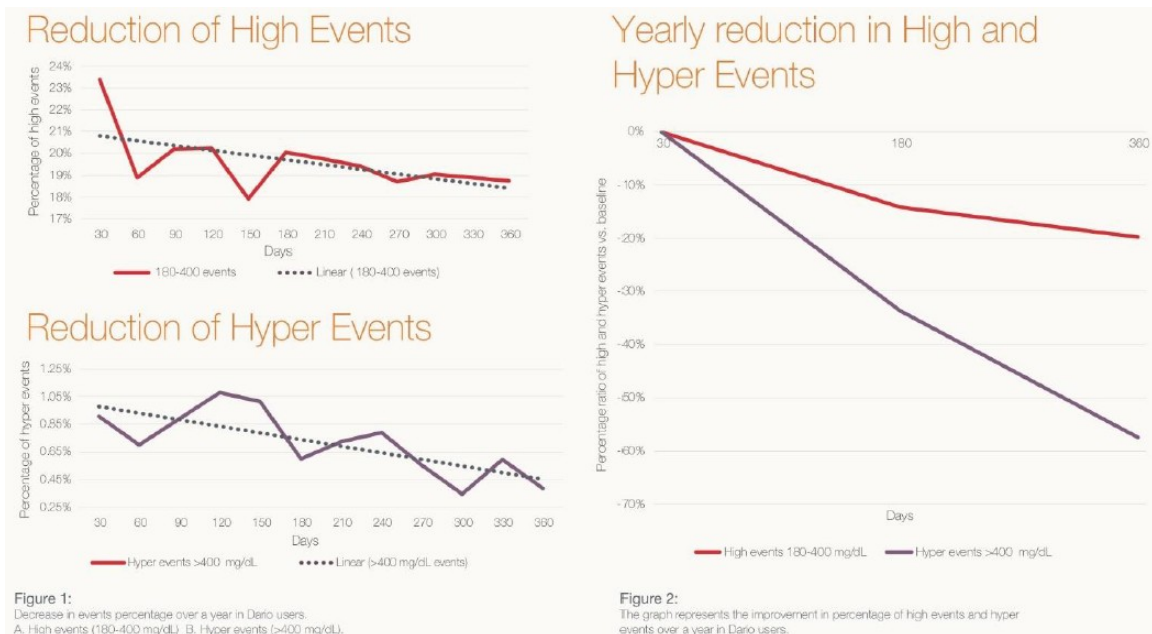


Figure 1: Decrease in events percentage over a year in Dario users. A. High events (180-400 mg/dL). B. Hyper events (>400 mg/dL).

Figure 2: The graph represents the improvement in percentage of high events and hyper events over a year in Dario users.

The blood glucose monitoring system also demonstrated a benefit in the high risk type 2 diabetes patient population. In a study evaluating 283 highly-engaged users with an average blood glucose level above 180 mg/dL at baseline, a steady reduction in blood glucose level was observed over the 12-month measurement period.

Exhibit VIII – Percent Reduction in Average Blood Glucose for High Risk Population⁵³

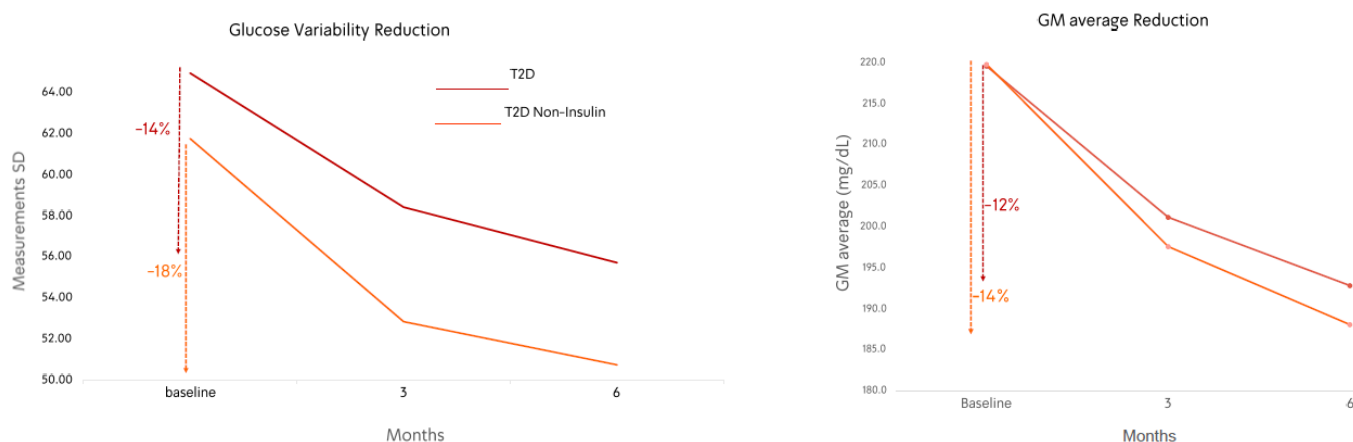


Reducing glycemic variability (GV) is another important target for treatment. Periodic high blood glucose exposure has been associated with negative effects such as endothelial dysfunction. GV can also encourage the development of chronic diabetes complications, including cardiovascular disease. In a retrospective study, Dario

⁵² Hershcovitz, Y., et al. Decrease in High Readings and Severe Hyperglycemic Events for People with T2D over the Full year of 2017 in Users Monitoring with a Digital Diabetes Management System. ADA 2018.
⁵³ Hershcovitz, Y., et al. Continuous Reduction of Blood Glucose Average During One Year of Glucose Monitoring Using a Digital Monitoring System in a High-Risk Population. The graph represents the decrease in average glucose readings compared to baseline over a one year period.

measured the effects of its digital diabetes management platform on GV. 698 type 2 diabetes patients with blood glucose above 180 mg/dL that measured more than 20 times over the first month of usage were included in the study. Patient data was again evaluated on days 60-90 and days 150-180. Standard deviation of observations and average blood glucose were calculated relative to baseline. Results demonstrated a 10% and 14% reduction in variability after three and six months. A subgroup analysis isolating 355 non-insulin dependent type 2 diabetes patients demonstrated a 14% and 18% reduction in variability after three and six months. A poster presented at the 2019 Advanced Technologies and Treatments for Diabetes conference concluded that Dario's digital platform can reduce glycemic variability, even in non-insulin dependent users.

Exhibit IX – Reduction in Glucose Variability and Glucose Levels⁵⁴



Dario has conducted additional studies that examine the benefits of the digital diabetes monitoring system. Other hypotheses that have been examined include glycemic control on diabetes, impact of digital intervention on improvement of in-range glucose levels, effect on hypoglycemic events and wellness indicators that have been presented at other industry conferences. All of the studies have demonstrated material improvements in the factor examined.

New studies were [announced](#) in mid-June regarding efforts in both diabetes and the company's next initiative in hypertension. Results were presented at the American Diabetes Association's 80th Scientific Sessions. On the diabetes front, Dario conducted a year-long retrospective study in 9,200 non-insulin treated type 2 diabetes patients using the Dario platform and found a 26% reduction in high glucose events which was sustained. Other findings include a 16% increase in the rate of fasting glucose levels. 75% of the patients were evaluated in the hypertensive subgroup who were at either stage 1, stage 2 or hypertensive crisis levels. 71% of the members using the hypertension digital therapeutic reduced their systolic and diastolic blood pressure by an average of 8.1 and 6.0 mm Hg. 38% of the participants were able to reduce their blood pressure level by one stage.⁵⁵

The second study was a long-term retrospective analysis evaluating the impact of Dario's system on sustained lower blood glucose levels. Over a two year period, 148 type 2 diabetes non-insulin users were able to sustainably reduce their blood glucose levels by 18%, which is equivalent to an eA1C reduction of 1.42%. A subgroup with higher than average blood glucose levels of over 240 mg/dL and estimated A1C (eA1C) of greater than 10 reduced their eA1C by 2.42%.

Adverse Events and Safety Profile

One of the benefits of DTx is the near absence of treatment-related side effects and lack of toxicity when compared to traditional medicines. Some risks do emerge. If DTx is a replacement for another therapy and fails to work properly, critical functions may not be properly controlled leading to health complications. If a patient does not engage with the program or the application fails to work properly, it could cause the condition to worsen.

In totality, the risks of using DTx is much lower compared with traditional medicines and the limited side effect and toxicity profile is one of the arguments in its favor compared to pharmacological agents. The safety benefit of DTx

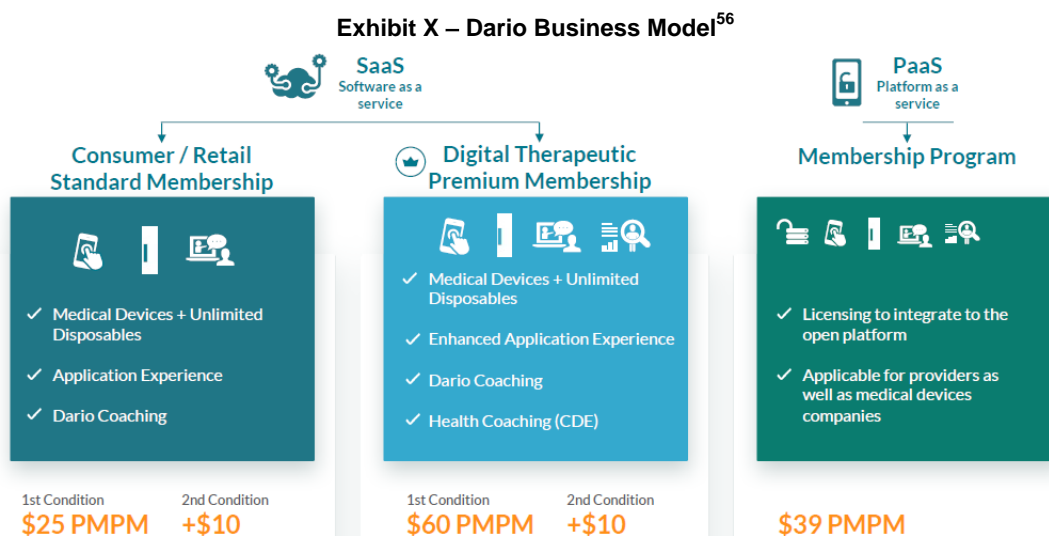
⁵⁴ Hershcovitz, Y., et al. Decrease in glycemic variability for T2D over six months in patients monitoring with a digital Diabetes management system. ATTD 2019.

⁵⁵ Stage 1 hypertension is defined as systolic pressure from 130 to 139 mm Hg and diastolic pressure from 89 to 89 mm Hg. Stage 2 hypertension is a systolic pressure of above 140 mm Hg and diastolic pressure of 90 mm Hg or higher. Hypertensive crisis is where blood pressure exceeds 180/120 mm Hg.

is highlighted when digital medicine can replace the need to use a drug that does have unwanted side effects or safety risks.

Dario Strategy

Dario is in the process of shifting from a business-to-consumer (B2C) company to a business-to-business-to-consumer (B2B2C) platform. The company's initial foray into the market began with the sale of blood glucose meters and associated supplies through Walmart, Best Buy, Amazon and its own online store among others while providing access to the monitoring application for free. Later, a subscription was offered to consumers where diagnostics and consumables are provided as part of a monthly subscription. Dario was able to accumulate over 50,000 paying members; however, acquisition costs are high and growth is relatively slow compared to the B2B2C market. With others in the space leveraging the customers that healthcare providers already had in place, Dario elected to advance into the B2B2C space, offering a scalable, integrated solution that can combine both Dario's services and allow access to provider services. Working with providers, health plans, payors and benefits administrators will allow Dario to leverage its product over the lives covered by these organizations.



The company is transforming itself from a retail-only DTx company, producing the majority of its revenues from product sales, to a software as a service (SaaS) and platform as a service (PaaS) enterprise that is generating revenues from a variety of sources. The healthcare provider market, which includes health plans, employer sponsored offerings and providers themselves, is substantially more attractive than the retail market given its more leveragable dynamics. Retail consumers are very costly to acquire and most only demand the basic service. Attracting retail customers in large numbers is also relatively slow and per member per month (PMPM) revenue is generally lower than what can be obtained in the healthcare provider market. This has encouraged Dario to advance into the healthcare provider market where starting PMPM revenue is anticipated to be \$60 and as much as \$80 when multiple chronic conditions are monitored. New members can also be added in large groups. If a 50,000 member health plan is added, they likely have from 5,000 to 10,000 individuals with a chronic disease, which would be added as new subscribers over the first several months of the partnership.

Dario outlines multiple growth drivers in its slide deck, illustrating the historical and future markets it will pursue with increasing PMPM revenue opportunity. It highlights efforts to continue to grow its direct to consumer segment, which is now about 50,000 users, to enhance its products by adding new chronic conditions, such as hypertension, obesity and behavioral health and to scale its business to business efforts by developing new relationships.

There are four primary categories of clients that Dario is pursuing: Retailers, Providers, Employers and Health Plans. While the Retail market has provided the dominant share of revenue to date and provided much of the data used to validate the platform, healthcare providers lend substantial leverage and can introduce Dario's services to large populations. Health care providers have existing relationships with members and are willing to add a positive return on investment (ROI) offering to their platform. Members of these health plans value health and wellness services which improves retention and provides desired outcomes.

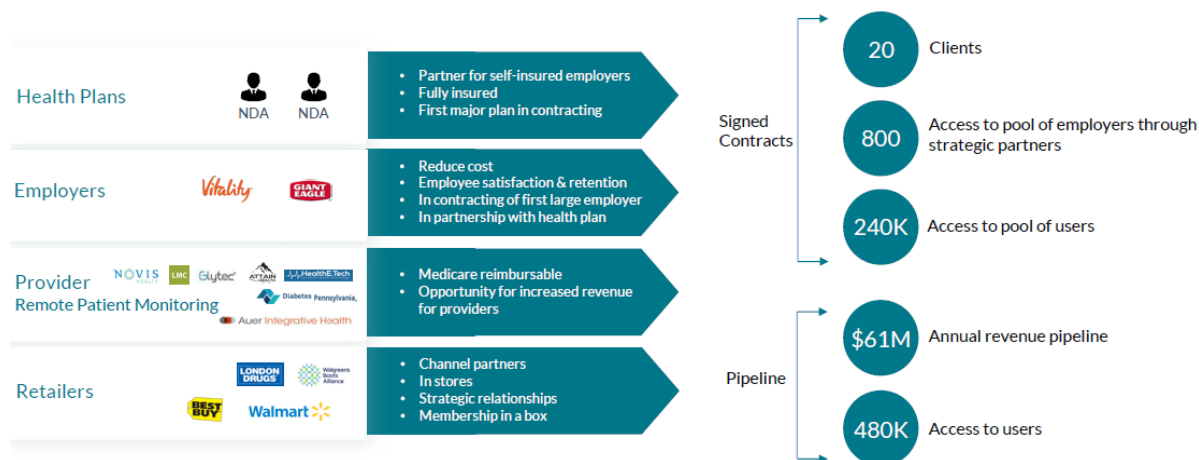
⁵⁶ Source: Dario Corporate Presentation June 2020

Dario has consumer plans that start at \$25 per month and move up to \$33 and \$70 for additional levels of service. A discount is offered for consumers that sign up for a 12-month plan. Customer acquisition cost for these individuals is high and in some cases over 80% of revenue. As Dario has matured, management has developed the necessary data to demonstrate that the tool is effective and to attract attention of business customers that serve large populations that can benefit from the DTx service.

Dario’s initial efforts in the consumer space revolved around selling devices and test strips to users and providing the application for free. The company is now shifting its retail strategy to a monthly subscription model which will charge based on different tiers of service. The programs start at \$25 PMPM and increase based on the number of conditions it can treat and other services such as coaching. By the end of the year 2020, Dario anticipates completely moving away from the product model and relying exclusively on subscriptions from retail members.

The provider market is another focus for the company’s efforts. In 2018 the American Medical Association (AMA) lobbied the Center for Medicare and Medicaid Services (CMS) to provide new remote patient monitoring (RPM) codes that incentivize providers to deploy RPM. CMS subsequently added new current procedural terminology (CPT) codes in September 2019 which allow for remote monitoring of several physiologic parameters, including blood pressure, blood sugar, weight and others. Providers pay DarioHealth to provide the monitored data and receive CMS reimbursement for the effort. The disruptions related to the coronavirus have created a surge in demand for RPM as trips to the physician’s office have become more difficult. Dario’s flexible remote platform allows providers to monitor patients between visits. The company has already signed two RPM contracts to administer this service and will leverage its glucose and blood pressure monitoring systems as the segment continues to grow. We anticipate further pursuit of larger provider practices and provider consolidators for RPM.

Exhibit XI – Client Base⁵⁷



Employers are another attractive target market. In May 2020, Dario announced that it would begin offering its services through **Vitality Group**, a subsidiary of South Africa-based Discovery Limited. DarioHealth will be offered on Vitality’s platform and Vitality will also begin co-marketing the blood glucose and hypertension monitoring services to its customers. Health plans are the other major channel for the company. Health plans seek an evidence-based and cost effective approach to improve health and lower costs. In 2020, Dario has hired three executives that have extensive experience building up business in the health plans market to help advance this initiative. This team has identified several leads and are in late stage discussions in this area which could be the most significant channel of the four presented.

One of the company’s most attractive features is its adaptable platform that can either provide Dario’s services and customized pass through services such as in behavioral health, or completely customizable services that ride on top of the platform. This can provide access to coaches, counselors and medical professionals and help meet the specific needs of large providers.

⁵⁷ Source: Dario Corporate Presentation June 2020

Exhibit XII – Dario’s Multifaceted Business Model⁵⁸



Healthcare providers, which include hospitals, health plans, payors and benefits administrators, will be offered a different tier of services that start at \$60 per month and include access to the DarioEngage platform (which provides support and connectivity between subscribers and caregivers). This can expand to \$70 and \$80 PMPM as additional monitoring and customizable coaching features are added.

Dario has been able to develop a differentiated approach in this wide open DTx market. Dario’s goal is to change behavior in order to modify the trajectory of chronic disease through customizable incentivized behavior. Primary care doctors do not always have the expertise or the time to consistently monitor patients, which makes Dario’s solution a strong complement to their services. Providers want outcomes and Dario has provided evidence that its systems can impact health for the better. With a customizable and proven platform, the benefits can be expanded beyond the retail segment and move into the health plan, employer and other healthcare services spaces to reduce cost and improve patient satisfaction. Early efforts that were focused on low revenue, low margin customers will be repositioned towards larger healthcare providers that manage thousands of lives, a strategy shift that yields both higher revenue per member and lower acquisition costs per member.

Convertible Series A Notes

On December 20, 2019, Dario completed a series of capital raises that secured \$21.4 million in private placements of convertible preferred stock to institutional and private investors. Over several weeks, the company closed several tranches of Series A Convertible Notes, totaling 21,375 Series A shares, with an average conversion price of \$4.31. The notes have a feature that provides for an annual dividend of equity shares on each anniversary of the transaction over the three year life of the notes. The notes distribute a 10% dividend in the first year, a 15% dividend in the second year and a 20% dividend in the third year for investors who continue to hold the shares until the first, second and third anniversary of the placement date. The first share dividend is expected to be paid in November 2020. Since the initial note issuance and as of May 9, 2020, approximately 665,000 equity shares have been converted, leaving approximately 4.3 million shares remaining. If no further notes are converted, the maximum incremental dilution by December 2022 will be 6.2 million shares. Our model reflects the conversion of all shares in our share count balance for calendar year 2023.

Partners, Collaborators and Investors

Dario has accumulated numerous partners as it grows its business. The company will rely on others to expand its services to large groups. Partners can be placed into a few categories including retail sales partners, health service providers, remote monitoring and other. While the identities of the health plans that are expected to materialize have not yet been publicized, Dario has numerous engagements in place with retailers, health service providers, remote monitoring and other categories.

⁵⁸ Source: Source: Dario Corporate Presentation June 2020

Exhibit XIII – Dario Partners and Collaborators⁵⁹

Retail	Health Service	Provider/RPM	Other
Walmart	Glytec	Novis	Vitality Group
Better Living Now	CCS Medical	Diabetes PA	Amer Diabetes Assoc
Best Buy	Auer Integrative	Attain Health	DTx Alliance
Giant Eagle	LMC Health	HealthE Tech	Apple/Google Play
Amazon	D&E Consult	LMC	Hub HighTechXL

Intellectual Property

Dario has been granted numerous patents for its testing device and for the technology behind the connection with a smartphone. Glucose and blood pressure monitors, scales and other measurement devices are commonplace and are less critical to Dario's success than its reputation and relationships with consumers and partners and efficacy of its platform. The company will need to continue to innovate not only its devices but also its user application and software platform which are of greater importance. Below we provide a list of Dario's key patents.

Exhibit XIV – Patents for Monitoring Systems⁶⁰

Title	Patent #	Region	Filed
Fluid testing apparatus and methods of use	8,797,180	US	10-Feb-14
Fluid testing apparatus and methods of use	9,125,549	US	4-Aug-14
Fluid testing apparatus and method of use thereof	2,569,622	EU	8-May-11
Fluids testing apparatus and methods of use	9,257,038	US	31-Jul-15
Systems and methods for adjusting power levels on a monitoring device	9,832,301	US	23-Feb-16
Systems & methods for enabling optical data transmission between sensor & smart device	10,455,072	US	20-Mar-18

Corporate Milestones

DarioHealth is in the process of shifting from a products company to a SaaS company which provides chronic condition monitoring services and application-based guidance to patients. Dario has a strong presence in the retail market and is advancing its efforts in the healthcare provider markets. We anticipate announcements this year of two health plans that will use the Dario platform. Below we list key milestones that have occurred in the last year and anticipated future events.

- Walmart distributes Digital Diabetes Management System – December 2019
- Closing of \$21.3 million private placement – December 2019
- Addition of several new board and management team members – 1Q:20
- [Presentation](#) at American Diabetes Association Scientific Session – June 2020
- Announcement of new signed contracts with health plans and other prospects – 2H:20

⁵⁹ Source: Dario investor materials and author's work.

⁶⁰ Source: Author's work, company filings and uspto.gov

RISKS

All investments contain an element of risk related to the uncertainty of a business and what it will ultimately achieve. Some investments exhibit higher predictability, with current cash flows and established sales. These enterprises will have a lower level of perceived risk while other companies that are developing an undefined, new technology have a much higher level of perceived risk. Like many smaller or early stage companies, Dario bears a broad variety of risks related to each aspect of its business ranging from competitive risks to the company's cash position and the trading volume of its shares.

The diagnostics space includes companies at both ends of the spectrum, from mega-cap device development and commercialization powerhouses that have multiple products currently generating revenues, to small operations with a handful of employees developing new technologies. Many of the risks faced by the large device companies and smaller single product-focused firms are similar; however, there are some hazards that are peculiar to smaller companies that have not yet established themselves or their products.

For smaller early-stage companies, investing in product and service development is a lengthy process. There are numerous development and regulatory hurdles to overcome which can take numerous years to accomplish, such as receiving the CE (Conformité Européenne) mark in Europe or 510(k) clearance in the United States.

Even if a company has a strong, experienced team that is developing a product or service with a high likelihood of success and a large addressable market, securing funding may be difficult. Access to financing is cyclical. During periods of improving confidence, capital may be easy to obtain; however, during a liquidity crisis or a period of heightened risk perception, even companies with bright prospects may be in trouble if they are dependent on the financial markets to fund their work. If capital is needed to sustain operations and it is not readily available, the company may be forced to suspend research and development, sell equity at a substantial discount to previous valuations and dilute earlier shareholders. A lack of funding may leave potentially promising products, services and therapies without a viable route forward or force a company to accept onerous terms.

All Class II devices must obtain regulatory approval in the US, EU and other countries before commercialization in those regions. Success is uncertain and may take years depending upon the needs and desires of the determining authority. Substantial expense is undertaken to conduct studies and have their results accepted by academic and regulatory authorities. A long history of research success in drug development, with opinion leaders and experts advocating for the product in the field are important factors that can help mitigate this risk. Previous success with the FDA or other regulatory agencies is another attractive attribute for a sponsor. Some accelerated pathways to approval are available such as those outlined in the Orphan Drug Act and the Breakthrough Therapy designation; however, changes in sentiment or perceived safety for pharmaceuticals drugs could change the regulatory environment to demand a more thorough process and these pathways may be extended or additional requirements may be put in place.

The ever present risk of disruption threatens Dario and the entire industry of diabetes management. While diabetes is a complex pathology, progress toward a cure continues. Drugs exist that go beyond the symptom-addressing insulin and insulin analogs to modulate appetite, blood glucose, insulin sensitivity, and insulin/glucagon production. While these medications may not immediately and completely reduce the need for a glucose monitoring system, they may reduce the frequency of necessary self-tests. Any new treatments that could cure diabetes would remove the chronic nature of the disease and the need for frequent monitoring.

The diabetes management industry is already quite mature and dominated by large companies including Roche Diagnostics, LifeScan (Johnson & Johnson), Ascensia, and Abbott Laboratories. These companies have greater marketing resources than emerging companies have. The diabetes management space has leveraged the abilities of smartphone applications to track activity and diet and integrate these inputs with portable glucose testing and monitoring devices which has few barriers to entry. The range of competitors are varied in size and features. We count no less than 20 other DTx companies that are focused on glucose monitoring or diabetes. While Dario has a well-liked and easy to use application, these apps are also highly imitable and Dario must rely on customer loyalty and relationships with health care providers for its success. Large peers including Abbott, Roche, Sanofi and Medtronic have sizeable budgets and could reproduce Dario's application platforms and marketing activities if they chose. Dario has elected to execute its own marketing efforts against larger companies with established sales teams and relationships. In order to compete, Dario must create a sales force and develop relationships with health care providers.

The recent coronavirus outbreak has resulted in a broad mandate of quarantine in many countries and the delay of non-critical and elective procedures. This may lead to a reduction in demand for health care services. While this may hinder the sales of Dario Blood Glucose Monitors via physicians and hospitals, it may also increase demand for remote access to health care services, which is one of Dario's service offerings.

Dario, like many early-stage technology companies, operates at a loss. In 2019, the company reported a net loss of (\$20.9) million and cash burn of (\$15.8) million. While the company holds cash of \$15.8 million as of March 31, 2020, the need for capital is persistent until greater revenues can sustain the company. Based on our estimates, funds are sufficient to carry Dario through to the end of 2020 at which time additional funding will be needed.

Competitors, Peers and Competing Approaches

The diabetes management space has experienced recent innovation in the form of smartphone apps that can track activity and diet and integrate with portable glucose testing and monitoring devices. The range of competitors are varied in size and features. Companies including Abbott, Roche, Sanofi and Medtronic have sizeable budgets and in-house manufacturing, distribution and sales forces. Others, like Livongo, are not in the megacap range but are larger and have a more dominant footprint than Dario. Yet another group of DTx providers have less access to funding than Dario and focus on less capital intensive smartphone applications. Dario maintains its competitive position against diabetes/chronic health condition management platforms by offering a comprehensive feature set and a team experienced with meeting the needs of healthcare service providers. Dario offers blood glucose monitoring, blood pressure monitoring, testing supply fulfillment, activity tracking, food tracking, personal coaching, data science analysis, education and performance incentives.

Exhibit XV – Peers and Competitors⁶¹

Ticker	Company	Price	MktCap (MM)	EV (MM)	Therapeutic Area
ABT	Abbott Labs	\$94.82	\$167,722	\$180,858	Blood glucose devices and softw are
BAYRY	Ascensia	\$18.24	\$68,039	\$103,208	Blood glucose monitoring devices & diabetes management softw are
OTRK	Catasys	\$26.94	\$459	\$482	Data predictive analytics, AI & telehealth services to 3rd party payors
DXCM	DexCom, Inc.	\$410.34	\$37,893	\$37,532	Continuous glucose monitoring device and app
JNJ	Lifescan	\$147.92	\$389,709	\$397,078	Blood glucose device and app
LVGO	Livongo Health	\$101.18	\$9,897	\$9,529	App based chronic condition management
MDT	Medtronic plc	\$94.65	\$126,954	\$138,027	Continuous glucose monitoring device and app
RHHBY	Roche Holding	\$44.48	\$304,621	\$305,436	Blood glucose testing devices
SNY	Sanofi	\$52.11	\$130,491	\$130,491	Blood glucose testing devices and app
pvt	2Morrow				Behavioral DTx for w eight, smoking & pain
pvt	Agamatrix				Blood glucose testing device/supplies and app
pvt	Akili Interactive				ADHD video game
pvt	Ayogo Health				Diabetes DTx
pvt	Beta Bionics				Digital pancreas
pvt	Better Tx				DTx for diabetes, hypertension, CVD & obesity
pvt	Canary Health				Multiple chronic conditions including diabetes
pvt	Click Tx				DTx for smoking, depression, insomnia, migraine, obesity & other
pvt	Cognoa				DTx pediatric behavioral health/early autism detection
pvt	Ginger.io				App based mental health support
pvt	Glooko				App based diabetes monitoring and management
pvt	Happify				Assists in drug compliance, mental health support.
pvt	Hello Heart				Cardiovascular risk management app
pvt	iHealth Align				Compact glucose meter
pvt	Intuity Medical				One step blood glucose testing device
pvt	Kaia Health				App-based musculoskeletal health program
pvt	Lyra				Mental health care platform
pvt	Mango Health				Medicine management using app
pvt	Medisana				Blood glucose device and app
pvt	Mindstrong Health				Mental health care platform w ith therapy sessions
pvt	Noom				App-based w eight loss, diabetes & hypertension treatment
pvt	Omada Health				App-based diabetes management
pvt	Onduo				Continuous glucose monitoring device/app diabetes management
pvt	One Drop				Blood glucose testing device/supplies and app
pvt	Pear				reSET-O for opioid use disorder
pvt	Pops				Phone-mounted blood glucose testing device and app
pvt	Propeller				App-based respiratory health management/COPD
pvt	Proteus Digital				Ingestible & wearable sensors for chronic conditions.
pvt	Sensulin				Agglomerated Vesicle Technology - activated liposomes
pvt	Talkspace				Instant messaging based therapy
pvt	Virta Health				App based diabetes monitoring and management
pvt	WellDoc				App based chronic condition management
DRIO	DarioHealth	\$6.40	\$52	\$36	DTx for diabetes, hypertension, obesity & behavioral health

⁶¹ Price and market capitalization data is as of July 14, 2020.

MANAGEMENT PROFILES

Erez Raphael, Chief Executive Officer and Director

Mr. Raphael has served as Dario's CEO since August 9, 2013 and as a director of the company since December 2013. He has served as Chairman of the Board of Directors from November 2014 to July 2018, and as a director from November 2014 to present. He previously and until October 2012 served as Dario's 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 Dario, 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 (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.

Richard Anderson, President and General Manager of North America

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

Zvi Ben David, Chief Financial Officer, Treasurer and Secretary

Mr. Ben David has served as Dario's CFO, Treasurer and Secretary since January 7, 2015. He 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, 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. From 2000 to 2005, he served as Vice President and CFO of Given Imaging, 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 CFO of RDC Rafael Development Corporation, one of Given Imaging's principal shareholders. From 1994 to 1995, Mr. Ben David served as manager of the finance division of Electrochemical Industries (Frutarom), 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.

Omar Manejwala, M.D., Chief Medical Officer

Dr. Manejwala has served as CMO of DarioHealth since March 2020 where he leads the company's clinical solutions efforts and provides visible internal and external leadership. Previous roles include CMO of Catasys, now OnTrak (Nasdaq: OTRK) where he led Product from zero to pilots and then to commercial scale, securing contracts for the OnTrak program with most of the largest US health plans. He developed solutions for commercial, exchange, managed Medicare Advantage, and managed Medicaid adult populations. These solutions and partnerships are directly responsible for Catasys/OnTrak's growth from zero to an approximately \$400m valuation. Prior to that, he has held various leadership roles most recently as Medical Director at Hazelden. He has an MBA from the University of Virginia's Darden School of Business, an M.D. from the University of Maryland School of Medicine and served as intern, resident and Executive Chief Resident at Duke University. He is a Distinguished Fellow of the APA, a Fellow of ASAM, and am board certified in Psychiatry, Addiction Medicine and Medical Management.

Financial and Operational Results

2020 began with the [appointment](#) of Richard Anderson, a digital health veteran with previous experience at Catasys Inc., as president and general manager for the North American region, marking a meaningful step forward in the initiative to expand US B2B sales. In February, at the Advanced Technologies & Treatments for Diabetes conference in Madrid, Spain, Dario presented study data investigating hypoglycemic events in type 1 and type 2 diabetics who used the Dario platform showing a reduction in hyperglycemic events of 40%, and hypoglycemic events of up to 50-57% after two years on the platform.

Dario [expanded](#) its retailer partnerships to include Albertsons where 'membership in a box' packages will be sold in more than 1,700 in-store pharmacies across the US. Two members, Yadin Shemmer and Adam Stern were [appointed](#) to the board of directors. Mr. Shemmer adds to the board's leadership experience in digital health and diagnostic services and the board gains experience in startup investment in the healthcare space with the addition of Mr. Stern.

In March, Dario [announced](#) a key partnership with Vitality to accelerate advances into the self-insured employer market which is another milestone in Dario's B2B initiative. In exchange for conditional, performance-based warrants, Vitality agreed to integrate Dario's chronic condition platform into its current wellness solution platform and market the integrated platform to its existing clients. Dr. Omar Manejwala [joined](#) the management team as the Chief Medical Officer and Barbara Stark as SVP and Head of Managed markets adding decades of industry and clinical experience to managed care and clinical support teams.

On April 29, 2020, and in the wake of the pandemic, Dario [announced](#) a partnership with telemedicine provider MediOrbis to provide Dario's 50,000 users access to a full suite of telemedicine capabilities, fully integrated into the DarioHealth application. In May, Dario announced emergency approval by the FDA for DarioHealth self-test BGM, allowing COVID-19 diabetic patients to self-monitor while in the hospital, minimizing healthcare professional exposure.

In the month of June, Dario [announced](#) the signing of its first two RPM agreements, allowing physicians to continue to care for their patients between visits, integrated into Dario's existing open platform, application technology and the DarioEngage coaching platform.

In July, Dario took another big step in its B2B2C initiative with the [appointment](#) of Dennis Matheis to its board. He is President of Optima Health and offers nearly 30 years of health plan leadership experience. Optima Health is a division of Sentara Healthcare which has more than 850,000 members and a network with over 26,000 providers.

In the financial reporting sphere, Dario provided first quarter 2020 [results](#) on May 12, 2020. Year-over-year quarterly performance is compared. Revenues were \$1.7 million, down from \$2.2 million, attributed to a decrease in direct-to-consumer acquisitions. Cost of revenues declined to \$0.9 million from \$1.7 million as a result of lower product sales and improved margin on existing sales yielding an increase in gross profit of \$779,000 compared with \$558,000 in the prior year period. R&D costs totaled \$1.2 million, up from \$1.0 million, sales and marketing costs were up to \$4.1 million versus \$3.9 million, both a result of increase in equity-based compensation, slightly offset by a reduction in development cost and digital marketing, respectively. General and administrative expenses increased to \$5.6 million from \$1.0 million in the prior year on a grant of equity based compensation and increase in consulting and insurance expenses. Dario registered a net loss of (\$11.2) million including the deemed dividend related to the Series A Preferred Stock compared with a (\$5.4) million loss in the prior year period. The firm held \$15.8 million in cash, down \$4.8 million over the prior three month period.

VALUATION

Dario is running in one of the fastest growing areas of the health care services space and is focused on a major disease that can be effectively remediated through behavioral change. Digital Therapeutics has been able to transform behavioral health with our constantly present smartphones. Through the use of AI algorithms, Dario can favorably influence behavior and generate quantifiable improvements in diabetes biomarkers. The company has historically generated revenues from the retail consumer segment and is shifting this group toward a subscription model. With supportive data in hand, Dario is now pursuing the healthcare provider market which should prove to be substantially more profitable with lower acquisition costs and higher PMPM revenues. The company began offering its service to address diabetes and has expanded it to include management of hypertension, obesity and mental health. Revenues in 2019 were \$7.6 million, generating a net loss of (\$20.9) million for the year. While the first quarter saw a year-over-year decline in revenues, gross profit actually increased from \$558,000 to \$779,000 demonstrating the favorable shift in margin. We expect to see flat revenues in the second quarter of 2020 followed by a rise in the second half of the year as subscribers from health plans and other healthcare providers begin to load the platform. These B2B2C customers will also have an average revenue per user of almost twice the retail segment.

The drivers for our forecast are active users (subscribers)⁶² and revenues PMPM. Dario does not provide sufficient detail to tie our estimates to actual subscribers or PMPM; however, we do know that the company has approximately 50,000 active users which implies a PMPM of \$12.60 for 2019 and \$11.11 in 1Q:20. We anticipate material improvement in subscriber additions and an increase in PMPM revenues. Our estimates are below.

Exhibit XVI – Revenue and Subscriber Estimates⁶³

DarioHealth Corp.	2019 A	2020 E	2021 E	2022 E	2023 E	2024 E
Total Revenues (\$US '000)	\$7,559	\$7,587	\$13,435	\$25,843	\$46,874	\$75,926
Average Subscribers	50.00	53.50	70.86	99.99	142.06	198.95
PMPM Revenues ('000)	\$12.60	\$11.82	\$15.80	\$21.54	\$27.50	\$31.80

We also provide a breakdown of our estimates by line item until 2024 which generate positive earnings in the final year of our forecast. These assumptions assume a dramatic increase in gross margins that will increase from under 50% this year to almost 70% by 2024. From 2019 to 2024, we anticipate a topline compound annual growth rate (CAGR) of almost 60% while R&D, S&M and G&A will grow 13%, 10% and 16% respectively, demonstrating the operational leverage in the model. We do not recognize cash taxes over the forecast period as Dario will work through what could be as much as \$150 million in net operating losses beginning in 2024.

Exhibit XVII – Income Statement Forecast 2019 – 2024⁶⁴

DarioHealth Corp.	2019 A	2020 E	2021 E	2022 E	2023 E	2024 E
Total Revenues (\$US '000)	\$7,559	\$7,587	\$13,435	\$25,843	\$46,874	\$75,926
YOY Growth	2%	0%	77%	92%	81%	62%
Cost of Revenues	\$4,962	\$4,026	\$6,698	\$10,510	\$15,911	\$24,290
Product Gross Margin	34%	47%	50%	59%	66%	68%
Research & Development	\$3,692	\$4,431	\$5,229	\$6,013	\$6,494	\$6,819
Sales & Marketing	\$11,127	\$12,391	\$13,960	\$15,356	\$16,124	\$17,575
General & Administrative	\$5,483	\$10,971	\$10,200	\$10,506	\$11,000	\$11,440
Income from operations	(\$17,705)	(\$24,232)	(\$22,652)	(\$16,542)	(\$2,655)	\$15,802
Operating Margin	-234%	-319%	-169%	-64%	-6%	21%
Financial Expenses	\$31	(\$222)	\$0	\$0	\$0	\$0
Deemed Dividend	\$3,155	\$2,075	\$1,100	\$1,000	\$0	\$0
Pre-Tax Income	(\$20,891)	(\$26,085)	(\$23,752)	(\$17,542)	(\$2,655)	\$15,802
Net Income	(\$20,891)	(\$26,085)	(\$23,752)	(\$17,542)	(\$2,655)	\$15,802
Net Margin	-276%	-344%	-177%	-68%	-6%	21%
Reported EPS	(\$9.22)	(\$6.91)	(\$3.96)	(\$2.22)	(\$0.25)	\$1.29
YOY Growth	-25%	-25%	-43%	-44%	-89%	-623%
Basic Shares Outstanding	2,266	3,773	6,000	7,905	10,759	12,250

Source: Company Filing // Zacks Investment Research, Inc. Estimates

⁶² Dario has provided an approximate number of 50,000 active users. As it changes its model all users will be converted to subscribers.

⁶³ Source: Author's work

⁶⁴ Source: Company filings, author's estimates

Reported basic shares outstanding do not include the Series A Convertible Preferred Stock shares as converted nor are the Series A instruments recognized as debt. To reflect the claims of the Series A we add the as converted shares when calculating our per share valuation. This instrument, which we discuss in an earlier section, now represents 4.3 million additional shares and could represent up to 6.2 million additional shares by 2022 if the instruments are held to maturity and all share dividends are distributed. Our valuation assessment includes the 6.2 million in converted Series A shares in basic shares outstanding as of the end of 2022,⁶⁵ which continue to be included in 2024, along with additional shares representing future capital raises. For calculating enterprise value, we include most recently reported shares outstanding along with the number of Series A shares that would convert today.

Our valuation employs a 20x multiple of future earnings per share as our primary valuation metric. The value is then discounted to present using a 25% rate. When we apply our 20x multiple to \$1.29, we generate a 2024 target price of \$25. Discounting this to present using a 25% discount rate generates a valuation (present value) of \$10.50. The valuation approach is very sensitive to assumptions regarding revenue growth, net margins, earnings multiples and discount rates. A one percentage point increase in net margin would result in a \$0.062 change in 2024 reported EPS and a 4.8% change in valuation. Delaying the \$1.29 in EPS by one year would have a 20% negative impact on our valuation while a one year advance of Dario's recognition of earnings would increase the target price by 25%. Below is a sensitivity table that shows present value of 2024 price to earnings (P/E) based valuation.

Exhibit XVIII – Valuation Sensitivity Table⁶⁶

P/E Multiple: 2024 EPS	Discount Rate				
	20.0%	22.5%	25.0%	27.5%	30.0%
15.0	\$9.33	\$8.59	\$7.93	\$7.32	\$6.77
17.5	\$10.89	\$10.02	\$9.25	\$8.54	\$7.90
20.0	\$12.44	\$11.46	\$10.57	\$9.76	\$9.03
22.5	\$14.00	\$12.89	\$11.89	\$10.98	\$10.16
25.0	\$15.55	\$14.32	\$13.21	\$12.20	\$11.29

Based on our target price of \$10.50, this implies a 2020 EV/Sales multiple of 13.8x⁶⁷. We compare this to multiples for the other companies in the space, as provided below. DarioHealth is currently trading at 6.5x 2020 estimated revenues.⁶⁸

Exhibit XIX – Comparable EV/Sales Multiples⁶⁹

Ticker	Company	EV/Sales
OTRK	Catasys	13.7x
DXCM	DexCom, Inc.	25.4x
LVGO	Livongo Health	56.0x

We also highlight the April transaction between Optum and AbleTo that was closed at an estimated \$470 million valuation which compares to our target enterprise valuation of \$105 million⁷⁰ for DarioHealth.

Based on the assumptions identified in our financial model, we generate a current valuation of \$10.50 per share.

⁶⁵ 2022 Basic Shares Outstanding represents an average share balance as the Series A converted shares are forecast to be converted in 4Q:22.

⁶⁶ Source: Author's own work.

⁶⁷ This valuation is based on our target price of \$10.50 multiplied by outstanding shares of 3.8 million and 2022 estimated converted shares of 6.2 million, the divided by \$7.6 million in 2020 estimated revenues. $(\$10.50 \times (3.8 + 6.2)) / \$7.6 = 13.8x$

⁶⁸ This assumes valuation of DRIO is $\$6.40 \times (3.8 \text{ mm shares} + 4.3 \text{ mm converted shares}) / \8 mm revenues .

⁶⁹ Source: Author's own work.

⁷⁰ This valuation is based on our target price of \$10.50 multiplied by outstanding shares of 3.8 million and 2022 estimated converted shares of 6.2 million.

CONCLUSION

DarioHealth is on the leading edge of one of the largest opportunities in health care. Digital therapeutics has been able to combine several disparate elements, AI, the ubiquity of smartphones and behavioral health, to achieve therapeutic outcomes in large populations. A new paradigm has shown that digital advice may improve health along the most important axes: our behavior and actions.

Dario began as a retail-focused product company and used this phase of its development to refine and quantify the beneficial impact that its platform can provide. Now that it has advanced to a stage where it can guarantee outcomes, the company is pursuing large healthcare providers that represent large populations that are relatively inexpensive to acquire and also generate more revenue per user. This fortuitous combination is expected to drive growth later this year as partner subscribers are layered onto the revenue stream. Despite the opportunities, Dario is valued well below other peers in the space and we anticipate high levels of growth and margin improvement over the next several years, justifying our valuation. With the new team in place that has extensive experience working with health plans, employer plans and other large health groups, combined with real world evidence of improved outcomes, Dario is strongly positioned to meet our forecasts.

The size of the market for DTx is immense. We have outlined the multi-billion dollar costs of just two chronic diseases. Combined with the incessant push to turn down the cost curve, there is willingness to spend upfront on proven approaches that can reduce spending on chronic disease in the future. Dario has generated numerous real-world studies sourced from user's biometric data which have been presented at diabetes conferences such as American Diabetes Association, American Association Endodontists and ATTD. Most recently, Dario has expanded its research into hypertension, where 38% of patients using the platform were able to reduce blood pressure severity by one stage. The findings from these studies demonstrate that populations can achieve better health resulting in lower cost and a positive ROI using the program. This will provide the justification that large healthcare providers require before adding a DTx to their own platform.

We anticipate that Dario will be able to drive increased revenues in the second half of 2020 now that all of the pieces are in place. Access to large provider groups is expected to yield stepwise increases in new subscribers at much higher PMPM than the legacy market. The opportunities are great; however, so are the risks. Despite the large market size and opportunity, Dario must generate rapid success to achieve our estimates and there are numerous other players in the industry, from megacap, established device players with deep pockets to small, agile companies that are looking for a piece of the action. Our valuation approach uses a multiple of future earnings discounted to present, corroborated by comparison with peer trading and transaction multiples.

Key reasons to own DarioHealth shares:

- **AI-driven behavioral change platform that is personalized and scalable**
- **Immense untapped market in Digital Therapeutics**
- **High and expanding gross margins**
- **Clinically-proven patient outcomes**
- **DTx market size forecast of almost \$10 billion by 2026**
- **Existing and growing partnerships with health plans, employers, providers and retailers**
- **Membership-based SaaS with recurring revenue**
- **Opportunity to address multiple chronic conditions in diabetes, hypertension & obesity**
- **Cash position of \$15.8 million with no debt on balance sheet**
- **Leadership and management team with experience in healthcare and technology**

Based on our review and analysis of the DTx market and DarioHealth's product offering, we see a rising trend in both revenues and margins as the company advances its strategic plan. Our valuation work takes into account success with marketing the Dario solution to large healthcare providers in the industry and expanding their product set to include multiple chronic diseases. While Dario's sales are predominantly in the US, we see global opportunity as the platform proves itself and will add other regions when there is a reasonable assumption that they can be developed. As we initiate on DarioHealth, Corp., our analysis and forecasts generate a valuation of \$10.50 per share.

PROJECTED FINANCIALS

DarioHealth Corp. - Income Statement

DarioHealth Corp.	2019 A	Q1 A	Q2 E	Q3 E	Q4 E	2020 E	2021 E	2022 E
Total Revenues (\$US '000)	\$7,559	\$1,667	\$1,720	\$2,000	\$2,200	\$7,587	\$13,435	\$25,843
YOY Growth	2%	-26%	4%	7%	22%	0%	77%	92%
Cost of Revenues	\$4,962	\$888	\$912	\$1,060	\$1,166	\$4,026	\$6,698	\$10,510
Product Gross Margin	34%	46.7%	47%	47%	47%	47%	50%	59%
Research & Development	\$3,692	\$1,231	\$1,050	\$1,100	\$1,050	\$4,431	\$5,229	\$6,013
Sales & Marketing	\$11,127	\$4,091	\$3,000	\$2,800	\$2,500	\$12,391	\$13,960	\$15,356
General & Administrative	\$5,483	\$5,571	\$1,800	\$1,800	\$1,800	\$10,971	\$10,200	\$10,506
Income from operations	(\$17,705)	(\$10,114)	(\$5,042)	(\$4,760)	(\$4,316)	(\$24,232)	(\$22,652)	(\$16,542)
Operating Margin	-234%	-607%	-293%	-238%	-196%	-319%	-169%	-64%
Financial Expenses	\$31	(\$222)	\$0	\$0	\$0	(\$222)	\$0	\$0
Deemed Dividend	\$3,155	\$1,275	\$800	\$0	\$0	\$2,075	\$1,100	\$1,000
Pre-Tax Income	(\$20,891)	(\$11,167)	(\$5,842)	(\$4,760)	(\$4,316)	(\$26,085)	(\$23,752)	(\$17,542)
Provision for Income Tax	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Tax Rate	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Net Income	(\$20,891)	(\$11,167)	(\$5,842)	(\$4,760)	(\$4,316)	(\$26,085)	(\$23,752)	(\$17,542)
Net Margin	-276%	-670%	-3.39627907	-238%	-196%	-344%	-177%	-68%
Reported EPS	(\$9.22)	(\$3.61)	(\$1.54)	(\$1.19)	(\$1.03)	(\$6.91)	(\$3.96)	(\$2.22)
YOY Growth		23.6%	-39.3%	7.6%	-64.1%	-25%	-43%	-44%
Basic Shares Outstanding	2,266	3,091	3,800	4,000	4,200	3,773	6,000	7,905

Source: Company Filing // Zacks Investment Research, Inc. Estimates

HISTORICAL STOCK PRICE

DarioHealth Corp. – Share Price Chart⁷¹



⁷¹ Source: Zacks Research System

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